ISSN 0378-6986

# Official Journal

## of the European Communities

C 365 E

**Volume 43**

**19 December 2000**

English edition

# Information and Notices

Notice No | Contents | Page



EN

(1) Text with EEA relevance

(1) Text with EEA relevance

(1) Text with EEA relevance

II

*(Preparatory Acts)*

# COMMISSION

## Proposal for a Directive of the European Parliament and of the Council concerning life assurance (recast version)

(2000/C 365 E/01)

*COM(2000) 398 final — 2000/0162(COD)*

*(Submitted by the Commission on 28 June 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 47(2) and 55 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

(1) The First Council Directive 79/267/EEC of 5 March 1979 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of direct life assurance [1], Council Directive 90/619/EEC of 8 November 1990 on the coordination of laws, regulations and administrative provisions relating to direct life assurance laying down provisions to facilitate the effective exercise of freedom to provide services and amending Directive 79/267/EEC [2] and Council Directive 92/96/EEC of 10 November 1992 on the coordination of laws, regulations and administrative provisions relating to direct life assurance and amending Directives 79/267/EEC and 90/619/EEC (third life assurance Directive) [3] have been substantially amended several times. Since further amendments are to be made, the Directives should be recast in the interests of clarity.

(2) In order to facilitate the taking-up and pursuit of the business of life assurance, it is essential to eliminate certain divergences which exist between national supervisory legislations. In order to achieve this objective and at the same time ensure adequate protection for policyholders and beneficiaries in all Member States, the provisions relating to the financial guarantees required of life assurance undertakings should be coordinated.

(3) It is necessary to complete the internal market in direct life assurance, from the point of view both of the right of establishment and of the freedom to provide services in the Member States, to make it easier for assurance undertakings with head offices in the Community to cover commitments situated within the Community and to make it possible for policy-holders to have recourse not only to assurers established in their own country, but also to assurers which have their head office in the Community and are established in other Member States.

(4) Under the Treaty, any discrimination with regard to freedom to provide services based on the fact that an undertaking is not established in the Member State in which the services are provided is prohibited. That prohibition applies to services provided from any establishment in the Community, whether it be the head office of an undertaking or an agency or branch.

(5) This Directive therefore represents an important step in the merging of national markets into an integrated market with a view to enabling all policy-holders to have recourse to any assurer with a head office in the Community who carries on business there, under the right of establishment or the freedom to provide services, while guaranteeing them adequate protection.

(6) This Directive forms part of the body of Community legislation in the field of life assurance which also includes Council Directive 91/674/EEC of 19 December 1991 on the annual accounts and consolidated accounts of insurance undertakings [4].

(7) The approach adopted consists in bringing about such harmonisation as is essential, necessary and sufficient to achieve the mutual recognition of authorisations and prudential control systems, thereby making it possible to grant a single authorisation valid throughout the Community and apply the principle of supervision by the home Member State.

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[1] OJ L 63, 13.3.1979, p. 1; Directive as last amended by Directive 95/26/EC of the European Parliament and of the Council (OJ L 168, 18.7.1995, p. 7).

[2] OJ L 330, 29.11.1990, p. 50; Directive as amended by Directive 92/96/EEC (OJ L 360, 9.12.1992, p. 1).

[3] OJ L 360, 9.12.1992, p. 1; Directive as amended by Directive 95/26/EC.

[4] OJ L 374, 31.12.1991, p. 7.

(8) As a result, the taking-up and the pursuit of the business of assurance are subject to the grant of a single official authorisation issued by the competent authorities of the Member State in which an assurance undertaking has its head office. Such authorisation enables an undertaking to carry on business throughout the Community, under the right of establishment or the freedom to provide services. The Member State of the branch or of the provision of services may not require assurance undertakings which wish to carry on assurance business there and which have already been authorised in their home Member State to seek fresh authorisation.

(9) Whereas the competent authorities should not authorise or continue the authorisation of an assurance undertaking where they are liable to be prevented from effectively exercising their supervisory functions by the close links between that undertaking and other natural or legal persons. Assurance undertakings already authorised must also satisfy the competent authorities in that respect.

(10) The definition of 'close links' in this Directive lays down minimum criteria and that does not prevent Member States from applying it to situations other than those envisaged by the definition.

(11) The sole fact of having acquired a significant proportion of a company's capital does not constitute participation for the purposes of this Directive if that holding has been acquired solely as a temporary investment which does not make it possible to exercise influence over the structure or financial policy of the undertaking.

(12) The principles of mutual recognition and of home Member State supervision require that Member States' competent authorities should not grant or should withdraw authorisation where factors such as the content of programmes of operations, the geographical distribution of the activities actually carried on indicate clearly that an assurance undertaking has opted for the legal system of one Member State for the purpose of evading the stricter standards in force in another Member State within whose territory it carries on or intends to carry on the greater part of its activities. An assurance undertaking which is a legal person must be authorised in the Member State in which it has its registered office. An assurance undertaking which is not a legal person must have its head office in the Member State in which it has been authorised. In addition, Member States must require that an assurance undertaking's head office always be situated in its home Member State and that it actually carries on its business there.

(13) For practical reasons, it is desirable to define provision of services taking into account both the assurer's establishment and the place where the commitment is to be covered. Therefore, commitment should also be defined. Moreover, it is desirable to distinguish between activities pursued by way of establishment and activities pursued by way of freedom to provide services.

(14) A classification by class of insurance is necessary in order to determine, in particular, the activities subject to compulsory authorisation.

(15) Certain mutual associations which, by virtue of their legal status, fulfil requirements as to security and other specific financial guarantees should be excluded from the scope of this Directive. Certain organisations whose activity covers only a very restricted sector and is limited by their articles of association should also be excluded.

(16) Life assurance is subject to official authorisation and supervision in each Member State. The conditions for the granting or withdrawal of such authorisation should be defined.

(17) It is desirable to clarify the powers and means of supervision vested in the competent authorities. It is also desirable to lay down specific provisions regarding the taking-up, pursuit and supervision of activity by way of freedom to provide services.

(18) The competent authorities of home Member States should be responsible for monitoring the financial health of assurance undertakings, including their state of solvency, the establishment of adequate technical provisions and the covering of those provisions by matching assets.

(19) It is appropriate to provide for the possibility of exchanges of information between the competent authorities and authorities or bodies which, by virtue of their function, help to strengthen the stability of the financial system. In order to preserve the confidential nature of the information forwarded, the list of addressees must remain within strict limits.

(20) Certain behaviour, such as fraud and insider offences, is liable to affect the stability, including integrity, of the financial system, even when involving undertakings other than financial ones.

(21) It is necessary to specify the conditions under which the abovementioned exchanges of information are authorised.

(22) Where it is stipulated that information may be disclosed only with the express agreement of the competent authorities, these may, where appropriate, make their agreement subject to compliance with strict conditions.

(23) For the purpose of strengthening the prudential supervision of assurance undertakings and protection of clients of assurance undertakings, it should be stipulated that an auditor must have a duty to report promptly to the competent authorities, wherever, as provided for by this Directive, he becomes aware, while carrying out his tasks, of certain facts which are liable to have a serious effect on the financial situation or the administrative and accounting organisation of an assurance undertaking.

(24) Having regard to the aim in view, it is desirable for Member States to provide that such a duty should apply in all circumstances where such facts are discovered by an auditor during the performance of his tasks in an undertaking which has close links with an assurance undertaking.

(25) The duty of auditors to communicate, where appropriate, to the competent authorities certain facts and decisions concerning an assurance undertaking which they discover during the performance of their tasks in a non-financial undertaking does not in itself change the nature of their tasks in that undertaking nor the manner in which they must perform those tasks in that undertaking.

(26) The performance of the operations of management of group pension funds cannot under any circumstances affect the powers conferred on the respective authorities with regard to the entities holding the assets.

(27) Certain provisions of this Directive define minimum standards. A home Member State may lay down stricter rules for assurance undertakings authorised by its own competent authorities.

(28) The competent authorities of the Member States must have at their disposal such means of supervision as are necessary to ensure the orderly pursuit of business by assurance undertakings throughout the Community whether carried on under the right of establishment or the freedom to provide services. In particular, they must be able to introduce appropriate safeguards or impose sanctions aimed at preventing irregularities and infringements of the provisions on assurance supervision.

(29) The provisions on transfer of portfolio should include provisions specifically concerning the transfer to another undertaking of the portfolio of contracts concluded by way of freedom to provide services.

(30) The provisions on transfers of portfolios must be in line with the single legal authorisation system provided for in this Directive.

(31) Undertakings formed after the dates referred to in Article 18(3) should not be authorised to carry on life assurance and non-life insurance activities simultaneously. Member States should be allowed to permit undertakings which, on the dates refered to in Article 18(3), carried on these activities simultaneously to continue to do so provided that separate management is adopted for each of their activities, in order that the respective interests of life policy-holders and non-life policy-holders are safeguarded and the minimum financial obligations in respect of one of the activities are not borne by the other activity. Member States should be given the option of requiring those existing undertakings established in their territory which carry on life assurance and non-life insurance simultaneously to put an end to this practice. Moreover, specialised undertakings should be subject to special supervision where a non-life undertaking belongs to the same financial group as a life undertaking.

(32) Nothing in this Directive would prevent a composite undertaking from dividing itself into two undertakings, one active in the field of life assurance, the other in non-life insurance. In order to allow such division to take place under the best possible conditions, it is desirable to permit Member States, in accordance with Community rules of competition law, to provide for appropriate tax arrangements, in particular with regard to the capital gains such division could entail.

(33) Those Member States which so wish should be able to grant the same undertaking authorisations for the classes referred to in Annex I and the insurance business coming under classes 1 and 2 in the Annex to Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance [1]. That possibility may, however, be subject to certain conditions as regards compliance with accounting rules and rules on winding-up.

(34) It is necessary from the point of view of the protection of lives assured that every assurance undertaking should establish adequate technical provisions. The calculation of such provisions is based for the most part on actuarial principles. Those principles should be coordinated in order to facilitate mutual recognition of the prudential rules applicable in the various Member States.

(35) It is desirable, in the interests of prudence, to establish a minimum of coordination of rules limiting the rate of interest used in calculating the technical provisions. For the purposes of such limitation, since existing methods are all equally correct, prudential and equivalent, it seems appropriate to leave Member States a free choice as to the method to be used.

(36) The rules governing the calculation of technical provisions, spread, localisation and matching of the assets used to cover technical provisions must be coordinated in order to facilitate the mutual recognition of Member States' rules. That coordination must take account of the liberalisation of capital movements provided for in Article 56 of the Treaty and the progress made by the Community towards economic and monetary union.

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[1] OJ L 228, 16.8.1973, p. 3; Directive as last amended by Directive 95/26/EC.

(37) The home Member State may not require assurance undertakings to invest the assets covering their technical provisions in particular categories of assets, as such a requirement would be incompatible with the liberalisation of capital movements provided for in Article 56 of the Treaty.

(38) It is necessary that, over and above technical provisions, including mathematical provisions, of sufficient amount to meet their underwriting liabilities, assurance undertakings should possess a supplementary reserve, known as the solvency margin, represented by free assets and, with the agreement of the competent authority, by other implicit assets, in order to provide against business fluctuations. In order to ensure that the requirements imposed for such purposes are determined according to objective criteria whereby undertakings of the same size will be placed on an equal footing as regards competition, it is desirable to provide that this margin shall be related to all the commitments of the undertaking and to the nature and gravity of the risks presented by the various activities falling within the scope of this Directive. This margin should therefore vary according to whether the risks are of investment, death or management only. It should accordingly be determined in terms of mathematical provisions and capital at risk underwritten by an undertaking, of premiums or contributions received, of technical provisions only or of the assets of tontines.

(39) Directive 92/96/EEC provided for a provisional definition of a regulated market, pending the adoption of a directive on investment services in the securities field, which would harmonise that concept at Community level. Council Directive 93/22/EEC of 10 May 1993 on investment services in the securities field [1], provides for a definition of regulated market, although it excludes from its scope life assurance activities. It is therefore appropriate to also apply the concept of regulated market to life assurance activities.

(40) The list of items of which the solvency margin required by this Directive may be made up takes account of new financial instruments and of the facilities granted to other financial institutions for the constitution of their own funds.

(41) It is necessary to require a guarantee fund, the amount and composition of which are such as to provide an assurance that the undertakings possess adequate resources when they are set up and that in the subsequent course of business the solvency margin in no event falls below a minimum of security. The whole or a specified part of this guarantee fund must consist of explicit asset items.

(42) The provisions in force in the Member States regarding contract law applicable to the activities referred to in this Directive differ. The harmonisation of assurance contract law is not a prior condition for the achievement of the internal market in assurance. Therefore, the opportunity afforded to the Member States of imposing the application of their law to assurance contracts covering commitments within their territories is likely to provide adequate safeguards for policy-holders. The freedom to choose, as the law applicable to the contract, a law other than that of the State of the commitment may be granted in certain cases, in accordance with rules which take into account specific circumstances.

(43) For life assurance contracts the policy-holder should be given the opportunity of cancelling the contract within a period of between 14 and 30 days.

(44) Within the framework of an internal market it is in the policy-holder's interest that they should have access to the widest possible range of assurance products available in the Community so that they can choose that which is best suited to their needs. It is for the Member State of the commitment to ensure that there is nothing to prevent the marketing within its territory of all the assurance products offered for sale in the Community as long as they do not conflict with the legal provisions protecting the general good in force in the Member State of the commitment and in so far as the general good is not safeguarded by the rules of the home Member State, provided that such provisions must be applied without discrimination to all undertakings operating in that Member State and be objectively necessary and in proportion to the objective pursued.

(45) The Member States must be able to ensure that the assurance products and contract documents used, under the right of establishment or the freedom to provide services, to cover commitments within their territories comply with such specific legal provisions protecting the general good as are applicable. The systems of supervision to be employed must meet the requirements of an internal market but their employment may not constitute a prior condition for carrying on assurance business. From this standpoint, systems for the prior approval of policy conditions do not appear to be justified. It is therefore necessary to provide for other systems better suited to the requirements of an internal market which enable every Member State to guarantee policy-holders adequate protection.

[1] OJ L 141, 11.6.1993, p. 27; Directive as last amended by European Parliament and Council Directive 97/9/EC (OJ L 84, 26.3.1997, p. 22).

(46) It is necessary to make provision for cooperation between the competent authorities of the Member States and between those authorities and the Commission.

(47) Provision should be made for a system of penalties to be imposed when, in the Member State in which the commitment is entered into, an assurance undertaking does not comply with those provisions protecting the general good that are applicable to it.

(48) It is necessary to provide for measures in cases where the financial position of the undertaking becomes such that it is difficult for it to meet its underwriting liabilities.

(49) For the purposes of implementing actuarial principles in conformity with this Directive, the home Member State may require systematic notification of the technical bases used for calculating scales of premiums and technical provisions, with such notification of technical bases excluding notification of the general and special policy conditions and the undertaking's commercial rates.

(50) In an internal assurance market the consumer will have a wider and more varied choice of contracts. If he is to profit fully from this diversity and from increased competition, he must be provided with whatever information is necessary to enable him to choose the contract best suited to his needs. This information requirement is all the more important as the duration of commitments can be very long. The minimum provisions must therefore be coordinated in order for the consumer to receive clear and accurate information on the essential characteristics of the products proposed to him as well as the particulars of the bodies to which any complaints of policy-holders, assured persons or beneficiaries of contracts may be addressed.

(51) Publicity for assurance products is an essential means of enabling assurance business to be carried on effectively within the Community. It is necessary to leave open to assurance undertakings the use of all normal means of advertising in the Member State of the branch or of provision of services. Member States may nevertheless require compliance with their national rules on the form and content of advertising, whether laid down pursuant to Community legislation on advertising or adopted by Member States for reasons of the general good.

(52) Within the framework of the internal market, no Member State may continue to prohibit the simultaneous carrying on of assurance business within its territory under the right of establishment and the freedom to provide services.

(53) Some Member States do not subject assurance transactions to any form of indirect taxation, while the majority apply special taxes and other forms of contribution. The structures and rates of such taxes and contributions vary considerably between the Member States in which they are applied. It is desirable to prevent existing differences leading to distortions of competition in assurance services between Member States. Pending subsequent harmonisation, application of the tax systems and other forms of contribution provided for by the Member States in which commitments entered into are likely to remedy that problem and it is for the Member States to make arrangements to ensure that such taxes and contributions are collected.

(54) It is important to introduce Community coordination on the winding-up of assurance undertakings. It is henceforth essential to provide, in the event of the winding-up of an assurance undertaking, that the system of protection in place in each Member State must guarantee equality of treatment for all assurance creditors, irrespective of nationality and of the method of entering into the commitment.

(55) The coordinated rules concerning the pursuit of the business of direct insurance within the Community should, in principle, apply to all undertakings operating on the market and, consequently, also to agencies and branches where the head office of the undertaking is situated outside the Community. As regards the methods of supervision this Directive lays down special provisions for such agencies or branches, in view of the fact that the assets of the undertakings to which they belong are situated outside the Community.

(56) It is desirable to provide for the conclusion of reciprocal agreements with one or more third countries in order to permit the relaxation of such special conditions, while observing the principle that such agencies and branches should not obtain more favourable treatment than Community undertakings.

(57) A provision should be made for a flexible procedure to make it possible to assess reciprocity with third countries on a Community basis. The aim of this procedure is not to close the Community's financial markets but rather, as the Community intends to keep its financial markets open to the rest of the world, to improve the liberalisation of the global financial markets in other third countries. To that end, this Directive provides for procedures for negotiating with third countries. As a last resort, the possibility of taking measures involving the suspension of new applications for authorisation or the restriction of new authorisations should be provided for using the regulatory procedure under Article 5 of Council Decision 1999/468/EC [1].

(58) This Directive should establish provisions concerning proof of good repute and no previous bankruptcy.

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[1] OJ L 184, 17.7.1999, p. 23.

(59) In order to clarify the legal regime applicable to life assurance activities covered by this Directive, some provisions of Directives 79/267/EEC, 90/619/EEC and 92/96/EEC should be adapted. For that purpose some provisions concerning the establishment of the solvency margin and the rights acquired by branches of assurance undertakings established before 1 July 1994 should be amended. The content of the scheme of operation of branches of third country undertakings to be established in the Community should also be defined.

(60) Technical adjustments to the detailed rules laid down in this Directive may be necessary from time to time to take account of the future development of the assurance industry. The Commission will make such adjustments as and when necessary, after consulting the Insurance Committee set up by Council Directive 91/675/EEC [1], in the exercise of the implementing powers conferred on it by the Treaty. These measures being measures of general scope within the meaning of Article 2 of Decision 1999/468/EC, they should be adopted by the use of the regulatory procedure provided for in Article 5 of that Decision.

(61) Provision must be made for the right to apply to the courts should an authorisation be refused or withdrawn.

(62) Pursuant to Article 15 of the Treaty, account should be taken of the extent of the effort which must be made by certain economies at different stages of development. Therefore, transitional arrangements should be adopted for the gradual application of this Directive by certain Member States.

(63) Directives 79/267/EEC and 90/619/EEC granted special derogation with regard to some undertakings existing at the time of the adoption of these Directives. Such undertakings have thereafter modified their structure. Therefore they do not need any longer such special derogation.

(64) This Directive should not affect the obligations of Member States concerning the deadlines for transposition and for application of the Directives set out in Annex IV, Part B,

HAVE ADOPTED THIS DIRECTIVE:

TITLE I

**DEFINITIONS AND SCOPE**

*Article 1*

**Definitions**

1. For the purposes of this Directive:

(a) *assurance undertaking:* shall mean an undertaking which has received official authorisation in accordance with Article 4;

(b) *branch:* shall mean an agency or branch of an assurance undertaking;

Any permanent presence of an undertaking in the territory of a Member State shall be treated in the same way as an agency or branch, even if that presence does not take the form of a branch or agency, but consists merely of an office managed by the undertaking's own staff or by a person who is independent but has permanent authority to act for the undertaking as an agency would;

(c) *establishment:* shall mean the head office, an agency or a branch of an undertaking;

(d) *commitment:* shall mean a commitment represented by one of the kinds of insurance or operations referred to in Article 2;

(e) *home Member State:* shall mean the Member State in which the head office of the assurance undertaking covering the commitment is situated;

(f) *Member State of the branch:* shall mean the Member State in which the branch covering the commitment is situated;

(g) *Member State of the commitment:* shall mean the Member State where the policy-holder has his habitual residence or, if the policy-holder is a legal person, the Member State where the latter's establishment, to which the contract relates, is situated;

(h) *Member State of the provision of services:* shall mean the Member State of the commitment, if the commitment is covered by an assurance undertaking or a branch situated in another Member State;

(i) *control:* shall mean the relationship between a parent undertaking and a subsidiary, as defined in Article 1 of Council Directive 83/349/EEC [2], or a similar relationship between any natural or legal person and an undertaking;

[1] OJ L 374, 31.12.1991, p. 32.

[2] OJ L 193, 18.7.1983, p. 1. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

(j) *qualifying holding:* shall mean a direct or indirect holding in an undertaking which represents 10 % or more of the capital or of the voting rights or which makes it possible to exercise a significant influence over the management of the undertaking in which a holding subsists;

For the purposes of this definition, in the context of Articles 8 and 15 and of the other levels of holding referred to in Article 15, the voting rights referred to in Article 7 of Council Directive 88/627/EEC [1] shall be taken into consideration;

(k) *parent undertaking:* shall mean a parent undertaking as defined in Articles 1 and 2 of Directive 83/349/EEC;

(l) *subsidiary:* shall mean a subsidiary undertaking as defined in Articles 1 and 2 of Directive 83/349/EEC; any subsidiary of a subsidiary undertaking shall also be regarded as a subsidiary of the undertaking which is those undertakings' ultimate parent undertaking;

(m) *regulated market shall mean:*

— in the case of a market situated in a Member State, a regulated market as defined in Article 1, point (13) of Directive 93/22/EEC, and

— in the case of a market situated in a third country, a financial market recognised by the home Member State of the assurance undertaking which meets comparable requirements. Any financial instruments dealt in on that market must be of a quality comparable to that of the instruments dealt in on the regulated market or markets of the Member State in question;

(n) *competent authorities:* shall mean the national authorities which are empowered by law or regulation to supervise assurance undertakings;

(o) *matching assets:* shall mean the representation of underwriting liabilities which can be required to be met in a particular currency by assets expressed or realisable in the same currency;

(p) *localisation of assets:* shall mean the existence of assets, whether movable or immovable, within a Member State but shall not be construed as involving a requirement that movable assets be deposited or that immovable assets be subjected to restrictive measures such as the registration of mortgages; assets represented by claims against debtors shall be regarded as situated in the Member State where they are realisable;

(q) *capital at risk:* shall mean the amount payable on death less the mathematical provision for the main risk;

(r) *close links:* shall mean a situation in which two or more natural or legal persons are linked by:

(i) *participation*, which shall mean the ownership, direct or by way of control, of 20 % or more of the voting rights or capital of an undertaking; or

(ii) *control*, any subsidiary undertaking of a subsidiary undertaking shall also be considered a subsidiary of the parent undertaking which is at the head of those undertakings.

A situation in which two or more natural or legal persons are permanently linked to one and the same person by a control relationship shall also be regarded as constituting a close link between such persons.

2. Wherever this Directive refers to the euro, the conversion value in national currency to be adopted shall as from 31 December of each year be that of the last day of the preceding month of October for which euro conversion values are available in all the Community currencies.

*Article 2*

**Scope**

This Directive concerns the taking up and pursuit of the self-employed activity of direct insurance carried on by undertakings which are established in a Member State or wish to become established there in the form of the activities defined below:

1. The following kinds of insurance where they are on a contractual basis:

(a) life assurance, that is to say, the class of insurance which comprises, in particular, assurance on survival to a stipulated age only, assurance on death only, assurance on survival to a stipulated age or on earlier death, life assurance with return of premiums, marriage assurance, birth assurance;

(b) annuities;

(c) supplementary insurance carried on by life assurance undertakings, that is to say, in particular, insurance against personal injury including incapacity for employment, insurance against death resulting from an accident and insurance against disability resulting from an accident or sickness, where these various kinds of insurance are underwritten in addition to life assurance;

(d) the type of insurance existing in Ireland and the United Kingdom known as permanent health insurance not subject to cancellation.

2. The following operations, where they are on a contractual basis, in so far as they are subject to supervision by the administrative authorities responsible for the supervision of private insurance:

(a) tontines whereby associations of subscribers are set up with a view to jointly capitalising their contributions and subsequently distributing the assets thus accumulated among the survivors or among the beneficiaries of the deceased;

[1] OJ L 348, 17.12.1988, p. 62.

(b) capital redemption operations based on actuarial calculation whereby, in return for single or periodic payments agreed in advance, commitments of specified duration and amount are undertaken;

(c) management of group pension funds, i.e. operations consisting, for the undertaking concerned, in managing the investments, and in particular the assets representing the reserves of bodies that effect payments on death or survival or in the event of discontinuance or curtailment of activity;

(d) the operations referred to in (c) where they are accompanied by insurance covering either conservation of capital or payment of a minimum interest;

(e) the operations carried out by insurance companies such as those referred to in Chapter 1, Title 4 of Book IV of the French 'Code des assurances'.

3. Operations relating to the length of human life which are prescribed by or provided for in social insurance legislation, when they are effected or managed at their own risk by assurance undertakings in accordance with the laws of a Member State.

*Article 3*

**Activities and bodies excluded**

This Directive shall not concern:

1. subject to the application of Article 2(1)(c), the classes designated in the Annex to Directive 73/239/EC;

2. operations of provident and mutual-benefit institutions whose benefits vary according to the resources available and which require each of their members to contribute at the appropriate flat rate;

3. operations carried out by organisations other than undertakings referred to in Article 2, whose object is to provide benefits for employed or self-employed persons belonging to an undertaking or group of undertakings, or a trade or group of trades, in the event of death or survival or of discontinuance or curtailment of activity, whether or not the commitments arising from such operations are fully covered at all times by mathematical provisions;

4. subject to the application of Article 2, point (3), insurance forming part of a statutory system of social security;

5. organisations which undertake to provide benefits solely in the event of death, where the amount of such benefits does not exceed the average funeral costs for a single death or where the benefits are provided in kind;

6. mutual associations, where:

— the articles of association contain provisions for calling up additional contributions or reducing their benefits or claiming assistance from other persons who have undertaken to provide it, and

— the annual contribution income for the activities covered by this Directive does not exceed 500 000 euro for three consecutive years. If this amount is exceeded for three consecutive years this Directive shall apply with effect from the fourth year;

7. the 'Versorgungsverband deutscher Wirtschaftsorganisationen' in Germany or the 'Caisse d'épargne de l'État' in Luxembourg unless their statutes are amended as regards the scope of their activities;

8. the pension activities of pension insurance undertakings prescribed in the Employees' Pension Act (TEL) and other related Finnish legislation provided that:

(a) pension insurance companies which already under Finnish law are obliged to have separate accounting and management systems for their pension activities will furthermore, as from the date of accession, set up separate legal entities for carrying out these activities;

(b) the Finnish authorities shall allow in a non-discriminatory manner all nationals and companies of Member States to perform according to Finnish legislation the activities specified in Article 2 related to this exemption whether by means of:

— ownership or participation in an existing insurance company or group;

— creation or participation of new insurance companies or groups, including pension insurance companies;

(c) the Finnish authorities will submit to the Commission for approval a report within three months from the date of accession, stating which measures have been taken to split up TEL activities from normal insurance activities carried out by Finnish insurance companies in order to conform to all the requirements of this Directive.

TITLE II

**THE TAKING UP OF THE BUSINESS OF LIFE ASSURANCE**

*Article 4*

**Principle of authorisation**

The taking-up of the activities covered by this Directive shall be subject to prior official authorisation.

Such authorisation shall be sought from the authorities of the home Member State by:

(a) any undertaking which establishes its head office in the territory of that State;

(b) any undertaking which, having received the authorisation required in the first subparagraph, extends its business to an entire class or to other classes.

*Article 5*

**Scope of authorisation**

1. Authorisation shall be valid for the entire Community. It shall permit an assurance undertaking to carry on business there, under either the right of establishment or freedom to provide services.

2. Authorisation shall be granted for a particular class of assurance as listed in Annex I. It shall cover the entire class, unless the applicant wishes to cover only some of the risks pertaining to that class.

The competent authorities may restrict authorisation requested for one of the classes to the operations set out in the scheme of operations referred to in Article 7.

Each Member State may grant authorisation for two or more of the classes, where its national laws permit such classes to be carried on simultaneously.

*Article 6*

**Conditions for obtaining authorisation**

1. The home Member State shall require every assurance undertaking for which authorisation is sought to:

(a) adopt one of the following forms:

— in the case of the Kingdom of Belgium: 'société anonyme/naamloze vennootschap', 'société en commandite par actions/commanditaire vennootschap op aandelen', 'association d'assurance mutuelle/onderlinge verzekeringsvereniging', 'société coopérative/coöperatieve vennootschap',

— in the case of the Kingdom of Denmark: 'aktieselskaber', 'gensidige selskaber', 'pensionskasser omfattet af lov om forsikringsvirksomhed (tværgående pensionskasser)',

— in the case of the Federal Republic of Germany: 'Aktiengesellschaft', 'Versicherungsverein auf Gegenseitigkeit', 'öffentlich-rechtliches Wettbewerbsversicherungsunternehmen',

— in the case of the French Republic: 'société anonyme', 'société d'assurance mutuelle', 'institution de prévoyance régie par le code de la sécurité sociale', 'institution de prévoyance régie par le code rural' and 'mutuelles régies par le code de la mutualité'

— in the case of Ireland: incorporated companies limited by shares or by guarantee or unlimited, societies registered under the Industrial and Provident Societies Acts and societies registered under the Friendly Societies Acts,

— in the case of the Italian Republic: 'societá per azioni', 'societá cooperativa', 'mutua di assicurazione',

— in the case of the Grand Duchy of Luxembourg: 'société anonyme', 'société en commandite par actions', 'association d'assurances mutuelles', 'société coopérative',

— in the case of the Kingdom of the Netherlands: 'naamloze vennootschap', 'onderlinge waarborgmaatschappij',

— in the case of the United Kingdom: incorporated companies limited by shares or by guarantee or unlimited societies registered under the Industrial and Provident Societies Acts, societies registered or incorporated under the Friendly Societies Acts, the association of underwriters known as Lloyd's,

— in the case of the Hellenic Republic: 'ανώνυμη εταιρία';

— in the case of the Kingdom of Spain: 'sociedad anonima', 'sociedad mutua', 'sociedad cooperativa',

— in the case of the Portuguese Republic: 'sociedade anónima', 'mútua de seguros',

— in the case of the Republic of Austria: 'Aktiengesellschaf', 'Versicherungsverein auf Gegenseitigkeit',

— in the case of the Republic of Finland: 'keskinäinen vakuutusyhtiö/ömsesidigt försäkringsbolag', 'vakuutusosakeyhtiö/försäkringsaktiebolag', 'vakuutusyhdistys/försäkringsförening',

— in the case of Kingdom of Sweden: 'försäkringsaktiebolag', 'ömsesidiga försäkringsbolag', 'understödsföreningar'.

An assurance undertaking may also adopt the form of a European company when that has been established.

Furthermore, Member States may, where appropriate, set up undertakings in any public-law form provided that such bodies have as their object insurance operations under conditions equivalent to those under which private-law undertakings operate;

(b) limit its objects to the business provided for in this Directive and operations directly arising therefrom, to the exclusion of all other commercial business;

(c) submit a scheme of operations in accordance with Article 7;

(d) possess the minimum guarantee fund provided for in Article 29(2);

(e) be effectively run by persons of good repute with appropriate professional qualifications or experience.

Moreover, where close links exist between the assurance undertaking and other natural or legal persons, the competent authorities shall grant authorisation only if those links do not prevent the effective exercise of their supervisory functions.

The competent authorities shall also refuse authorisation if the laws, regulations or administrative provisions of a non-member country governing one or more natural or legal persons with which the undertaking has close links, or difficulties involved in their enforcement, prevent the effective exercise of their supervisory functions.

The competent authorities shall require assurance undertakings to provide them with the information they require to monitor compliance with the conditions referred to in this paragraph on a continuous basis.

2. Member States shall require that the head offices of insurance undertakings be situated in the same Member State as their registered offices.

3. An assurance undertaking seeking authorisation to extend its business to other classes or to extend an authorisation covering only some of the risks pertaining to one class shall be required to submit a scheme of operations in accordance with Article 7.

It shall, furthermore, be required to show proof that it possesses the solvency margin provided for in Article 28 and the guarantee fund referred to in Article 29(1) and (2).

4. Member States shall not adopt provisions requiring the prior approval or systematic notification of general and special policy conditions, of scales of premiums, of the technical bases, used in particular for calculating scales of premiums and technical provisions or of forms and other printed documents which an assurance undertaking intends to use in its dealings with policy-holders.

Notwithstanding the first subparagraph, for the sole purpose of verifying compliance with national provisions concerning actuarial principles, the home Member State may require systematic notification of the technical bases used for calculating scales of premiums and technical provisions, without that requirement constituting a prior condition for an assurance undertaking to carry on its business.

Nothing in this Directive shall prevent Member States from maintaining in force or introducing laws, regulations or administrative provisions requiring approval of the memorandum and articles of association and the communication of any other documents necessary for the normal exercise of supervision.

Not later than 1 July 1999, the Commission shall submit a report to the Council on the implementation of this paragraph.

5. The provisions set out in paragraphs 1 to 4 may not require that any application for authorisation be considered in the light of the economic requirements of the market.

*Article 7*

**Scheme of operations**

The scheme of operations referred to in Article 6(1) (c) and (3) shall include particulars or evidence of:

(a) the nature of the commitments which the assurance undertaking proposes to cover;

(b) the guiding principles as to reassurance;

(c) the items constituting the minimum guarantee fund;

(d) estimates relating to the costs of setting up the administrative services and the organisation for securing business and the financial resources intended to meet those costs;

in addition, for the first three financial years:

(e) a plan setting out detailed estimates of income and expenditure in respect of direct business, reassurance acceptances and reassurance cessions;

(f) a forecast balance sheet;

(g) estimates relating to the financial resources intended to cover underwriting liabilities and the solvency margin.

*Article 8*

**Shareholders and members with qualifying holdings**

The competent authorities of the home Member State shall not grant an undertaking authorisation to take up the business of assurance before they have been informed of the identities of the shareholders or members, direct or indirect, whether natural or legal persons, who have qualifying holdings in that undertaking and of the amounts of those holdings.

The same authorities shall refuse authorisation if, taking into account the need to ensure the sound and prudent management of an assurance undertaking, they are not satisfied as to the qualifications of the shareholders or members.

*Article 9*

**Refusal of authorisation**

Any decision to refuse an authorisation shall be accompanied by the precise grounds for doing so and notified to the undertaking in question.

Each Member State shall make provision for a right to apply to the courts should there be any refusal.

Such provision shall also be made with regard to cases where the competent authorities have not dealt with an application for an authorisation upon the expiry of a period of six months from the date of its receipt.

TITLE III

## CONDITIONS GOVERNING THE BUSINESS OF ASSURANCE

Chapter 1

Principles and methods of financial supervision

*Article 10*

### Competent authorities and object of supervision

1. The financial supervision of an assurance undertaking, including that of the business it carries on either through branches or under the freedom to provide services, shall be the sole responsibility of the home Member State. If the competent authorities of the Member State of the commitment have reason to consider that the activities of an assurance undertaking might affect its financial soundness, they shall inform the competent authorities of the undertaking's home Member State. The latter authorities shall determine whether the undertaking is complying with the prudential principles laid down in this Directive.

2. That financial supervision shall include verification, with respect to the assurance undertaking's entire business, of its state of solvency, the establishment of technical provisions, including mathematical provisions, and of the assets covering them, in accordance with the rules laid down or practices followed in the home Member State pursuant to the provisions adopted at Community level.

3. The competent authorities of the home Member State shall require every assurance undertaking to have sound administrative and accounting procedures and adequate internal control mechanisms.

*Article 11*

### Supervision of branches established in another Member State

The Member State of the branch shall provide that, where an assurance undertaking authorised in another Member State carries on business through a branch, the competent authorities of the home Member State may, after having first informed the competent authorities of the Member State of the branch, carry out themselves, or through the intermediary of persons they appoint for that purpose, on-the-spot verification of the information necessary to ensure the financial supervision of the undertaking. The authorities of the Member State of the branch may participate in that verification.

*Article 12*

### Prohibition on compulsory ceding of part of underwriting

Member States may not require assurance undertakings to cede part of their underwriting of activities listed in Article 2 to an organisation or organisations designated by national regulations.

*Article 13*

### Accounting, prudential and statistical information: supervisory powers

1. Each Member State shall require every assurance undertaking whose head office is situated in its territory to produce an annual account, covering all types of operation, of its financial situation and solvency.

2. Member States shall require assurance undertakings with head offices within their territories to render periodically the returns, together with statistical documents, which are necessary for the purposes of supervision. The competent authorities shall provide each other with any documents and information that are useful for the purposes of supervision.

3. Every Member State shall take all steps necessary to ensure that the competent authorities have the powers and means necessary for the supervision of the business of assurance undertakings with head offices within their territories, including business carried on outside those territories, in accordance with the Council directives governing those activities and for the purpose of seeing that they are implemented.

These powers and means must, in particular, enable the competent authorities to:

(a) make detailed enquiries regarding the assurance undertaking's situation and the whole of its business, *inter alia* by:

— gathering information or requiring the submission of documents concerning its assurance business,

— carrying out on-the-spot investigations at the assurance undertaking's premises;

(b) take any measures, with regard to the assurance undertaking, its directors or managers or the persons who control it, that are appropriate and necessary to ensure that the undertaking's business continues to comply with the laws, regulations and administrative provisions with which the undertaking must comply in each Member State and in particular with the scheme of operations in so far as it remains mandatory, and to prevent or remedy any irregularities prejudicial to the interests of the assured persons;

(c) ensure that those measures are carried out, if need be by enforcement, where appropriate through judicial channels.

Member States may also make provision for the competent authorities to obtain any information regarding contracts which are held by intermediaries.

*Article 14*

**Transfer of portfolio**

1. Under the conditions laid down by national law, each Member State shall authorise assurance undertakings with head offices within its territory to transfer all or part of their portfolios of contracts, concluded under either the right of establishment or the freedom to provide services, to an accepting office established within the Community, if the competent authorities of the home Member State of the accepting office certify that after taking the transfer into account the latter possesses the necessary solvency margin.

2. Where a branch proposes to transfer all or part of its portfolio of contracts, concluded under either the right of establishment or the freedom to provide services, the Member State of the branch shall be consulted.

3. In the circumstances referred to in paragraphs 1 and 2, the authorities of the home Member State of the transferring assurance undertaking shall authorise the transfer after obtaining the agreement of the competent authorities of the Member States of the commitment.

4. The competent authorities of the Member States consulted shall give their opinion or consent to the competent authorities of the home Member State of the transferring assurance undertaking within three months of receiving a request; the absence of any response within that period from the authorities consulted shall be considered equivalent to a favourable opinion or tacit consent.

5. A transfer authorised in accordance with this Article shall be published as laid down by national law in the Member State of the commitment. Such transfers shall automatically be valid against policy-holders, the assured persons and any other person having rights or obligations arising out of the contracts transferred.

This provision shall not affect the Member States' rights to give policy-holders the option of cancelling contracts within a fixed period after a transfer.

*Article 15*

**Qualifying holdings**

1. Member States shall require any natural or legal person who proposes to acquire, directly or indirectly, a qualifying holding in an assurance undertaking first to inform the competent authorities of the home Member State, indicating the size of the intended holding. Such a person must likewise inform the competent authorities of the home Member State if he proposes to increase his qualifying holding so that the proportion of the voting rights or of the capital held by him would reach or exceed 20 %, 33 % or 50 % or so that the assurance undertaking would become his subsidiary.

The competent authorities of the home Member State shall have a maximum of three months from the date of the notification provided for in the first subparagraph to oppose such a plan if, in view of the need to ensure sound and prudent management of the assurance undertaking, they are not satisfied as to the qualifications of the person referred to in the first subparagraph. If they do not oppose the plan in question they may fix a maximum period for its implementation.

2. Member States shall require any natural or legal person who proposes to dispose, directly or indirectly, of a qualifying holding in an assurance undertaking first to inform the competent authorities of the home Member State, indicating the size of his intended holding. Such a person must likewise inform the competent authorities if he proposes to reduce his qualifying holding so that the proportion of the voting rights or of the capital held by him would fall below 20 %, 33 % or 50 % or so that the assurance undertaking would cease to be his subsidiary.

3. On becoming aware of them, assurance undertakings shall inform the competent authorities of their home Member States of any acquisitions or disposals of holdings in their capital that cause holdings to exceed or fall below one of the thresholds referred to in paragraphs 1 and 2.

They shall also, at least once a year, inform them of the names of shareholders and members possessing qualifying holdings and the sizes of such holdings as shown, for example, by the information received at the annual general meetings of shareholders and members or as a result of compliance with the regulations relating to companies listed on stock exchanges.

4. Member States shall require that, if the influence exercised by the persons referred to in paragraph 1 is likely to operate to the detriment of the prudent and sound management of the assurance undertaking, the competent authorities of the home Member State shall take appropriate measures to put an end to that situation. Such measures may consist, for example, in injunctions, sanctions against directors and managers, or the suspension of the exercise of the voting rights attaching to the shares held by the shareholders or members in question.

Similar measures shall apply to natural or legal persons failing to comply with the obligation to provide prior information, as laid down in paragraph 1. If a holding is acquired despite the opposition of the competent authorities, the Member States shall, regardless of any other sanctions to be adopted, provide either for exercise of the corresponding voting rights to be suspended, or for the nullity of votes cast or for the possibility of their annulment.

*Article 16*

**Professional secrecy**

1. Member States shall provide that all persons working or who have worked for the competent authorities, as well as auditors or experts acting on behalf of the competent authorities, shall be bound by the obligation of professional secrecy. This means that no confidential information which they may receive in the course of their duties may be divulged to any person or authority whatsoever, except in summary or aggregate form, such that individual assurance undertakings cannot be identified, without prejudice to cases covered by criminal law.

Nevertheless, where an assurance undertaking has been declared bankrupt or is being compulsorily wound up, confidential information which does not concern third parties involved in attempts to rescue that undertaking may be divulged in civil or commercial proceedings.

2. Paragraph 1 shall not prevent the competent authorities of the different Member States from exchanging information in accordance with the directives applicable to assurance undertakings. That information shall be subject to the conditions of professional secrecy indicated in paragraph 1.

3. Member States may conclude cooperation agreements, providing for exchanges of information, with the competent authorities of third countries only if the information disclosed is subject to guarantees of professional secrecy at least equivalent to those referred to in this Article.

4. Competent authorities receiving confidential information under paragraphs 1 or 2 may use it only in the course of their duties:

— to check that the conditions governing the taking-up of the business of assurance are met and to facilitate monitoring of the conduct of such business, especially with regard to the monitoring of technical provisions, solvency margins, administrative and accounting procedures and internal control mechanisms, or

— to impose sanctions, or

— in administrative appeals against decisions of the competent authority, or

— in court proceedings initiated pursuant to Article 68 or under special provisions provided for in this Directive and other directives adopted in the field of assurance undertakings.

5. Paragraphs 1 and 4 shall not preclude the exchange of information within a Member State, where there are two or more competent authorities in the same Member State, or, between Member States, between competent authorities and:

— authorities responsible for the official supervision of credit institutions and other financial organisations and the authorities responsible for the supervision of financial markets,

— bodies involved in the liquidation and bankruptcy of assurance undertakings and in other similar procedures, and

— persons responsible for carrying out statutory audits of the accounts of assurance undertakings and other financial institutions,

in the discharge of their supervisory functions, and the disclosure, to bodies which administer (compulsory) winding-up proceedings or guarantee funds, of information necessary to the performance of their duties. The information received by these authorities, bodies and persons shall be subject to the obligation of professional secrecy laid down in paragraph 1.

6. Notwithstanding paragraphs 1 to 4, Member States may authorise exchanges of information between the competent authorities and:

— the authorities responsible for overseeing the bodies involved in the liquidation and bankruptcy of assurance undertakings and other similar procedures, or

— the authorities responsible for overseeing the persons charged with carrying out statutory audits of the accounts of insurance undertakings, credit institutions, investment firms and other financial institutions, or

— independent actuaries of insurance undertakings carrying out legal supervision of those undertakings and the bodies responsible for overseeing such actuaries.

Member States which have recourse to the option provided for in the first subparagraph shall require at least that the following conditions are met:

— this information shall be for the purpose of carrying out the overseeing or legal supervision referred to in the first subparagraph;

— information received in this context shall be subject to the conditions of professional secrecy imposed in paragraph 1;

— where the information originates in another Member State, it may not be disclosed without the express agreement of the competent authorities which have disclosed it and, where appropriate, solely for the purposes for which those authorities gave their agreement.

Member States shall communicate to the Commission and to the other Member States the names of the authorities, persons and bodies which may receive information pursuant to this paragraph.

7. Notwithstanding paragraphs 1 to 4, Member States may, with the aim of strengthening the stability, including integrity, of the financial system, authorise the exchange of information between the competent authorities and the authorities or bodies responsible under the law for the detection and investigation of breaches of company law.

Member States which have recourse to the option provided for in the first subparagraph shall require at least that the following conditions are met:

— the information shall be for the purpose of performing the task referred to in the first subparagraph;

— information received in this context shall be subject to the conditions of professional secrecy imposed in paragraph 1;

— where the information originates in another Member State, it may not be disclosed without the express agreement of the competent authorities which have disclosed it and, where appropriate, solely for the purposes for which those authorities gave their agreement.

Where, in a Member State, the authorities or bodies referred to in the first subparagraph perform their task of detection or investigation with the aid, in view of their specific competence, of persons appointed for that purpose and not employed in the public sector, the possibility of exchanging information provided for in the first subparagraph may be extended to such persons under the conditions stipulated in the second subparagraph.

In order to implement the third indent of the second subparagraph, the authorities or bodies referred to in the first subparagraph shall communicate to the competent authorities which have disclosed the information, the names and precise responsibilities of the persons to whom it is to be sent.

Member States shall communicate to the Commission and to the other Member States the names of the authorities or bodies which may receive information pursuant to this paragraph.

Before 31 December 2000, the Commission shall draw up a report on the application of this paragraph.

8. Member States may authorise the competent authorities to transmit:

— to central banks and other bodies with a similar function in their capacity as monetary authorities;

— where appropriate, to other public authorities responsible for overseeing payment systems,

information intended for the performance of their task and may authorise such authorities or bodies to communicate to the competent authorities such information as they may need for the purposes of paragraph 4. Information received in this context shall be subject to the conditions of professional secrecy imposed in this Article.

9. In addition, notwithstanding paragraphs 1 and 4, Member States may, under provisions laid down by law, authorise the disclosure of certain information to other departments of their central government administrations responsible for legislation on the supervision of credit institutions, financial institutions, investment services and assurance undertakings and to inspectors acting on behalf of those departments.

However, such disclosures may be made only where necessary for reasons of prudential control.

However, Member States shall provide that information received under paragraphs 2 and 5 and that obtained by means of the on-the-spot verification referred to in Article 11 may never be disclosed in the cases referred to in this paragraph except with the express consent of the competent authorities which disclosed the information or of the competent authorities of the Member State in which on-the-spot verification was carried out.

*Article 17*

**Duties of auditors**

1. Member States shall provide at least that:

(a) any person authorised within the meaning of Council Directive 84/253/EEC [1], performing in an assurance undertaking the task described in Article 51 of Council Directive 78/660/EEC [2], Article 37 of Directive 83/349/EEC or Article 31 of Council Directive 85/611/EEC [3] or any other statutory task, shall have a duty to report promptly to the competent authorities any fact or decision concerning that undertaking of which he has become aware while carrying out that task which is liable to:

— constitute a material breach of the laws, regulations or administrative provisions which lay down the conditions governing authorisation or which specifically govern pursuit of the activities of assurance undertakings, or

[1] OJ L 126, 12.5.1984, p. 20.

[2] OJ L 222, 14.8.1978, p. 11. Directive as last amended by Directive 1999/60/EC (OJ L 162, 26.6.1999, p. 65).

[3] OJ L 375, 31.12.1985, p. 3. Directive as amended by Directive 95/26/EEC.

— affect the continuous functioning of the assurance undertaking, or

— lead to refusal to certify the accounts or to the expression of reservations;

(b) that person shall likewise have a duty to report any facts and decisions of which he becomes aware in the course of carrying out a task as described in (a) in an undertaking having close links resulting from a control relationship with the assurance undertaking within which he is carrying out the abovementioned task.

2. The disclosure in good faith to the competent authorities, by persons authorised within the meaning of Directive 84/253/EEC, of any fact or decision referred to in paragraph 1 shall not constitute a breach of any restriction on disclosure of information imposed by contract or by any legislative, regulatory or administrative provision and shall not involve such persons in liability of any kind.

*Article 18*

**Pursuit of life assurance and non-life insurance activities**

1. Without prejudice to paragraphs 3 and 7, no undertaking may be authorised both pursuant to this Directive and pursuant to Directive 73/239/EEC.

2. By way of derogation from paragraph 1, Member States may provide that:

— undertakings authorised pursuant to this Directive may also obtain authorisation, in accordance with Article 6 of Directive 73/239/EEC for the risks listed in classes 1 and 2 in the Annex to that Directive,

— undertakings authorised pursuant to Article 6 of Directive 73/239/EEC solely for the risks listed in classes 1 and 2 in the Annex to that Directive may obtain authorisation pursuant to this Directive.

3. Subject to paragraph 6, undertakings referred to in paragraph 2 and those which on:

— 1 January 1981 for undertakings authorised in Greece,

— 1 January 1986 for undertakings authorised in Spain and Portugal,

— 2 May 1992 for undertakings authorised in Austria, Finland and Sweden, and

— 15 March 1979 for all other undertakings,

carried on simultaneously both of the activities covered by this Directive and by Directive 73/239/EEC may continue to do so, provided that each activity is separately managed in accordance with Article 19 of this Directive.

4. Member States may provide that the undertakings referred to in paragraph 2 shall comply with the accounting rules governing assurance undertakings authorised pursuant to this Directive for all of their activities. Pending coordination in this respect, Member States may also provide that, with regard to rules on winding-up, activities relating to the risks listed in classes 1 and 2 in the Annex to Directive 73/239/EEC carried on by the undertakings referred to in paragraph 2 shall be governed by the rules applicable to life assurance activities.

5. Where an undertaking carrying on the activities referred to in the Annex to Directive 73/239/EEC has financial, commercial or administrative links with an assurance undertaking carrying on the activities covered by this Directive, the competent authorities of the Member States within whose territories the head offices of those undertakings are situated shall ensure that the accounts of the undertakings in question are not distorted by agreements between these undertakings or by any arrangement which could affect the apportionment of expenses and income.

6. Any Member State may require assurance undertakings whose head offices are situated in its territory to cease, within a period to be determined by the Member State concerned, the simultaneous pursuit of activities in which they were engaged on the dates referred to in paragraph 3.

7. The provisions of this Article shall be reviewed on the basis of a report from the Commission to the Council in the light of future harmonisation of the rules on winding-up, and in any case before 31 December 1999.

*Article 19*

**Separation of life assurance and non-life insurance management**

1. The separate management referred to in Article 18(3) must be organised in such a way that the activities covered by this Directive are distinct from the activities covered by Directive 73/239/EEC in order that:

— the respective interests of life policy-holders and non-life policy-holders are not prejudiced and, in particular, that profits from life assurance benefit life policy-holders as if the assurance undertaking only carried on the activity of life assurance,

— the minimum financial obligations, in particular solvency margins, in respect of one or other of the two activities, namely an activity under this Directive and an activity under Directive 73/239/EEC are not borne by the other activity.

However, as long as the minimum financial obligations are fulfilled under the conditions laid down in the second indent of the first subparagraph and, provided the competent authority is informed, the undertaking may use those explicit items of the solvency margin which are still available for one or other activity.

The competent authorities shall analyse the results in both activities so as to ensure that the provisions of this paragraph are complied with.

2. (a) Accounts shall be drawn up in such a manner as to show the sources of the results for each of the two activities, life assurance and non-life insurance. To this end all income (in particular premiums, payments by re-insurers and investment income) and expenditure (in particular insurance settlements, additions to technical provisions, reinsurance premiums, operating expenses in respect of insurance business) shall be broken down according to origin. Items common to both activities shall be entered in accordance with methods of apportionment to be accepted by the competent authority.

(b) Assurance undertakings must, on the basis of the accounts, prepare a statement clearly identifying the items making up each solvency margin, in accordance with Article 27 of this Directive and Article 16(1) of Directive 73/239/EEC.

3. If one of the solvency margins is insufficient, the competent authorities shall apply to the deficient activity the measures provided for in the relevant Directive, whatever the results in the other activity. By way of derogation from the second indent of the first subparagraph of paragraph 1, these measures may involve the authorisation of a transfer from one activity to the other.

## Chapter 2

## Rules relating to technical provisions

*Article 20*

### Establishment of technical provisions

1. The home Member State shall require every assurance undertaking to establish sufficient technical provisions, including mathematical provisions, in respect of its entire business.

The amount of such technical provisions shall be determined according to the following principles:

A. (i) The amount of the technical life-assurance provisions shall be calculated by a sufficiently prudent prospective actuarial valuation, taking account of all future liabilities as determined by the policy conditions for each existing contract, including:

— all guaranteed benefits, including guaranteed surrender values,

— bonuses to which policy-holders are already either collectively or individually entitled, however those bonuses are described — vested, declared or allotted,

— all options available to the policy-holder under the terms of the contract,

— expenses, including commissions;

taking credit for future premiums due;

(ii) the use of a retrospective method is allowed, if it can be shown that the resulting technical provisions are not lower than would be required under a sufficiently prudent prospective calculation or if a prospective method cannot be used for the type of contract involved;

(iii) a prudent valuation is not a 'best estimate' valuation, but shall include an appropriate margin for adverse deviation of the relevant factors;

(iv) the method of valuation for the technical provisions must not only be prudent in itself, but must also be so having regard to the method of valuation for the assets covering those provisions;

(v) technical provisions shall be calculated separately for each contract. The use of appropriate approximations or generalisations is allowed, however, where they are likely to give approximately the same result as individual calculations. The principle of separate calculation shall in no way prevent the establishment of additional provisions for general risks which are not individualised;

(vi) where the surrender value of a contract is guaranteed, the amount of the mathematical provisions for the contract at any time shall be at least as great as the value guaranteed at that time.

B. The rate of interest used shall be chosen prudently. It shall be determined in accordance with the rules of the competent authority in the home Member State, applying the following principles:

(a) for all contracts, the competent authority of the assurance undertaking's home Member State shall fix one or more maximum rates of interest, in particular in accordance with the following rules:

(i) when contracts contain an interest rate guarantee, the competent authority in the home Member State shall set a single maximum rate of interest. It may differ according to the currency in which the contract is denominated, provided that it is not more than 60 % of the rate on bond issues by the State in whose currency the contract is denominated. In the case of a contract denominated in euro, this limit shall be set by reference to euro-denominated issues by the Community institutions.

If a Member State decides, pursuant to the second sentence of the first subparagraph, to set a maximum rate of interest for contracts denominated in another Member State's currency, it shall first consult the competent authority of the Member State in whose currency the contract is denominated;

(ii) however, when the assets of the assurance undertaking are not valued at their purchase price, a Member State may stipulate that one or more maximum rates may be calculated taking into account the yield on the corresponding assets currently held, minus a prudential margin and, in particular for contracts with periodic premiums, furthermore taking into account the anticipated yield on future assets. The prudential margin and the maximum rate or rates of interest applied to the anticipated yield on future assets shall be fixed by the competent authority of the home Member State;

(b) the establishment of a maximum rate of interest shall not imply that the assurance undertaking is bound to use a rate as high as that;

(c) the home Member State may decide not to apply (a) to the following categories of contracts:

— unit-linked contracts,

— single-premium contracts for a period of up to eight years,

— without-profits contracts, and annuity contracts with no surrender value.

In the cases referred to in the second and third indents of the first subparagraph, in choosing a prudent rate of interest, account may be taken of the currency in which the contract is denominated and corresponding assets currently held and where the undertaking's assets are valued at their current value, the anticipated yield on future assets.

Under no circumstances may the rate of interest used be higher than the yield on assets as calculated in accordance with the accounting rules in the home Member State, less an appropriate deduction;

(d) the Member State shall require an assurance undertaking to set aside in its accounts a provision to meet interest-rate commitments vis-à-vis policy-holders if the present or foreseeable yield on the undertaking's assets is insufficient to cover those commitments;

(e) the Commission and the competent authorities of the Member States which so request shall be notified of the maximum rates of interest set under (a).

C. The statistical elements of the valuation and the allowance for expenses used shall be chosen prudently, having regard to the Member State of the commitment, the type of policy and the administrative costs and commissions expected to be incurred.

D. In the case of participating contracts, the method of calculation for technical provisions may take into account, either implicitly or explicitly, future bonuses of all kinds, in a manner consistent with the other assumptions on future experience and with the current method of distribution of bonuses.

E. Allowance for future expenses may be made implicitly, for instance by the use of future premiums net of management charges. However, the overall allowance, implicit or explicit, shall be not less than a prudent estimate of the relevant future expenses.

F. The method of calculation of technical provisions shall not be subject to discontinuities from year to year arising from arbitrary changes to the method or the bases of calculation and shall be such as to recognise the distribution of profits in an appropriate way over the duration of each policy.

2. Assurance undertakings shall make available to the public the bases and methods used in the calculation of the technical provisions, including provisions for bonuses.

3. The home Member State shall require every assurance undertaking to cover the technical provisions in respect of its entire business by matching assets, in accordance with Article 26. In respect of business written in the Community, these assets must be localised within the Community. Member States shall not require assurance undertakings to localise their assets in a particular Member State. The home Member State may, however, permit relaxations in the rules on the localisation of assets.

4. If the home Member State allows any technical provisions to be covered by claims against reassurers, it shall fix the percentage so allowed. In such case, it may not require the localisation of the assets representing such claims.

*Article 21*

**Premiums for new business**

Premiums for new business shall be sufficient, on reasonable actuarial assumptions, to enable assurance undertakings to meet all their commitments and, in particular, to establish adequate technical provisions.

For this purpose, all aspects of the financial situation of an assurance undertaking may be taken into account, without the input from resources other than premiums and income earned thereon being systematic and permanent in such a way that it may jeopardise the undertaking's solvency in the long term.

*Article 22*

**Assets covering technical provisions**

The assets covering the technical provisions shall take account of the type of business carried on by an assurance undertaking in such a way as to secure the safety, yield and marketability of its investments, which the undertaking shall ensure are diversified and adequately spread.

*Article 23*

**Categories of authorised assets**

1. The home Member State may not authorise assurance undertakings to cover their technical provisions with any but the following categories of assets:

A. Investments

(a) debt securities, bonds and other money- and capital-market instruments;

(b) loans;

(c) shares and other variable-yield participations;

(d) units in undertakings for collective investment in transferable securities (UCITS) and other investment funds;

(e) land, buildings and immovable property rights;

B. Debts and claims

(f) debts owed by reassurers, including reassurers' shares of technical provisions;

(g) deposits with and debts owed by ceding undertakings;

(h) debts owed by policy-holders and intermediaries arising out of direct and reassurance operations;

(i) advances against policies;

(j) tax recoveries;

(k) claims against guarantee funds;

C. Others

(l) tangible fixed assets, other than land and buildings, valued on the basis of prudent amortisation;

(m) cash at bank and in hand, deposits with credit institutions and any other body authorised to receive deposits;

(n) deferred acquisition costs;

(o) accrued interest and rent, other accrued income and prepayments;

(p) reversionary interests.

2. In the case of the association of underwriters known as Lloyd's, asset categories shall also include guarantees and letters of credit issued by credit institutions within the meaning of European Parliament and Council Directive . . ./. . ./EC or by assurance undertakings, together with verifiable sums arising out of life assurance policies, to the extent that they represent funds belonging to members.

3. The inclusion of any asset or category of assets listed in . . . paragraph (1) shall not mean that all these assets should automatically be accepted as cover for technical provisions. The home Member State shall lay down more detailed rules fixing the conditions for the use of acceptable assets; in this connection, it may require valuable security or guarantees, particularly in the case of debts owed by reassurers.

In determining and applying the rules which it lays down, the home Member State shall, in particular, ensure that the following principles are complied with:

(i) assets covering technical provisions shall be valued net of any debts arising out of their acquisition;

(ii) all assets must be valued on a prudent basis, allowing for the risk of any amounts not being realisable. In particular, tangible fixed assets other than land and buildings may be accepted as cover for technical provisions only if they are valued on the basis of prudent amortisation;

(iii) loans, whether to undertakings, to a State or international organisation, to local or regional authorities or to natural persons, may be accepted as cover for technical provisions only if there are sufficient guarantees as to their security, whether these are based on the status of the borrower, mortgages, bank guarantees or guarantees granted by assurance undertakings or other forms of security;

(iv) derivative instruments such as options, futures and swaps in connection with assets covering technical provisions may be used in so far as they contribute to a reduction of investment risks or facilitate efficient portfolio management. They must be valued on a prudent basis and may be taken into account in the valuation of the underlying assets;

(v) transferable securities which are not dealt in on a regulated market may be accepted as cover for technical provisions only if they can be realised in the short term or if they are holdings in credit institutions, in assurance undertakings, within the limits permitted by Article 6, or in investment undertakings established in a Member State;

(vi) debts owed by and claims against a third party may be accepted as cover for the technical provisions only after deduction of all amounts owed to the same third party;

(vii) the value of any debts and claims accepted as cover for technical provisions must be calculated on a prudent basis, with due allowance for the risk of any amounts not being realisable. In particular, debts owed by policy-holders and intermediaries arising out of assurance and reassurance operations may be accepted only in so far as they have been outstanding for not more than three months;

(viii) where the assets held include an investment in a subsidiary undertaking which manages all or part of the assurance undertaking's investments on its behalf, the home Member State must, when applying the rules and principles laid down in this Article, take into account the underlying assets held by the subsidiary undertaking; the home Member State may treat the assets of other subsidiaries in the same way;

(ix) deferred acquisition costs may be accepted as cover for technical provisions only to the extent that this is consistent with the calculation of the mathematical provisions.

4. Notwithstanding paragraphs 1, 2 and 3, in exceptional circumstances and at an assurance undertaking's request, the home Member State may, temporarily and under a properly reasoned decision, accept other categories of assets as cover for technical provisions, subject to Article 22.

*Article 24*

**Rules for investment diversification**

1. As regards the assets covering technical provisions, the home Member State shall require every assurance undertaking to invest no more than:

(a) 10 % of its total gross technical provisions in any one piece of land or building, or a number of pieces of land or buildings close enough to each other to be considered effectively as one investment;

(b) 5 % of its total gross technical provisions in shares and other negotiable securities treated as shares, bonds, debt securities and other money- and capital-market instruments from the same undertaking, or in loans granted to the same borrower, taken together, the loans being loans other than those granted to a State, regional or local authority or to an international organisation of which one or more Member States are members. This limit may be raised to 10 % if an undertaking invests not more than 40 % of its gross technical provisions in the loans or securities of issuing bodies and borrowers in each of which it invests more than 5 % of its assets;

(c) 5 % of its total gross technical provisions in unsecured loans, including 1 % for any single unsecured loan, other than loans granted to credit institutions, assurance undertakings in so far as Article 6 allows it and investment undertakings established in a Member State. The limits may be raised to 8 % and 2 % respectively by a decision taken on a case-by-case basis by the competent authority of the home Member State;

(d) 3 % of its total gross technical provisions in the form of cash in hand;

(e) 10 % of its total gross technical provisions in shares, other securities treated as shares and debt securities which are not dealt in on a regulated market.

2. The absence of a limit in paragraph 1 on investment in any particular category does not imply that assets in that category should be accepted as cover for technical provisions without limit. The home Member State shall lay down more detailed rules fixing the conditions for the use of acceptable assets. In particular it shall ensure, in the determination and the application of those rules, that the following principles are complied with:

(i) assets covering technical provisions must be diversified and spread in such a way as to ensure that there is no excessive reliance on any particular category of asset, investment market or investment;

(ii) investment in particular types of asset which show high levels of risk, whether because of the nature of the asset or the quality of the issuer, must be restricted to prudent levels;

(iii) limitations on particular categories of asset must take account of the treatment of reassurance in the calculation of technical provisions;

(iv) where the assets held include an investment in a subsidiary undertaking which manages all or part of the assurance undertaking's investments on its behalf, the home Member State must, when applying the rules and principles laid down in this Article, take into account the underlying assets held by the subsidiary undertaking; the home Member State may treat the assets of other subsidiaries in the same way;

(v) the percentage of assets covering technical provisions which are the subject of non-liquid investments must be kept to a prudent level;

(vi) where the assets held include loans to or debt securities issued by certain credit institutions, the home Member State may, when applying the rules and principles contained in this Article, take into account the underlying assets held by such credit institutions. This treatment may be applied only where the credit institution has its head office in a Member State, is entirely owned by that Member State and/or that State's local authorities and its business, according to its memorandum and articles of association, consists of extending, through its intermediaries, loans to, or guaranteed by, States or local authorities or of loans to bodies closely linked to the State or to local authorities.

3. In the context of the detailed rules laying down the conditions for the use of acceptable assets, the Member State shall give more limitative treatment to:

— any loan unaccompanied by a bank guarantee, a guarantee issued by an assurance undertaking, a mortgage or any other form of security, as compared with loans accompanied by such collateral,

— UCITS not coordinated within the meaning of Directive 85/611/EEC and other investment funds, as compared with UCITS coordinated within the meaning of that Directive,

— securities which are not dealt in on a regulated market, as compared with those which are,

— bonds, debt securities and other money- and capital-market instruments not issued by States, local or regional authorities or undertakings belonging to Zone A as defined in Directive ../.../EC or the issuers of which are international organisations not numbering at least one Community Member State among their members, as compared with the same financial instruments issued by such bodies.

4. Member States may raise the limit laid down in paragraph 1(b) to 40 % in the case of certain debt securities when these are issued by a credit institution which has its head office in a Member State and is subject by law to special official supervision designed to protect the holders of those debt securities. In particular, sums deriving from the issue of such debt securities must be invested in accordance with the law in assets which, during the whole period of validity of the debt securities, are capable of covering claims attaching to debt securities and which, in the event of failure of the issuer, would be used on a priority basis for the reimbursement of the principal and payment of the accrued interest.

5. Member States shall not require assurance undertakings to invest in particular categories of assets.

6. Notwithstanding paragraph 1, in exceptional circumstances and at the assurance undertaking's request, the home Member State may, temporarily and under a properly reasoned decision, allow exceptions to the rules laid down in paragraph 1 (a) to (e), subject to Article 22.

*Article 25*

**Contracts linked to UCITS or share index**

1. Where the benefits provided by a contract are directly linked to the value of units in a UCITS or to the value of assets contained in an internal fund held by the insurance undertaking, usually divided into units, the technical provisions in respect of those benefits must be represented as closely as possible by those units or, in the case where units are not established, by those assets.

2. Where the benefits provided by a contract are directly linked to a share index or some other reference value other than those referred to in paragraph 1, the technical provisions in respect of those benefits must be represented as closely as possible either by the units deemed to represent the reference value or, in the case where units are not established, by assets of appropriate security and marketability which correspond as closely as possible with those on which the particular reference value is based.

3. Articles 22 and 24 shall not apply to assets held to match liabilities which are directly linked to the benefits referred to in paragraphs 1 and 2. References to the technical provisions in Article 24 shall be to the technical provisions excluding those in respect of such liabilities.

4. Where the benefits referred to in paragraphs 1 and 2 include a guarantee of investment performance or some other guaranteed benefit, the corresponding additional technical provisions shall be subject to Articles 22, 23 and 24.

*Article 26*

**Matching rules**

1. For the purposes of Articles 20 (3) and 52, Member States shall comply with Annex II as regards the matching rules.

2. This Article shall not apply to the commitments referred to in Article 25.

Chapter 3

Rules Relating to the Solvency Margin and to the Guarantee Fund

*Article 27*

**Solvency margin**

Each Member State shall require of every assurance undertaking whose head office is situated in its territory an adequate solvency margin in respect of its entire business.

The solvency margin shall consist of:

1. the assets of the assurance undertaking free of any foreseeable liabilities, less any intangible items. In particular the following shall be included:

   — the paid-up share capital or, in the case of a mutual assurance undertaking, the effective initial fund plus any members' accounts which meet all the following criteria:

      (a) the memorandum and articles of association must stipulate that payments may be made from these accounts to members only in so far as this does not cause the solvency margin to fall below the required level, or, after the dissolution of the undertaking, if all the undertaking's other debts have been settled;

      (b) the memorandum and articles of association must stipulate, with respect to any such payments for reasons other than the individual termination of membership, that the competent authorities must be notified at least one month in advance and can prohibit the payment within that period;

      (c) the relevant provisions of the memorandum and articles of association may be amended only after the competent authorities have declared that they have no objection to the amendment, without prejudice to the criteria stated in (a) and (b),

   — one half of the unpaid share capital or initial fund, once the paid-up part amounts to 25 % of that share capital or fund,

   — reserves (statutory reserves and free reserves) not corresponding to underwriting liabilities,

   — any profits brought forward,

   — cumulative preferential share capital and subordinated loan capital may be included but, if so, only up to 50 % of the margin, no more than 25 % of which shall consist of subordinated loans with a fixed maturity, or fixed-term cumulative preferential share capital, if the following minimum criteria are met:

      (a) in the event of the bankruptcy or liquidation of the assurance undertaking, binding agreements must exist under which the subordinated loan capital or preferential share capital ranks after the claims of all other creditors and is not to be repaid until all other debts outstanding at the time have been settled.

      Subordinated loan capital must also fulfil the following conditions:

      (b) only fully paid-up funds may be taken into account;

      (c) for loans with a fixed maturity, the original maturity must be at least five years. No later than one year before the repayment date the assurance undertaking must submit to the competent authorities for their approval a plan showing how the solvency margin will be kept at or brought to the required level at maturity, unless the extent to which the loan may rank as a component of the solvency margin is gradually reduced during at least the last five years before the repayment date. The competent authorities may authorise the early repayment of such loans provided application is made by the issuing assurance undertaking and its solvency margin will not fall below the required level;

(d) loans the maturity of which is not fixed must be repayable only subject to five years' notice unless the loans are no longer considered as a component of the solvency margin or unless the prior consent of the competent authorities is specifically required for early repayment. In the latter event the assurance undertaking must notify the competent authorities at least six months before the date of the proposed repayment, specifying the actual and required solvency margin both before and after that repayment. The competent authorities shall authorise repayment only if the assurance undertaking's solvency margin will not fall below the required level;

(e) the loan agreement must not include any clause providing that in specified circumstances, other than the winding-up of the assurance undertaking, the debt will become repayable before the agreed repayment dates;

(f) the loan agreement may be amended only after the competent authorities have declared that they have no objection to the amendment,

— securities with no specified maturity date and other instruments that fulfil the following conditions, including cumulative preferential shares other than those mentioned in the fifth indent, up to 50 % of the margin for the total of such securities and the subordinated loan capital referred to in the fifth indent:

(a) they may not be repaid on the initiative of the bearer or without the prior consent of the competent authority;

(b) the contract of issue must enable the assurance undertaking to defer the payment of interest on the loan;

(c) the lender's claims on the assurance undertaking must rank entirely after those of all non-subordinated creditors;

(d) the documents governing the issue of the securities must provide for the loss-absorption capacity of the debt and unpaid interest, while enabling the assurance undertaking to continue its business;

(e) only fully paid-up amounts may be taken into account;

2. in so far as authorised under national law, profit reserves appearing in the balance sheet where they may be used to cover any losses which may arise and where they have not been made available for distribution to policy-holders;

3. upon application, with supporting evidence, by the undertaking to the competent authority of the Member State in the territory of which its head office is situated and with the agreement of that authority:

(a) an amount equal to 50 % of the undertaking's future profits; the amount of the future profits shall be obtained by multiplying the estimated annual profit by a factor which represents the average period left to run on policies; the factor used may not exceed 10; the estimated annual profit shall be the arithmetical average of the profits made over the last five years in the activities listed in Article 2.

The bases for calculating the factor by which the estimated annual profit is to be multiplied and the items comprising the profits made shall be defined by common agreement by the competent authorities of the Member States in collaboration with the Commission. Pending such agreement, those items shall be determined in accordance with the laws of the home Member State.

When the competent authorities have defined the concept of profits made, the Commission shall submit proposals for the harmonisation of this concept by means of a Directive on the harmonisation of the annual accounts of insurance undertakings and providing for the coordination set out in Article 1(2) of Directive 78/660/EEC;

(b) where Zillmerizing is not practised or where, if practised, it is less than the loading for acquisition costs included in the premium, the difference between a non-Zillmerized or partially Zillmerized mathematical provision and a mathematical provision Zillmerized at a rate equal to the loading for acquisition costs included in the premium; this figure may not, however, exceed 3,5 % of the sum of the differences between the relevant capital sums of life assurance activities and the mathematical provisions for all policies for which Zillmerizing is possible; the difference shall be reduced by the amount of any undepreciated acquisition costs entered as an asset;

(c) where approval is given by the competent authorities of the Member States concerned in which the assurance undertaking is carrying on its activities any hidden reserves resulting from the under-estimation of assets and over-estimation of liabilities other than mathematical provisions in so far as such hidden reserves are not of an exceptional nature.

*Article 28*

**Minimum solvency margin**

Subject to Article 29, the minimum solvency margin shall be determined as shown below according to the classes of insurance underwritten:

(a) For the kinds of insurance referred to in Article 2, point (1)(a) and (b) other than assurances linked to investment funds and for the operations referred to in Article 2(3), it must be equal to the sum of the following two results:

— first result:

a 4 % fraction of the mathematical provisions, relating to direct business gross of reinsurance cessions and to reinsurance acceptances shall be multiplied by the ratio, for the last financial year, of the total mathematical provisions net of reinsurance cessions to the gross total mathematical provisions as specified above; that ratio may in no case be less than 85 %;

— second result:

for policies on which the capital at risk is not a negative figure, a 0,3 % fraction of such capital underwritten by the assurance undertaking shall be multiplied by the ratio, for the last financial year, of the total capital at risk retained as the undertaking's liability after reinsurance cessions and retrocessions to the total capital at risk gross of reinsurance; that ratio may in no case be less than 50 %.

For temporary assurance on death of a maximum term of three years the above fraction shall be 0,1 %; for such assurance of a term of more than three years but not more than five years the above fraction shall be 0,15 %.

(b) For the supplementary insurance referred to in Article 2, point (1)(c), it shall be equal to the result of the following calculation:

— the premiums or contributions (inclusive of charges ancillary to premiums or contributions) due in respect of direct business in the last financial year in respect of all financial years shall be aggregated;

— to this aggregate there shall be added the amount of premiums accepted for all reinsurance in the last financial year;

— from this sum shall then be deducted the total amount of premiums or contributions cancelled in the last financial year as well as the total amount of taxes and levies pertaining to the premiums or contributions entering into the aggregate.

The amount so obtained shall be divided into two portions, the first extending up to 10 million euro and the second comprising the excess; 18 % and 16 % of these portions respectively shall be calculated and added together.

The result shall be obtained by multiplying the sum so calculated by the ratio existing in respect of the last financial year between the amount of claims remaining to be borne by the assurance undertaking after deduction of transfers for reinsurance and the gross amount of claims; this ratio may in no case be less than 50 %.

In the case of the association of underwriters known as Lloyd's, the calculation of the solvency margin shall be made on the basis of net premiums, which shall be multiplied by flat-rate percentage fixed annually by the competent authority of the head-office Member State. This flat-rate percentage must be calculated on the basis of the most recent statistical data on commissions paid. The details together with the relevant calculations shall be sent to the competent authorities of the countries in whose territory Lloyd's is established.

(c) For permanent health insurance not subject to cancellation referred to in Article 2, point (1)(d), and for capital redemption operations referred to in Article 2, point (2)(b), it shall be equal to a 4 % fraction of the mathematical provisions calculated in compliance with the conditions set out in the first result in (a) of this Article.

(d) For tontines, referred to in Article 2, point (2)(a), it shall be equal to 1 % of their assets.

(e) For assurances covered by Article 2, point (1)(a) and (b) linked to investment funds and for the operations referred to in Article 2, point (2)(c), (d) and (e) it shall be equal to

— a 4 % fraction of the mathematical provisions, calculated in compliance with the conditions set out in the first result in (a) of this Article in so far as the assurance undertaking bears an investment risk, and a 1 % fraction of the provisions calculated in the same way, in so far as the undertaking bears no investment risk provided that the term of the contract exceeds five years and the allocation to cover management expenses set out in the contract is fixed for a period exceeding five years,

— a 0,3 % fraction of the capital at risk calculated in compliance with the conditions set out in the first subparagraph of the second result of (a) of this Article in so far as the assurance undertaking covers a death risk.

*Article 29*

**Guarantee fund**

1. One third of the minimum solvency margin as specified in Article 28 shall constitute the guarantee fund. Subject to paragraph 2, at least 50 % of this fund shall consist of the items listed in Article 27, points (1) and (2).

2. (a) The guarantee fund may not, however, be less than a minimum of 800 000 euro.

(b) Any Member State may provide for the minimum of the guarantee fund to be reduced to 600 000 euro in the case of mutual associations and mutual-type associations and tontines.

(c) For mutual associations referred to in the second sentence of the second indent of Article 3, point (6), as soon as they come within the scope of this Directive, and for tontines, any Member State may permit the establishment of a minimum of the guarantee fund of 100 000 euro to be increased progressively to the amount fixed in (b) by successive tranches of 100 000 euro whenever the contributions increase by 500 000 euro.

(d) The minimum of the guarantee fund referred to in (a), (b) and (c) must consist of the items listed in Article 27, points (1) and (2).

3. Mutual associations wishing to extend their business within the meaning of Article 6(3) or Article 38 may not do so unless they comply immediately with the requirements of paragraph 2(a) and (b) of this Article.

*Article 30*

**Assets not used to cover technical provisions**

1. Member States shall not prescribe any rules as to the choice of the assets that need not be used as cover for the technical provisions referred to in Article 20.

2. Subject to Article 20(3), Article 36(1), (2), (3) and (5), and the second subparagraph of Article 37(1), Member States shall not restrain the free disposal of those assets, whether movable or immovable, that form part of the assets of authorised assurance undertakings.

3. Paragraphs 1 and 2 shall not preclude any measures which Member States, while safeguarding the interests of the lives assured, are entitled to take as owners or members of or partners in the assurance undertakings in question.

Chapter 4

Contract Law and Conditions of Assurance

*Article 31*

**Law applicable**

1. The law applicable to contracts relating to the activities referred to in this Directive shall be the law of the Member State of the commitment. However, where the law of that State so allows, the parties may choose the law of another country.

2. Where the policy-holder is a natural person and has his habitual residence in a Member State other than that of which he is a national, the parties may choose the law of the Member State of which he is a national.

3. Where a State includes several territorial units, each of which has its own rules of law concerning contractual obligations, each unit shall be considered a country for the purposes of identifying the law applicable under this Directive.

A Member State in which various territorial units have their own rules of law concerning contractual obligations shall not be bound to apply the provisions of this Directive to conflicts which arise between the laws of those units.

4. Nothing in this Article shall restrict the application of the rules of the law of the forum in a situation where they are mandatory, irrespective of the law otherwise applicable to the contract.

If the law of a Member State so stipulates, the mandatory rules of the law of the Member State of the commitment may be applied if and in so far as, under the law of that Member State, those rules must be applied whatever the law applicable to the contract.

5. Subject to paragraphs 1 to 4, the Member States shall apply to the assurance contracts referred to in this Directive their general rules of private international law concerning contractual obligations.

*Article 32*

**General good**

The Member State of the commitment shall not prevent a policy-holder from concluding a contract with an assurance undertaking authorised under the conditions of Article 4 as long as that does not conflict with legal provisions protecting the general good in the Member State of the commitment.

*Article 33*

**Rules relating to conditions of assurance and scales of premiums**

Member States shall not adopt provisions requiring the prior approval or systematic notification of general and special policy conditions, scales of premiums, technical bases used in particular for calculating scales of premiums and technical provisions or forms and other printed documents which an assurance undertaking intends to use in its dealings with policy-holders.

Notwithstanding the first subparagraph, for the sole purpose of verifying compliance with national provisions concerning actuarial principles, ... the home Member State may require systematic communication of the technical bases used in particular for calculating scales of premiums and technical provisions, without that requirement constituting a prior condition for an assurance undertaking to carry on its business.

Not later than 1 July 1999 the Commission shall submit a report to the Council on the implementation of those provisions.

*Article 34*

**Cancellation period**

1. Each Member State shall prescribe that a policy-holder who concludes an individual life-assurance contract shall have a period of between 14 and 30 days from the time when he was informed that the contract had been concluded within which to cancel the contract.

The giving of notice of cancellation by the policy-holder shall have the effect of releasing him from any future obligation arising from the contract.

The other legal effects and the conditions of cancellation shall be determined by the law applicable to the contract as defined in Article 31, notably as regards the arrangements for informing the policy-holder that the contract has been concluded.

2. The Member States need not apply paragraph 1 to contracts of six months' duration or less, nor where, because of the status of the policy-holder or the circumstances in which the contract is concluded, the policy-holder does not need this special protection. Member States shall specify in their rules where paragraph 1 is not applied.

*Article 35*

**Information for policy-holders**

1. Before the assurance contract is concluded, at least the information listed in point A of Annex III shall be communicated to the policy-holder.

2. The policy-holder shall be kept informed throughout the term of the contract of any change concerning the information listed in point B of Annex III.

3. The Member State of the commitment may require assurance undertakings to furnish information in addition to that listed in Annex III only if it is necessary for a proper understanding by the policy-holder of the essential elements of the commitment.

4. The detailed rules for implementing this Article and Annex III shall be laid down by the Member State of the commitment.

Chapter 5

Assurance undertakings in difficulty or in an irregular situation

*Article 36*

**Assurance undertakings in difficulty**

1. If an assurance undertaking does not comply with Article 20, the competent authority of its home Member State may prohibit the free disposal of its assets after having communicated its intention to the competent authorities of the Member States of commitment.

2. For the purposes of restoring the financial situation of an assurance undertaking the solvency margin of which has fallen below the minimum required under Article 28, the competent authority of the home Member State shall require that a plan for the restoration of a sound financial position be submitted for its approval.

In exceptional circumstances, if the competent authority is of the opinion that the financial situation of the assurance undertaking will further deteriorate, it may also restrict or prohibit the free disposal of the assurance undertaking's assets. It shall inform the authorities of other Member States within the territories of which the assurance undertaking carries on business of any measures it has taken and the latter shall, at the request of the former, take the same measures.

3. If the solvency margin falls below the guarantee fund as defined in Article 29, the competent authority of the home Member State shall require the assurance undertaking to submit a short-term finance scheme for its approval.

It may also restrict or prohibit the free disposal of the assurance undertaking's assets. It shall inform the authorities of other Member States within the territories of which the assurance undertaking carries on business accordingly and the latter shall, at the request of the former, take the same measures.

4. The competent authorities may further take all measures necessary to safeguard the interests of the assured persons in the cases provided for in paragraphs 1, 2 and 3.

5. Each Member State shall take the measures necessary to be able in accordance with its national law to prohibit the free disposal of assets located within its territory at the request, in the cases provided for in paragraphs 1, 2 and 3, of the assurance undertaking's home Member State, which shall designate the assets to be covered by such measures.

*Article 37*

**Withdrawal of authorisation**

1. Authorisation granted to an assurance undertaking by the competent authority of its home Member State may be withdrawn by that authority if that undertaking:

(a) does not make use of the authorisation within 12 months, expressly renounces it or ceases to carry on business for more than 6 months, unless the Member State concerned has made provision for authorisation to lapse in such cases;

(b) no longer fulfils the conditions for admission;

(c) has been unable, within the time allowed, to take the measures specified in the restoration plan or finance scheme referred to in Article 36;

(d) fails seriously in its obligations under the regulations to which it is subject.

In the event of the withdrawal or lapse of the authorisation, the competent authority of the home Member State shall notify the competent authorities of the other Member States accordingly and they shall take appropriate measures to prevent the assurance undertaking from commencing new operations within their territories, under either the freedom of establishment or the freedom to provide services. The home Member State's competent authority shall, in conjunction with those authorities, take all necessary measures to safeguard the interests of the assured persons and shall restrict, in particular, the free disposal of the assets of the assurance undertaking in accordance with Article 36(1), (2), second subparagraph, and (3), second subparagraph.

2. Any decision to withdraw an authorisation shall be supported by precise reasons and notified to the assurance undertaking in question.

TITLE IV

**PROVISIONS RELATING TO RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES**

*Article 38*

**Conditions for branch establishment**

1. An assurance undertaking that proposes to establish a branch within the territory of another Member State shall notify the competent authorities of its home Member State.

2. The Member States shall require every assurance undertaking that proposes to establish a branch within the territory of another Member State to provide the following information when effecting the notification provided for in paragraph 1:

(a) the Member State within the territory of which it proposes to establish a branch;

(b) a scheme of operations setting out *inter alia* the types of business envisaged and the structural organisation of the branch;

(c) the address in the Member State of the branch from which documents may be obtained and to which they may be delivered, it being understood that that address shall be the one to which all communications to the authorised agent are sent;

(d) the name of the branch's authorised agent, who must possess sufficient powers to bind the assurance undertaking in relation to third parties and to represent it in relations with the authorities and courts of the Member State of the branch. With regard to Lloyd's, in the event of any litigation in the Member State of the branch arising out of underwritten commitments, the assured persons must not be treated less favourably than if the litigation had been brought against businesses of a conventional type. The authorised agent must, therefore, possess sufficient powers for proceedings to be taken against him and must in that capacity be able to bind the Lloyd's underwriters concerned.

3. Unless the competent authorities of the home Member State have reason to doubt the adequacy of the administrative structure or the financial situation of the assurance undertaking or the good repute and professional qualification or experience of the directors or managers or the authorised agent, taking into account the business planned, they shall within three months of receiving all the information referred to in paragraph 2 communicate that information to the competent authorities of the Member State of the branch and shall inform the undertaking concerned accordingly.

The competent authorities of the home Member State shall also attest that the assurance undertaking has the minimum solvency margin calculated in accordance with Articles 28 and 29.

Where the competent authorities of the home Member State refuse to communicate the information referred to in paragraph 2 to the competent authorities of the Member State of the branch they shall give the reasons for their refusal to the assurance undertaking concerned within three months of receiving all the information in question. That refusal or failure to act shall be subject to a right to apply to the courts in the home Member State.

4. Before the branch of an assurance undertaking starts business, the competent authorities of the Member State of the branch shall, within two months of receiving the information referred to in paragraph 3, inform the competent authority of the home Member State, if appropriate, of the conditions under which, in the interest of the general good, that business must be carried on in the Member State of the branch.

5. On receiving a communication from the competent authorities of the Member State of the branch or, if no communication is received from them, on expiry of the period provided for in paragraph 4, the branch may be established and start business.

6. In the event of a change in any of the particulars communicated under paragraph 2 (b), (c) or (d), an assurance undertaking shall give written notice of the change to the competent authorities of the home Member State and of the Member State of the branch at least one month before making the change so that the competent authorities of the home Member State and the competent authorities of the Member State of the branch may fulfil their respective roles under paragraphs 3 and 4.

*Article 39*

**Freedom to provide services: Prior notification to the home Member State**

Any assurance undertaking that intends to carry on business for the first time in one or more Member States under the freedom to provide services shall first inform the competent authorities of the home Member State, indicating the nature of the commitments it proposes to cover.

*Article 40*

**Freedom to provide services: Notification by the home Member State**

1. Within one month of the notification provided for in Article 39 the competent authorities of the home Member State shall communicate to the Member State or Member States within the territory of which the assurance undertaking intends to carry on business by way of the freedom to provide services:

(a) a certificate attesting that the assurance undertaking has the minimum solvency margin calculated in accordance with Articles 28 and 29;

(b) the classes which the assurance undertaking has been authorised to offer;

(c) the nature of the commitments which the assurance undertaking proposes to cover in the Member State of the provision of services.

At the same time, they shall inform the assurance undertaking concerned accordingly.

2. Where the competent authorities of the home Member State do not communicate the information referred to in paragraph 1 within the period laid down, they shall give the reasons for their refusal to the assurance undertaking within that same period. The refusal shall be subject to a right to apply to the courts in the home Member State.

3. The assurance undertaking may start business on the certified date on which it is informed of the communication provided for in the first subparagraph of paragraph 1.

*Article 41*

**Freedom to provide services: Changes in the nature of commitments**

Any change which an assurance undertaking intends to make to the information referred to in Article 39 shall be subject to the procedure provided for in Articles 39 and 40.

*Article 42*

**Language**

The competent authorities of the Member State of the branch or the Member State of the provision of services may require that the information which they are authorised under this Directive to request with regard to the business of assurance undertakings operating in the territory of that State shall be supplied to them in the official language or languages of that State.

*Article 43*

**Rules relating to conditions of assurance and scales of premiums**

The Member State of the branch or of provision of services shall not lay down provisions requiring the prior approval or systematic notification of general and special policy conditions, scales of premiums, technical bases used in particular for calculating scales of premiums and technical provisions, forms and other printed documents which an assurance undertaking intends to use in its dealings with policy-holders. For the purpose of verifying compliance with national provisions concerning assurance contracts, it may require an assurance undertaking that proposes to carry on assurance business within its territory, under the right of establishment or the freedom to provide services, to effect only non-systematic notification of those policy conditions and other printed documents without that requirement constituting a prior condition for an assurance undertaking to carry on its business.

*Article 44*

**Assurance undertakings not complying with the legal provisions**

1. Any assurance undertaking carrying on business under the right of establishment or the freedom to provide services shall submit to the competent authorities of the Member State of the branch and/or of the Member State of the provision of services all documents requested of it for the purposes of this Article in so far as assurance undertakings the head office of which is in those Member States are also obliged to do so.

2. If the competent authorities of a Member State establish that an assurance undertaking with a branch or carrying on business under the freedom to provide services in its territory is not complying with the legal provisions applicable to it in that State, they shall require the assurance undertaking concerned to remedy that irregular situation.

3. If the assurance undertaking in question fails to take the necessary action, the competent authorities of the Member State concerned shall inform the competent authorities of the home Member State accordingly. The latter authorities shall, at the earliest opportunity, take all appropriate measures to ensure that the assurance undertaking concerned remedies that irregular situation. The nature of those measures shall be communicated to the competent authorities of the Member State concerned.

4. If, despite the measures taken by the home Member State or because those measures prove inadequate or are lacking in that State, the assurance undertaking persists in violating the legal provisions in force in the Member State concerned, the latter may, after informing the competent authorities of the home Member State, take appropriate measures to prevent or penalise further irregularities, including, in so far as is strictly necessary, preventing that undertaking from continuing to conclude new assurance contracts within its territory. Member States shall ensure that in their territories it is possible to serve the legal documents necessary for such measures on assurance undertakings.

5. Paragraphs 2, 3 and 4 shall not affect the emergency power of the Member States concerned to take appropriate measures to prevent or penalise irregularities committed within their territories. This shall include the possibility of preventing assurance undertakings from continuing to conclude new assurance contracts within their territories.

6. Paragraphs 2, 3 and 4 shall not affect the power of the Member States to penalise infringements within their territories.

7. If an assurance undertaking which has committed an infringement has an establishment or possesses property in the Member State concerned, the competent authorities of the latter may, in accordance with national law, apply the administrative penalties prescribed for that infringement by way of enforcement against that establishment or property.

8. Any measure adopted under paragraphs 3 to 7 involving penalties or restrictions on the conduct of assurance business must be properly reasoned and communicated to the assurance undertaking concerned.

9. Every two years, the Commission shall submit to the Insurance Committee a report summarising the number and type of cases in which, in each Member State, authorisation has been refused pursuant to Articles 38 or 40 or measures have been taken under paragraph 4 of this Article. Member States shall cooperate with the Commission by providing it with the information required for that report.

*Article 45*

**Advertising**

Nothing in this Directive shall prevent assurance undertakings with head offices in other Member States from advertising their services through all available means of communication in the Member State of the branch or Member State of the provision of services, subject to any rules governing the form and content of such advertising adopted in the interest of the general good.

*Article 46*

**Winding up**

Should an assurance undertaking be wound up, commitments arising out of contracts underwritten through a branch or under the freedom to provide services shall be met in the same way as those arising out of that undertaking's other assurance contracts, without distinction as to nationality as far as the lives assured and the beneficiaries are concerned.

*Article 47*

**Statistical information on cross-border activities**

Every assurance undertaking shall inform the competent authority of its home Member State, separately in respect of transactions carried out under the right of establishment and those carried out under the freedom to provide services, of the amount of the premiums, without deduction of reassurance, by Member State and by each of classes I to IX, as defined in Annex I.

The competent authority of the home Member State shall, within a reasonable time and on an aggregate basis forward this information to the competent authorities of each of the Member States concerned which so request.

*Article 48*

**Taxes on premiums**

1. Without prejudice to any subsequent harmonisation, every assurance contract shall be subject exclusively to the indirect taxes and parafiscal charges on assurance premiums in the Member State of the commitment, and also, with regard to Spain, to the surcharges legally established in favour of the Spanish 'Consorcio de Compensación de Seguros' for the performance of its functions relating to the compensation of losses arising from extraordinary events occurring in that Member State.

2. The law applicable to the contract pursuant to Article 31 shall not affect the fiscal arrangements applicable.

3. Pending future harmonisation, each Member State shall apply to those assurance undertakings which cover commitments situated within its territory its own national provisions for measures to ensure the collection of indirect taxes and parafiscal charges due under paragraph 1.

TITLE V

## RULES APPLICABLE TO AGENCIES OR BRANCHES ESTABLISHED WITHIN THE COMMUNITY AND BELONGING TO UNDERTAKINGS WHOSE HEAD OFFICES ARE OUTSIDE THE COMMUNITY

*Article 49*

### Principles and conditions of authorisation

1. Each Member State shall make access to the activities referred to in Article 2 by any undertaking whose head office is outside the Community subject to an official authorisation.

2. A Member State may grant an authorisation if the undertaking fulfils at least the following conditions:

(a) it is entitled to undertake insurance activities covered by Article 2 under its national law;

(b) it establishes an agency or branch in the territory of such Member State;

(c) it undertakes to establish at the place of management of the agency or branch accounts specific to the activity which it carries on there and to keep there all the records relating to the business transacted;

(d) it designates a general representative, to be approved by the competent authorities;

(e) it possesses in the Member State where it carries on an activity assets of an amount equal in value to at least one half of the minimum amount prescribed in Article 29(2)(a) in respect of the guarantee fund and deposits one fourth of the minimum amount as security;

(f) it undertakes to keep a solvency margin complying with Article 53;

(g) it submits a scheme of operations in accordance with the provisions in paragraphs 3 and 4.

3. The scheme of operation of the agency or branch referred to in paragraph 2(g) shall contain the following particulars or evidence of:

(a) the nature of the commitments which the undertaking proposes to take on in the host country; the general and special policy conditions which it proposes to use;

(b) the technical bases which the undertaking proposes to employ for each class of business, including the data needed to calculate premium rates and technical provisions referred to in Article 20;

(c) the guiding principles as to reinsurance;

(d) the state of the undertaking's solvency margin and guarantee fund referred to in Articles 27, 28 and 29;

(e) estimates relating to the expenses of installing the administrative services and the organisation for securing business and the financial resources intended to cover them;

and, in addition shall include, for the first three financial years:

(f) a forecast balance sheet for the agency or branch;

(g) a plan setting out detailed estimates of income and expenditure in respect of direct business, reinsurance acceptances and reinsurance cessions.

4. The scheme of operations shall be accompanied by the balance sheet and profit and loss account of the undertaking for each of the past three financial years. If, however, it has not yet been in business for three financial years it shall be required to furnish them only for the financial years completed.

*Article 50*

### Rules applicable to branches of third country undertakings

1. (a) Subject to point (b), agencies and branches referred to in this Title may not simultaneously carry on in a Member State the activities referred to in the Annex to Directive 73/239/EEC and those covered by this Directive.

(b) Subject to point (c), Member States may provide that agencies and branches referred to in this Title which on the date referred to in Article 18(3) carried on both activities simultaneously in a Member State may continue to do so there provided that each activity is separately managed in accordance with Article 19.

(c) Any Member State which under Article 18(6) requires undertakings established in its territory to cease the simultaneous pursuit of the activities in which they were engaged on the dates referred to in Article 18(3) must also impose this requirement on agencies and branches referred to in this Title which are established in its territory and simultaneously carry on both activities there.

(d) Member States may provide that agencies and branches referred to in this Title whose head office simultaneously carries on both activities and which on the dates referred to in Article 18(3) carried on in the territory of a Member State solely the activity covered by this Directive may continue their activity there. If the undertaking wishes to carry on the activity referred to in Directive 73/239/EEC in that territory it may only carry on the activity covered by this Directive through a subsidiary.

2. Articles 13 and 36 shall apply *mutatis mutandis* to agencies and branches referred to in this title.

For the purposes of applying Article 36, the competent authority which supervises the overall solvency of agencies or branches shall be treated in the same way as the competent authority of the head-office Member State.

3. In the case of a withdrawal of authorisation by the authority referred to in Article 54(2), this authority shall notify the competent authorities of the other Member States where the undertaking operates and the latter authorities shall take the appropriate measures. If the reason for the withdrawal of authorisation is the inadequacy of the solvency margin calculated in accordance with Article 54(1)(a), the competent authorities of the other Member States concerned shall also withdraw their authorisations.

*Article 51*

**Transfer of portfolio**

1. Under the conditions laid down by national law, each Member State shall authorise agencies and branches set up within its territory and covered by this Title to transfer all or part of their portfolios of contracts to an accepting office established in the same Member State if the competent authorities of that Member State or, if appropriate, those of the Member State referred to in Article 54 certify that after taking the transfer into account the accepting office possesses the necessary solvency margin.

2. Under the conditions laid down by national law, each Member State shall authorise agencies and branches set up within its territory and covered by this Title to transfer all or part of their portfolios of contracts to an assurance undertaking with a head office in another Member State if the competent authorities of that Member State certify that after taking the transfer into account the accepting office possesses the necessary solvency margin.

3. If under the conditions laid down by national law a Member State authorises agencies and branches set up within its territory and covered by this Title to transfer all or part of their portfolios of contracts to an agency or branch covered by this Title and set up within the territory of another Member State it shall ensure that the competent authorities of the Member State of the accepting office or, if appropriate, of the Member State referred to in Article 54 certify that after taking the transfer into account the accepting office possesses the necessary solvency margin, that the law of the Member State of the accepting office permits such a transfer and that the State has agreed to the transfer.

4. In the circumstances referred to in paragraphs 1, 2 and 3 the Member State in which the transferring agency or branch is situated shall authorise the transfer after obtaining the agreement of the competent authorities of the Member State of the commitment, where different from the Member State in which the transferring agency or branch is situated.

5. The competent authorities of the Member States consulted shall give their opinion or consent to the competent authorities of the home Member State of the transferring assurance undertaking within three months of receiving a request; the absence of any response from the authorities consulted within that period shall be considered equivalent to a favourable opinion or tacit consent.

6. A transfer authorised in accordance with this Article shall be published as laid down by national law in the Member State of the commitment. Such transfers shall automatically be valid against policy-holders, assured persons and any other persons having rights or obligations arising out of the contracts transferred.

This provision shall not affect the Member States' right to give policy-holders the option of cancelling contracts within a fixed period after a transfer.

*Article 52*

**Technical provisions**

Member States shall require undertakings to establish provisions, referred to in Article 20, adequate to cover the underwriting liabilities assumed in their territories. Member States shall see that the agency or branch covers such provisions by means of assets which are equivalent to such provisions and matching assets in accordance with Annex II.

The law of the Member States shall be applicable to the calculation of such provisions, the determination of categories of investment and the valuation of assets, and, where appropriate, the determination of the extent to which these assets may be used for the purpose of covering such provisions.

The Member State in question shall require that the assets covering these provisions shall be localised in its territory. Article 20(4) shall, however, apply.

*Article 53*

**Solvency margin and guarantee fund**

1. Each Member State shall require of agencies or branches set up in its territory a solvency margin consisting of the items listed in Article 27. The minimum solvency margin shall be calculated in accordance with Article 28. However, for the purpose of calculating this margin, account shall be taken only of the operations effected by the agency or branch concerned.

2. One third of the minimum solvency margin shall constitute the guarantee fund.

However, the amount of this fund may not be less than one half of the minimum required under Article 29(2)(a). The initial deposit lodged in accordance with Article 49(2)(e) shall be counted towards such guarantee fund.

The guarantee fund and the minimum of such fund shall be constituted in accordance with Article 29.

3. The assets representing the minimum solvency margin must be kept within the Member State where activities are carried on up to the amount of the guarantee fund and the excess within the Community.

*Article 54*

**Advantages to undertakings authorised in more than one Member State**

1. Any undertaking which has requested or obtained authorisation from more than one Member State may apply for the following advantages which may be granted only jointly:

(a) the solvency margin referred to in Article 53 shall be calculated in relation to the entire business which it carries on within the Community; in such case, account shall be taken only of the operations effected by all the agencies or branches established within the Community for the purposes of this calculation;

(b) the deposit required under Article 49(2)(e) shall be lodged in only one of those Member States;

(c) the assets representing the guarantee fund shall be localised in any one of the Member States in which it carries on its activities.

2. Application to benefit from the advantages provided for in paragraph 1 shall be made to the competent authorities of the Member States concerned. The application must state the authority of the Member State which in future is to supervise the solvency of the entire business of the agencies or branches established within the Community. Reasons must be given for the choice of authority made by the undertaking. The deposit shall be lodged with that Member State.

3. The advantages provided for in paragraph 1 may only be granted if the competent authorities of all Member States in which an application has been made agree to them. They shall take effect from the time when the selected competent authority informs the other competent authorities that it will supervise the state of solvency of the entire business of the agencies or branches within the Community.

The competent authority selected shall obtain from the other Member States the information necessary for the supervision of the overall solvency of the agencies and branches established in their territory.

4. At the request of one or more of the Member States concerned, the advantages granted under this Article shall be withdrawn simultaneously by all Member States concerned.

*Article 55*

**Agreements with third countries**

The Community may, by means of agreements concluded pursuant to the Treaty with one or more third countries, agree to the application of provisions different from those provided for in this Title, for the purpose of ensuring, under conditions of reciprocity, adequate protection for policy-holders in the Member States.

TITLE VI

**RULES APPLICABLE TO SUBSIDIARIES OF PARENT UNDERTAKINGS GOVERNED BY THE LAWS OF A THIRD COUNTRY AND TO THE ACQUISITIONS OF HOLDINGS BY SUCH PARENT UNDERTAKINGS**

*Article 56*

**Information from Member States to the Commission**

The competent authorities of the Member States shall inform the Commission:

(a) of any authorisation of a direct or indirect subsidiary one or more parent undertakings of which are governed by the laws of a third country. The Commission shall inform the Committee referred to in Article 58(2) accordingly;

(b) whenever such a parent undertaking acquires a holding in a Community assurance undertaking which would turn the latter into its subsidiary. The Commission shall inform the Committee referred to in Article 58(2) accordingly.

When authorisation is granted to the direct or indirect subsidiary of one or more parent undertakings governed by the law of third countries, the structure of the group shall be specified in the notification which the competent authorities shall address to the Commission.

*Article 57*

**Third country treatment of Community assurance undertakings**

1. The Member States shall inform the Commission of any general difficulties encountered by their assurance undertakings in establishing themselves or carrying on their activities in a third country.

2. Periodically, the Commission shall draw up a report examining the treatment accorded to Community assurance undertakings in third countries, in the terms referred to in paragraphs 3 and 4, as regards establishment and the carrying on of insurance activities, and the acquisition of holdings in third-country insurance undertakings. The Commission shall submit those reports to the Council, together with any appropriate proposals.

3. Whenever it appears to the Commission, either on the basis of the reports referred to in paragraph 2 or on the basis of other information, that a third country is not granting Community assurance undertakings effective market access comparable to that granted by the Community to insurance undertakings from that third country, the Commission may submit proposals to the Council for the appropriate mandate for negotiation with a view to obtaining comparable competitive opportunities for Community assurance undertakings. The Council shall decide by a qualified majority.

4. Whenever it appears to the Commission, either on the basis of the reports referred to in paragraph 2 or on the basis of other information, that Community assurance undertakings in a third country are not receiving national treatment offering the same competitive opportunities as are available to domestic insurance undertakings and that the conditions of effective market access are not being fulfilled, the Commission may initiate negotiations in order to remedy the situation.

In the circumstances described in the first subparagraph, it may also be decided at any time, and in addition to initiating negotiations, in accordance with the procedure laid down in Article 58(2), that the competent authorities of the Member States must limit or suspend their decisions:

— regarding requests pending at the moment of the decision or future requests for authorisations, and

— regarding the acquisition of holdings by direct or indirect parent undertakings governed by the laws of the third country in question.

The duration of the measures referred to may not exceed three months.

Before the end of that three-month period, and in the light of the results of the negotiations, the Council may, acting on a proposal from the Commission, decide by a qualified majority whether the measures shall be continued.

Such limitations or suspension may not apply to the setting up of subsidiaries by assurance undertakings or their subsidiaries duly authorised in the Community, or to the acquisition of holdings in Community assurance undertakings by such undertakings or subsidiaries.

5. Whenever it appears to the Commission that one of the situations described in paragraphs 3 and 4 has arisen, the Member States shall inform it at its request:

(a) of any request for the authorisation of a direct or indirect subsidiary one or more parent undertakings of which are governed by the laws of the third country in question;

(b) of any plans for such an undertaking to acquire a holding in a Community assurance undertaking such that the latter would become the subsidiary of the former.

This obligation to provide information shall lapse whenever an agreement is reached with the third country referred to in paragraph 3 or 4 when the measures referred to in the second and third subparagraphs of paragraph 4 cease to apply.

6. Measures taken under this Article shall comply with the Community's obligations under any international agreements, bilateral or multilateral, governing the taking-up and pursuit of the business of insurance undertakings.

*Article 58*

**Committee procedure**

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

TITLE VII

**TRANSITIONAL AND OTHER PROVISIONS**

*Article 59*

**Derogations and abolition of restrictive measures**

1. Undertakings set up in the United Kingdom by Royal Charter or by private Act or by special Public Act may carry on their activity in the form in which they were constituted on 15 March 1979 for an unlimited period.

The United Kingdom shall draw up a list of such undertakings and communicate it to the other Member States and the Commission.

2. The societies registered in the United Kingdom under the Friendly Societies Acts may continue the activities which they were carrying on on 15 March 1979.

*Article 60*

**Proof of good repute**

1. Where a Member State requires of its own nationals proof of good repute and proof of no previous bankruptcy, or proof of either of these, that State shall accept as sufficient evidence in respect of nationals of other Member States the production of an extract from the 'judicial record' or, failing this, of an equivalent document issued by a competent judicial or administrative authority in the home Member State or the Member State whence the foreign national comes showing that these requirements have been met.

2. Where the home Member State or the Member State whence the foreign national concerned comes does not issue the document referred to in paragraph 1, it may be replaced by a declaration on oath — or in States where there is no provision for declaration on oath by a solemn declaration — made by the person concerned before a competent judicial or administrative authority or, where appropriate, a notary in the home Member State or the Member State whence that person comes; such authority or notary shall issue a certificate attesting the authenticity of the declaration on oath or solemn declaration. The declaration in respect of no previous bankruptcy may also be made before a competent professional or trade body in the said country.

3. Documents issued in accordance with paragraphs 1 and 2 must not be produced more than three months after their date of issue.

4. Member States shall designate the authorities and bodies competent to issue the documents referred to in paragraphs 1 and 2 and shall forthwith inform the other Member States and the Commission thereof.

Each Member State shall also inform the other Member States and the Commission of the authorities or bodies to which the documents referred to in this Article are to be submitted in support of an application to carry on in the territory of this Member State the activities referred to in Article 2.

*Article 61*

**Transitional regime for investments in land and buildings**

Member States may allow assurance undertakings with head offices in their territories, and whose buildings and land covering their technical provisions exceed, on 27 November 1992, the percentage laid down in Article 24(1)(a), a period expiring no later than 31 December 1998 within which to comply with that provision.

*Article 62*

**Transitional regime for Sweden**

1. The Kingdom of Sweden may operate a transitional arrangement up to 1 January 2000 for complying with Article 24(1)(b), it being understood that the Swedish authorities have submitted, before 1 July 1994 for approval by the Commission, a schedule of the measures to have the exposures exceeding the limits of Article 24(1)(b) brought within the limits laid down by this Directive.

2. No later than the date of Swedish accession and on 31 December 1997 the Swedish authorities shall present progress reports to the Commission on the measures taken to comply with this Directive. The Commission shall on the basis of these reports review these measures. In the light of developments, these measures shall, if appropriate, be adapted with a view to accelerating the process of reduction of the exposures. The Swedish authorities shall require the life assurance undertakings concerned to initiate immediately the process of reduction of the relevant exposures. The assurance undertakings concerned will at no time increase these exposures, unless they are already within the limits prescribed by this Directive and any such increase does not lead them to exceed those limits. The Swedish authorities shall submit by the end of the transitional period a final report on the results of the above measures.

TITLE VIII

**FINAL PROVISIONS**

*Article 63*

**Cooperation between the Member States and the Commission**

The Commission and the competent authorities of the Member States shall collaborate closely with a view to facilitating the supervision of the kinds of insurance and the operations referred to in this Directive within the Community.

Each Member State shall inform the Commission of any major difficulties to which application of this Directive gives rise, *inter alia* any arising if a Member State becomes aware of an abnormal transfer of business referred to in this Directive to the detriment of undertakings established in its territory and to the advantage of agencies and branches located just beyond its borders.

The Commission and the competent authorities of the Member States concerned shall examine such difficulties as quickly as possible in order to find an appropriate solution.

Where necessary, the Commission shall submit appropriate proposals to the Council.

*Article 64*

**Reports on the development of the market under the freedom to provide services**

The Commission shall forward to the European Parliament and the Council regular reports, the first on 20 November 1995, on the development of the market in assurance and operations transacted under conditions of freedom to provide services.

*Article 65*

**Technical adjustment**

The following technical adjustments to be made to this Directive shall be adopted in accordance with the procedure laid down in Article 66(2):

— extension of the legal forms provided for in Article 6(1)(a),

— amendments to the list set out in Annex I, or adaptation of the terminology used in that list to take account of the development of assurance markets,

— clarification of the items constituting the solvency margin listed in Article 27 to take account of the creation of new financial instruments,

— alteration of the minimum guarantee fund provided for in Article 29(2) to take account of economic and financial developments,

— amendments, to take account of the creation of new financial instruments, to the list of assets acceptable as cover for technical provisions set out in Article 23 and to the rules on the spreading of investments laid down in Article 24,

— changes in the relaxations in the matching rules laid down in Annex II, to take account of the development of new currency-hedging instruments or progress made in economic and monetary union,

— clarification of the definitions in order to ensure uniform application of this Directive throughout the Community,

— the technical adjustments necessary to the rules for setting the maxima applicable to interest rates, pursuant to Article 20, in particular to take account of progress made in economic and monetary union.

*Article 66*

**Committee procedure**

1. The Commission shall be assisted by the Insurance Committee instituted by Directive 91/675/EEC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 67*

**Rights acquired by existing branches and assurance undertakings**

1. Branches which have started business, in accordance with the provisions in force in the Member State of the branch, before 1 July 1994 shall be presumed to have been subject to the procedure laid down in Article 38(1) to (5).

They shall be governed from that date by Articles 13, 20, 36, 37 and 44.

2. Articles 39 and 40 shall not affect rights acquired by assurance undertakings carrying on business under the freedom to provide services before 1 July 1994.

*Article 68*

**Right to apply to the courts**

Member States shall ensure that decisions taken in respect of an assurance undertaking under laws, regulations and administrative provisions adopted in accordance with this Directive may be subject to the right to apply to the courts.

*Article 69*

**Review of amounts expressed in euro**

1. The Commission shall submit to the Council before 15 March 1985 a report dealing with the effects of the financial requirements imposed by this Directive on the situation in the insurance markets of the Member States.

2. The Council, acting on a proposal from the Commission, shall every two years examine and, where appropriate, review the amounts expressed in euro in this Directive, in the light of how the Community's economic and monetary situation has evolved.

*Article 70*

**Implementation of new provisions**

Member States shall adopt not later than 31 December 2001 the laws, regulations and administrative provisions necessary to comply with Article 1(1), point (m), Article 18(3), Article 27, point (3)(a), second subparagraph, second sentence, Article 49(2)(g), and (3) and (4), Article 59(2) and Article 67(1). They shall immediately inform the Commission thereof.

They shall apply those provisions with effect from 1 January 2002.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 71*

**Information to the Commission**

The Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 72*

**Repealed directives and their correlation with this Directive**

1. The Directives listed in Annex IV, Part A are hereby repealed, without prejudice to the obligations of the Member States concerning the time-limits for transposition and for application of the said Directives listed in Annex IV, Part B.

2. References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V.

*Article 73*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 74*

**Adressees**

This Directive is addressed to the Member States.

*ANNEX I*

**CLASSES OF INSURANCE**

I. The assurance referred to in Article 2(1)(a), (b) and (c) excluding those referred to in II and III

II. Marriage assurance, birth assurance

III. The assurance referred to in Article 2(1)(a) and (b), which are linked to investment funds

IV. Permanent health insurance, referred to in Article 2(1)(d)

V. Tontines, referred to in Article 2(2)(a)

VI. Capital redemption operations, referred to in Article 2(2)(b)

VII. Management of group pension funds, referred to in Article 2(2)(c) and (d)

VIII. The operations referred to in Article 2(2)(e)

IX. The operations referred to in Article 2(3)

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*ANNEX II*

**MATCHING RULES**

The currency in which the assurer's commitments are payable shall be determined in accordance with the following rules:

1. Where the cover provided by a contract is expressed in terms of a particular currency, the assurer's commitments are considered to be payable in that currency.

2. Member States may authorise assurance undertakings not to cover their technical provisions, including their mathematical provisions, by matching assets if application of the above procedures would result in the undertaking being obliged, in order to comply with the matching principle, to hold assets in a currency amounting to not more than 7 % of the assets existing in other currencies.

3. Member States may choose not to require assurance undertakings to apply the matching principle where commitments are payable in a currency other than the currency of one of the Member States, if investments in that currency are regulated, if the currency is subject to transfer restrictions or if, for similar reasons, it is not suitable for covering technical provisions.

4. Assurance undertakings are authorised not to hold matching assets to cover an amount not exceeding 20 % of their commitments in a particular currency.

   However, total assets in all currencies combined must be at least equal to total commitments in all currencies combined.

5. Each Member State may provide that, whenever under the preceding procedures a commitment has to be covered by assets expressed in the currency of a Member State, this requirement shall also be considered to be satisfied when the assets are expressed in euro.

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*ANNEX III*

**INFORMATION FOR POLICY-HOLDERS**

The following information, which is to be communicated to the policy-holder before the contract is concluded (A) or during the term of the contract (B), must be provided in a clear and accurate manner, in writing, in an official language of the Member State of the commitment.

However, such information may be in another language if the policy-holder so requests and the law of the Member State so permits or the policy-holder is free to choose the law applicable.

A. Before concluding the contract

| Information about the assurance undertaking | Information about the commitment |
|---|---|
| (a) 1. The name of the undertaking and its legal form | (a) 4. Definition of each benefit and each option |
| (a) 2. The name of the Member State in which the head office and, where appropriate, the agency or branch concluding the contract is situated | (a) 5. Term of the contract |
| (a) 3. The address of the head office and, where appropriate, of the agency or branch concluding the contract | (a) 6. Means of terminating the contract |
| | (a) 7. Means of payment of premiums and duration of payments |
| | (a) 8. Means of calculation and distribution of bonuses |
| | (a) 9. Indication of surrender and paid-up values and the extent to which they are guaranteed |
| | (a) 10. Information on the premiums for each benefit, both main benefits and supplementary benefits, where appropriate |
| | (a) 11. For unit-linked policies, definition of the units to which the benefits are linked |
| | (a) 12. Indication of the nature of the underlying assets for unit-linked policies |
| | (a) 13. Arrangements for application of the cooling-off period |
| | (a) 14. General information on the tax arrangements applicable to the type of policy |
| | (a) 15. The arrangements for handling complaints concerning contracts by policy-holders, lives assured or beneficiaries under contracts including, where appropriate, the existence of a complaints body, without prejudice to the right to take legal proceedings |
| | (a) 16. Law applicable to the contract where the parties do not have a free choice or, where the parties are free to choose the law applicable, the law the assurer proposes to choose |

B. During the term of the contract

In addition to the policy conditions, both general and special, the policy-holder must receive the following information throughout the term of the contract.

| Information about the assurance undertaking | Information about the commitment |
|---|---|
| (b) 1. Any change in the name of the undertaking, its legal form or the address of its head office and, where appropriate, of the agency or branch which concluded the contract | (b) 2. All the information listed in points (a) (4) to (a) (12) of A in the event of a change in the policy conditions or amendment of the law applicable to the contract |
| | (b) 3. Every year, information on the state of bonuses |

*ANNEX IV*

**REPEALED DIRECTIVES AND TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW**

PART A

**Repealed Directives**

(referred to in Article 72)

1. Council Directive 79/267/EEC,

   as amended by European Parliament and Council Directive 95/26/EC

2. Council Directive 90/619/EEC

3. Council Directive 92/96/EEC,

   as amended by European Parliament and Council Directive 95/26/EC

PART B

**Time-limits for transposition and for application**

(referred to in Article 72)

| Directive | Time-limits for transposition | Time-limits for application |
|---|---|---|
| 79/267/EEC (OJ L 63, 13.3.1979, p. 1) | 15 September 1980 | 15 September 1981 |
| 90/619/EEC (OJ L 330, 29.11.1990, p. 50) | 20 November 1992 | 20 May 1993 |
| 92/96/EEC (OJ L 360, 9.12.1992, p. 1) | 31 December 1993 | 1 July 1994 |
| 95/26/EC (OJ L 168, 18.7.1995, p. 7) | 18 July 1996 | 18 July 1996 |

*ANNEX V*

**CORRELATION TABLE**

| This Directive | Directive 79/267/EEC | Directive 90/619/EEC | Directive 92/96/EEC | Directive 95/26/EC | Other Acts | |
|---|---|---|---|---|---|---|
| Article 1(1)(a) | | | Article 1(a) | | | |
| Article 1(1)(b) | | Article 3 | Article 1(b) | | | |
| Article 1(1)(c) | | Article 2(c) | | | | |
| Article 1(1)(d) | | | Article 1(c) | | | |
| Article 1(1)(e) | | | Article 1(d) | | | |
| Article 1(1)(f) | | | Article 1(e) | | | |
| Article 1(1)(g) | | Article 2(e) | | | | |
| Article 1(1)(h) to (l) | | | Article 1(f) to (j) | | | |
| Article 1(1)(m) | | | | | | New |
| Article 1(1)(n) | | | Article 1(1) | | | |
| Article 1(1)(o), (p), (q) | Article 5(b), (c) and (d) | | | | | |
| Article 1(1)(r) | | | | Article 2(1) | | |
| Article 1(2) | Article 5 (a), second sentence | | | | | |
| Article 2 | Article 1 | | | | | |
| Article 3(1) to (4) | Article 2 | | | | | |
| Article 3(5) and (6) | Article 3 | | | | | |
| Article 3(7) | Article 4 | | | | | |
| Article 3(8) | | | | | Act of Accession of Austria, Finland and Sweden, adapted by Decision 95/1/EC, Euratom, ECSC | |
| Article 4 | Article 6 | | | | | |
| Article 5 | Article 7 | | | | | |
| Article 6(1) | Article 8(1) | | | | | |
| Article 6(2) | Article 8(1a) | | | | | |
| Article 6(3) | Article 8(2) | | | | | |
| Article 6(4) | Article 8(3) | | | | | |

| This Directive | Directive 79/267/EEC | Directive 90/619/EEC | Directive 92/96/EEC | Directive 95/26/EC | Other Acts | |
|---|---|---|---|---|---|---|
| Article 6(5) | Article 8(4) | | | | | |
| Article 7 | Article 9 | | | | | |
| Article 8 | | | Article 7 | | | |
| Article 9 | Article 12 | | | | | |
| Article 10 | Article 15 | | | | | |
| Article 11 | Article 16 | | | | | |
| Article 12 | Article 22(1) | | | | | |
| Article 13 | Article 23 | | | | | |
| Article 14(1) to (5) | | | Article 11(2) to (6) | | | |
| Article 15 | | | Article 14 | | | |
| Article 16(1) to (5) | | | Article 15(1) to (5) | | | |
| Article 16(6) | | | Article 15(5a) | | | |
| Article 16(7) | | | Article 15(5b) | | | |
| Article 16(8) | | | Article 15(5c) | | | |
| Article 16(9) | | | Article 15(6) | | | |
| Article 17 | | | Article 15 a | | | |
| Article 18(1) to (2) | Article 13(1) to (2) | | | | | |
| Article 18(3) | | | | | | New |
| Article 18(4) to (7) | Article 13(3) to (7) | | | | | |
| Article 19 | Article 14 | | | | | |
| Article 20 | Article 17 | | | | | |
| Article 21 | | | Article 19 | | | |
| Article 22 | | | Article 20 | | | |
| Article 23(1) | | | Article 21(1), first subparagraph | | | |
| Article 23(2) | | | Article 21(1), second subparagraph | | | |
| Article 23(3) first subparagraph | | | Article 21(1), third subparagraph | | | |
| Article 23(3) second subparagraph | | | Article 21(1), fourth subparagraph | | | |

| This Directive | Directive 79/267/EEC | Directive 90/619/EEC | Directive 92/96/EEC | Directive 95/26/EC | Other Acts | |
|---|---|---|---|---|---|---|
| Article 23(4) | | | Article 21(2) | | | |
| Article 24 | | | Article 22 | | | |
| Article 25 | | | Article 23 | | | |
| Article 26 | | | Article 24 | | | |
| Article 27(1-2) | Article 18(1-2) | | | | | |
| Article 27(3)(a), first subparagraph | Article 18(3)(a) | | | | | |
| Article 27(3)(a), second subparagraph, first sentence | Article 18(3)(a), second subparagraph first sentence | | | | | |
| Article 27(3)(a), second subparagraph, second sentence | | | | | | New |
| Article 27(3)(a), third subparagraph | Article 18(3)(a) | | | | | |
| Article 27(3) (b) and (c) | Article 18(3) (b) and (c) | | | | | |
| Article 28 | Article 19 | | | | | |
| Article 29 | Article 20 | | | | | |
| Article 30 | Article 21 | | | | | |
| Article 31 | | Article 4 | | | | |
| Article 32 | | | Article 28 | | | |
| Article 33 | | | Article 29 | | | |
| Article 34 | | Article 15 | | | | |
| Article 35 | | | Article 31 | | | |
| Article 36 | Article 24 | | | | | |
| Article 37 | Article 26 | | | | | |
| Article 38 | Article 10 | | | | | |
| Article 39 | | Article 11 | | | | |
| Article 40 | | Article 14 | | | | |
| Article 41 | | Article 17 | | | | |
| Article 42 | | | Article 38 | | | |
| Article 43 | | | Article 39(2) | | | |
| Article 44(1) to (9) | | | Article 40 (2) to (10) | | | |
| Article 45 | | | Article 41 | | | |
| Article 46 | | | Article 42(2) | | | |

| This Directive | Directive 79/267/EEC | Directive 90/619/EEC | Directive 92/96/EEC | Directive 95/26/EC | Other Acts | |
|---|---|---|---|---|---|---|
| Article 47 | | | Article 43(2) | | | |
| Article 48(1) | | | Article 44(2), first subparagraph | | | |
| Article 48(2) | | | Article 44(2), second subparagraph | | | |
| Article 48(3) | | | Article 44(2), third subparagraph | | | |
| Article 49(1) to (2)(f) | Article 27(1) to (2)(f) | | | | | |
| Article 49(2)(g) | | | | | | New |
| Article 49(3) and (4) | | | | | | New |
| Article 50 | Article 31 | | | | | |
| Article 51 | Article 31(a) | | | | | |
| Article 52 | Article 28 | | | | | |
| Article 53 | Article 29 | | | | | |
| Article 54 | Article 30 | | | | | |
| Article 55 | Article 32 | | | | | |
| Article 56 | Article 32(a) | | | | | |
| Article 57(1) | Article 32(b)(1) | | | | | |
| Article 57(2) | Article 32(b)(2) | | | | | |
| Article 57(3) | Article 32(b)(3) | | | | | |
| Article 57(4) | Article 32(b)(4) | | | | | |
| Article 57(5) | Article 32(b)(5) | | | | | |
| Article 57(6) | Article 32(b)(7) | | | | | |
| Article 58 | Article 32(b)(6) | | | | | |
| Article 59(1) | Article 33(4) | | | | | |
| Article 59(2) | | | | | | New |
| Article 60 | Article 37 | | | | | |
| Article 61 | | | Article 45 | | | |

| This Directive | Directive 79/267/EEC | Directive 90/619/EEC | Directive 92/96/EEC | Directive 95/26/EC | Other Acts | |
|---|---|---|---|---|---|---|
| Article 62 | | | | | Act of Accession of Austria, Finland and Sweden, adapted by Decision 95/1/EC, Euratom, ECSC | |
| Article 63, first subparagraph | Article 38 | Article 28, first subparagraph | | | | |
| Article 63, second to fourth subparagraph | | Article 28, second to fourth subparagraph | | | | |
| Article 64 | | Article 29 | | | | |
| Article 65 | | | Article 47 | | | |
| Article 66 | | | Article 47 | | | |
| Article 67(1), first subparagraph | | | | | | New |
| Article 67(1), second subparagraph | | | Article 48(1) | | | |
| Article 67(2) | | | Article 48(2) | | | |
| Article 68 | | | Article 50 | | | |
| Article 69(1) | Article 39(1) | | | | | |
| Article 69(2) | Article 39(3) | | | | | |
| Article 70 | | | | | | New |
| Article 71 | Article 41 | Article 31 | Article 51(2) | Article 6(2) | | |
| Article 72 | | | | | | |
| Article 73 | | | | | | |
| Article 74 | | | | | | |
| Annex I | Annex | | | | | |
| Annex II | | | Annex I | | | |
| Annex III | | | Annex II | | | |
| Annex IV | | | | | | |
| Annex V | | | | | | |

# Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs

(2000/C 365 E/02)

**(Text with EEA relevance)**

*COM(2000) 438 final — 2000/0178(COD)*

*(Submitted by the Commission on 14 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The protection of human health is of paramount importance.

(2) In the context of the internal market, Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs [1] has been adopted in order to ensure the safety of foodstuffs for human consumption in free circulation.

(3) This Directive fixes the principles with regard to food hygiene and in particular:

— the standard of hygiene throughout all stages of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the final consumer,

— the need to base the standard of hygiene on the use of hazard analysis, risk assessment and other management techniques to identify, control and monitor critical points,

— the possibility of adopting microbiological criteria and temperature control requirements for certain classes of foodstuffs in accordance with scientifically accepted general principles,

— the development of guides to good hygiene practice to which food businesses may refer,

— the need for the competent authorities of the Member States to ensure the observance of the hygiene rules with the aim of preventing the final consumer from being harmed by foodstuffs unfit for human consumption,

— the obligation on food operators to ensure that only foodstuffs not harmful to human health are placed on the market.

(4) Experience has shown that these principles constitute a sound basis for ensuring food safety.

(5) In the context of the common agricultural policy, specific health rules affecting the production and placing on the market of products included in the list contained in Annex I to the Treaty have been established.

(6) These health rules have ensured that barriers to trade for the products concerned were removed, thus contributing to the creation of the internal market, whilst ensuring a high level of protection of public health.

(7) These specific rules are contained in a large number of Directives.

(8) With regard to public health, these Directives contain common principles such as those related to the responsibilities of manufacturers of products of animal origin, the obligations of the competent authorities, the technical requirements for the structure and operation of establishments handling products of animal origin, the hygiene requirements which must be complied with in these establishments, the procedures for the approval of establishments, the conditions for storage and transport, the health marking of the products, etc.

(9) Many of these principles are the same as the principles laid down in Council Directive 93/43/EEC.

(10) The principles laid down in Directive 93/43/EEC can therefore be considered to be a common basis for the hygienic production of all food, including products of animal origin included in Annex I to the Treaty.

(11) In addition to this common basis, specific hygiene rules are needed in order to take the specificity of certain foodstuffs into account. The specific hygiene rules for products of animal origin are contained in European Parliament and Council Regulation ... laying down specific hygiene rules for food of animal origin.

[1] OJ L 175, 19.7.1993, p. 1.

(12) The principle objective of the general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety, taking into account in particular:

— the principle that primary responsibility for food safety rests with the manufacturer,

— the need to ensure food safety throughout the food chain, starting with primary production,

— maintaining the cold chain for food that cannot safely be stored at ambient temperatures,

— general implementation of the hazard analysis critical control points system which, together with the application of good hygiene practice, should reinforce the responsibility of food business operators,

— that codes to good practice are a valuable instrument for guiding food business operators at all levels of the food chain on the compliance with food hygiene rules,

— the need to carry out official controls at all stages of production, manufacture and placing on the market,

— the establishment of microbiological criteria and temperature control requirements based on a scientific assessment of risk,

— the need to ensure that imported foods are of at least the same or an equivalent health standard.

(13) Food safety from the place of primary production up to the point of sale to the consumer requires an integrated approach where all food business operators must ensure that food safety is not compromised.

(14) Food hazards already present at the level of primary production must be identified and adequately controlled.

(15) Hygiene at farm level can be organised through the use of codes of good practice, supplemented where necessary with specific hygiene rules to be observed during the production of primary products.

(16) Food safety is a result of several factors including the respect of mandatory requirements, the implementation of food safety programmes established and operated by food business operators and the implementation of the Hazard Analysis Critical Control points system (HACCP).

(17) The hazard analysis critical control point system in food production should take account of the principles already laid down by the Codex Alimentarius allowing at the same time the flexibility needed for its application in all situations, and in particular in small businesses.

(18) Flexibility is also needed so as to take account of the specific character of traditional ways of food production and of the supply difficulties that may arise due to geographical constraints; such flexibility must not however compromise the objectives of food safety.

(19) For food which cannot be safely stored at ambient temperatures, the maintenance of the integrity of the cold chain is a basic principle of food hygiene.

(20) The implementation of the hygiene rules can be guided by the setting of objectives such as pathogen reduction targets or performance standards and it is necessary to foresee the procedures for that purpose.

(21) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety.

(22) Food businesses should be registered with the competent authority in order to allow official controls to be performed efficiently.

(23) Food operators shall give all assistance required in order to ensure that official controls can be carried out efficiently by the competent authorities.

(24) Food imported into the Community shall be of the same hygiene level as the food obtained in the Community, or be of level equivalent thereto.

(25) In order to ensure a high level of protection and to prevent deflections of trade, food obtained in the Community and exported towards third countries shall not be of a lesser hygiene standard than the food produced and consumed within the Community.

(26) Scientific advice must underpin Community legislation on food hygiene; to this end, the scientific committees in the field of consumer protection and food safety set up by Commission Decision 97/579/EC of 23 July 1997 [1] and the Scientific Steering Committee set up by Commission Decision 97/404/EC of 10 June 1997 [2] should be consulted wherever necessary.

(27) In order to take account of technical and scientific progress, a procedure should be available to adopt certain requirements called for in the present Regulation.

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[1] OJ L 237, 28.8.1997, p. 18.

[2] OJ L 169, 27.6.1997, p. 85.

(28) The present Regulation takes into account the international obligations laid down on the WTO-Sanitary and Phytosanitary Agreement and in Codex Alimentarius.

(29) The present recast of existing Community hygiene rules means that the existing hygiene rules can be repealed; this is achieved through Council Directive . . /. . ./EC repealing certain Directives on the hygiene of foodstuffs and on the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC.

(30) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of council Decision 1999/468/EEC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Scope**

This Regulation lays down the rules to ensure the hygiene of foodstuffs at all stages from and including primary production up to and including the offering for sale or supply of a foodstuff to the final consumer. This Regulation shall apply without prejudice to more specific requirements relating to food safety, and does not cover issues relating to nutrition or compositional matters.

It applies to food businesses and does not apply to the primary production of food for private domestic use or the domestic preparation of foodstuffs for private consumption.

*Article 2*

**Definitions**

For the purposes of this Regulation:

— 'food hygiene', hereinafter called 'hygiene', means the measures and conditions necessary to control hazards and ensure fitness for human consumption of a foodstuff taking into account its intended use,

— 'food safety' means the assurance that food will not cause adverse health effects to the final consumer when it is prepared and eaten taking into account its intended use,

— 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any or all of the stages from and including primary production up to and including the offering for sale or supply of foodstuffs to the final consumer,

— 'food business operator' means the person or persons responsible for ensuring that the requirements of this Regulation are met within the food business under his/their control,

— 'primary products' means products of the soil, of stock farming, of hunting and fisheries,

— 'primary production' means the production, rearing or growing of primary products up to and including harvesting, hunting, fishing, milking and all stages of animal production prior to slaughter,

— 'competent authority/ies' means the central authority/ies of a Member State responsible for the purposes and controls set out in this Regulation or any other authority or body to which competence has been delegated by the central authority/ies,

— 'certification' means the procedure by which the competent authorities provide written or equivalent assurance of conformity to requirements,

— 'equivalence' means the capability of different systems to meet the same objectives,

— 'hazard' means a biological, chemical or physical agent with the potential to compromise food safety,

— 'contamination' means the presence of a substance not intentionally added to the food or present in the food environment, which may compromise the safety or fitness for human consumption of the food,

— 'marketing' means holding, displaying and offering for sale, selling, delivering or any other form of placing on the market in the Community,

— 'retail trade' means the handling and processing of food and its storage at the point of sale or delivery to the final consumer, and includes mass catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres, wholesale outlets selling wrapped and packaged foodstuffs,

— 'final consumer' means the ultimate consumer of a foodstuff who shall not use the food as part of any food business operation or activity,

— 'wrapping' means the protection of a product by the use of an initial wrapping or initial container in direct contact with the product concerned, and the initial wrapper or initial container itself,

[1] OJ L 184, 17.7.1999, p. 23.

— 'packaging' means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself; if wrapping is strong enough to ensure effective protection, it can be considered to be packaging,

— 'products of animal origin' means foodstuffs obtained from animals, including honey,

— 'product of plant origin' means foodstuffs obtained from plants,

— 'unprocessed product' means foodstuffs which have not undergone a treatment, including products which have been, for example, divided, parted, severed, boned, minced, skinned, ground, cut, cleaned, trimmed, husked or milled, chilled, frozen or deep-frozen,

— 'processed product' means foodstuffs resulting from the application to unprocessed products of a treatment such as heating, smoking, curing, maturing, pickling, drying, marinating, extraction, extrusion, etc. or a combination of these processes and/or products; substances necessary for their manufacture or for giving specific characteristics to the products may be added,

— 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of micro-organisms,

— 'where necessary', 'where appropriate', 'sufficient' mean where revealed necessary, appropriate or sufficient after hazard analysis in the context of the HACCP system.

*Article 3*

**General obligation**

Food business operators shall ensure that all stages for which they are responsible from and including primary production up to and including the offering for sale or supply of foodstuffs to the final consumer are carried out in a hygienic way in accordance with this Regulation.

*Article 4*

**General hygiene requirements and specific hygiene requirements**

1. Food business operators at the level of primary production shall comply with the general hygiene provisions in Annex I hereto, any other specific provisions in Regulation ... (laying down specific hygiene rules for food of animal origin), and in any other Annexes which may be added in accordance with the procedure laid down in Article 15.

2. Food business operators, other than referred to in paragraph 1, shall comply with the general hygiene provisions in Annex II, any other specific provisions laid down in Regulation ... (laying down specific hygiene rules for food of animal origin) and in any other annexes which may be added in accordance with the procedure laid down in Article 15.

3. Exemptions from provisions of the Annexes referred to in paragraphs 1 and 2 may be granted by the Commission in accordance with the procedure laid down in Article 15, provided that such exemptions do not affect the achievement of the objectives of this Regulation.

4. Member States may adapt the requirements laid down in Annex II with a view to accommodate the needs of food businesses situated in regions suffering from special geographical constraints or affected by supply difficulties which are serving the local market, or with a view to take account of traditional methods of production. The objectives of food hygiene shall not be compromised.

Member States having recourse to this possibility shall inform the Commission and the other Member States thereof. Member States shall have one month from the receipt of the notification to send written comments to the Commission. Where written comments are made, the Commission shall take a decision in accordance with the procedure referred to in Article 15(2).

*Article 5*

**Hazard analysis and critical control points system**

1. Food business operators other than at the level of primary production shall put in place, implement and maintain a permanent procedure developed in accordance with the following principles of the system of hazard analysis and critical control points (HACCP):

(a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels,

(b) identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels,

(c) establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards,

(d) establish and implement effective monitoring procedures at critical control points,

(e) establish corrective actions when monitoring indicates that a critical control point is not under control.

2. Food business operators shall establish procedures to verify whether the measures outlined in paragraph 1 are working effectively. Verification procedures shall be carried out regularly and whenever the food business operation changes in a manner that could adversely affect food safety.

3. Food business operators shall establish documents and records commensurate to the nature and size of the food business to demonstrate the effective application of the measures outlined in paragraphs 1 and 2, and to facilitate official controls. Such documents shall be kept by the food business operator for at least the time of the shelf life of the product.

4. As part of the system referred to in paragraphs 1, 2 and 3, food business operators may use guides to good practice in conjunction with guides on the application of HACCP, as developed in accordance with Articles 7 and 8. Such guides must be appropriate for the operations and foods to which they are applied by the food business operator.

5. In accordance with the procedure referred to in Article 15, the Commission may adopt measures in order to facilitate the implementation of this Article, in particular in small businesses.

*Article 6*

**Specific food safety requirements**

In accordance with the procedure referred to in Article 15 and after consulting the competent Scientific Committee or Committees:

1. Microbiological criteria and temperature criteria for foodstuffs may be adopted and/or amended.

2. Targets and/or performance standards in order to facilitate the implementation of this Regulation may be set.

*Article 7*

**National guides to good practice and guides to the application of HACCP**

1. Member States shall encourage the development of guides to good practice which shall include guidance on the compliance with Article 3, 4 and where Article 5 applies, the application of the principles of HACCP (hereinafter referred to as national guides).

2. Where the guides to good practice referred to in paragraph 1 are developed, they shall be developed as follows:

— by food business sectors and representatives of other interested parties, such as appropriate authorities and consumer groups,

— in consultation with interests substantially affected, including competent authorities,

— where appropriate, having regard to the Recommended International Codes of Practice of the Codex Alimentarius.

National guides may be developed under the aegis of a national standards institute referred to in Annex I to Directive 98/34/EC [1] of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC [2].

3. Member States shall assess national guides to ensure:

— that the contents of such guides are practicable for the sectors to which they refer,

— have been developed in association with representatives of the sector concerned and other interested parties, such as appropriate competent authorities and consumer groups,

— have been developed having regard to the Recommended International Code of Practice, General Principles of Food Hygiene, of the Codex Alimentarius,

— that all interested parties substantially affected have been consulted and the relevant comments taken into account,

— their suitability as guides to compliance with the provisions of Articles 3, 4, and 5 in the sectors and/or for the foodstuffs covered.

4. Twelve months following the coming into force of this Regulation, and thereafter annually, the Member States shall forward to the Commission a report concerning the steps taken to develop national guides specified in paragraph 1.

5. Member States shall forward to the Commission those national guides which they have determined to comply with paragraphs 3 of this Article. The Commission shall keep a register of such guides and make this available to the Member States.

*Article 8*

**Community guides**

1. Where a Member State or the Commission considers that there is a need for uniform Community guides to good practice, and/or Community guides on the application of the principles of HACCP (hereinafter referred to as Community guides), the Commission shall consult the relevant Committee referred to in Article 15. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.

[1] OJ L 204, 21.7.1998, p. 37.

[2] OJ L 217, 5.8.1998, p. 18.

2. Where Community guides are prepared, steps shall be taken to ensure that they are developed with representatives of the sector concerned and other interested parties, such as appropriate competent authorities and consumer groups, taking into account the Recommended International Code of Practice, General Principles of Food Hygiene, of the Codex Alimentarius and any national guides developed in accordance with Article 7.

3. The relevant Committee or Committees referred to in Article 15 shall be responsible for assessing Community guides. Measures shall be taken by such Committee or Committees to ensure that:

— the contents of such guides are practicable for the sectors to which they refer throughout the Community,

— all interests substantially affected by such guides have been consulted, and the relevant comments taken into account,

— where they exist, national guides forwarded to the Commission under Article 7(5) have been taken into account,

— their suitability as guides to compliance with the provisions of Articles 3, 4, and 5 in the sectors and/or for the foodstuffs covered.

4. Where national guides have been produced in accordance with Article 7 and subsequently Community guides are produced in accordance with this Article, food business operators may refer to either.

5. The titles and references of Community guides prepared in accordance with the procedure in paragraphs 1 to 3 shall be published in the C series of the *Official Journal of the European Communities*. Member States shall ensure that such published guides are drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

*Article 9*

**Registration or approval of food businesses**

1. Food business operators shall ensure that all establishments under their control and covered by this Regulation are registered with the competent authority/ies outlining the nature of the business, the name and address of all premises where food business activities are carried out. The competent authority/ies shall allocate a registration number to each food establishment and keep an up to date list thereof.

2. Food business operators except those operating at retail level shall ensure that foodstuffs produced by them are identified with their registration number.

3. Where the competent authority/ies considers it necessary for the purposes of assuring that the requirements of this Regulation are met, or where required by more specific Community rules, food businesses must be approved and shall not operate without such approval. The competent authority shall only approve those establishments where, after a visit by officials of the competent authority/ies it has been ascertained that all the requirements of this regulation are met.

*Article 10*

**Withdrawal of products/traceability**

1. Food business operators shall ensure that adequate procedures are in place to withdraw food from the market where such food presents a serious risk to the health of consumers. Where a food business operator identifies that a foodstuff presents a serious risk to health it shall immediately withdraw that foodstuff from the market. When a serious risk has been identified and when a foodstuff has been withdrawn from the market due to risk to the health of the consumer, food business operators shall immediately inform the competent authority thereof.

2. Food business operators shall keep adequate records which enable them to identify the supplier of ingredients and foods used in their operation and where appropriate the provenance of the animals used for food production.

3. Where necessary to ensure appropriate traceability of food or food ingredients, the Commission shall lay down detailed rules in accordance with the procedure provided for in Article 15.

*Article 11*

**Official controls**

Food business operators shall give all assistance needed to ensure that official controls carried out by the competent authority can be performed efficiently. They shall in particular:

— give access to all buildings, premises, installations or other infrastructures,

— make available any documentation and record required under the present Regulation or considered necessary by the competent authority for judging the situation.

*Article 12*

**Imports/exports**

1. Foodstuffs imported into the Community shall comply with the provisions of Articles 3, 4 and 5 and any provision laid down pursuant to Article 6, or with provisions that are equivalent to those laid down in this Regulation.

2. Foodstuffs for exportation out of the Community shall comply with the provisions of Articles 3, 4, 5, 9 and any provisions laid down under Article 6, except where the importing country specifies otherwise.

*Article 13*

**Amending of annexes and implementing measures**

1. Provisions in the Annexes to this Regulation may be repealed, adapted, supplemented and/or amended in accordance with the procedure laid down in Article 15.

2. Implementing measures in relation to Articles 4, 5, 9, 10 and 12 may be adopted in accordance with the procedure laid down in Article 15.

*Article 14*

**References to international standards**

Amendments to references to international standards contained in this Regulation, such as those of the Codex Alimentarius, may be adopted in accordance with the procedure referred to in Article 15.

*Article 15*

**Standing committee procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee instituted by Council Decision 68/361/EEC [1] and by the Standing Committee for foodstuffs, instituted by European Parliament and Council Decision 69/414/EEC [2].

2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 3 months.

*Article 16*

**Report to Council and Parliament**

1. The Commission shall submit a report to the European Parliament and the Council, where appropriate with any relevant proposals, within seven years of this Regulation entering into force, reviewing the experience gained from implementing this Regulation.

2. In order to allow the Commission to establish the report referred to in paragraph 1, Member States shall submit all necessary information to the Commission 12 months before the period referred to in paragraph 1.

*Article 17*

**Entry into force**

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2004.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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[1] OJ L 255, 18.10.1968, p. 23.

[2] OJ L 291, 19.11.1969, p. 9.

*ANNEX I*

## GENERAL HYGIENE RULES FOR PRIMARY PRODUCTION

### *Preface*

This Annex applies to the production of primary products and includes any activity carried out to that effect at that level (farms, hunting, etc).

CHAPTER I

### Requirements for all food

1. Possible hazards occurring in primary production and methods to control such hazards shall, where possible, be addressed in the guides to good practice referred to in Articles 7 and 8. These guides may be combined with other guides or codes of practice required in particular under other relevant Community legislation.

2. Primary production shall be carried out in accordance with good practice and managed in such a way that hazards are monitored and where necessary eliminated or reduced to an acceptable level, taking into account normal processing procedures carried out after primary production. This includes, where appropriate,

   — adopting practices and measures to ensure that food and food sources are produced under appropriate hygienic conditions,

   — adopting measures with regard to hazards from the environment,

   — controlling contaminants, pests, diseases and infections of animals and plants,

   — the obligation to inform the competent authority if a problem that may affect human health is suspected.

CHAPTER II

### Requirements for products of animal origin

1. In the codes of good practice, actions to be taken in order to ensure the hygiene of food shall be described. This includes, where appropriate:

   — implementing suitable cleaning and disinfection procedures for animal housing, equipment, premises, transport crates and vehicles, etc.,

   — taking precautions when introducing new animals onto a farm, fish farm, molluscs growing area, etc.,

   — proper use of veterinary medicinal products and feed additives,

   — proper disposal of dead animals, waste and litter,

   — implementing effective pest-control programmes,

   — isolating diseased animals,

   — the cleanliness of slaughter animals,

   — protective measures to prevent the introduction of contagious diseases or diseases transmissible to humans,

   — the possible hazards associated with feedingstuffs,

   — a description of the problems that may affect human health and that need to be reported to the competent authority,

   — the implementation of hygiene control programmes, zoonoses control programmes and herd health surveillance programmes.

2. Farmers shall keep records or documentation containing information relevant to health protection. They shall in particular include information on:

   — the nature and origin of feedingstuffs,

   — the animal health status and the welfare of the animals at the farm,

— the use of veterinary medicinal products (nature of the treatment and date of application),

— the occurrence of diseases which may affect the safety of products of animal origin (e.g. udder infections),

— the results of any analyses carried out on samples taken from animals or other samples that have importance to human health, in particular with regard to control programmes for certain zoonotic agents,

— any reports from the slaughterhouse about ante- and post-mortem findings.

Farmers shall be assisted by the those responsible for the animals at the farm (veterinarians, agronomists, farm technicians. etc.) for completing the above records or documentation.

Records or documentation may be combined with records that may be required under other Community or national acts. Farmers must keep the records or documentation referred to above for submission to the competent authority on demand during a period to be set by the latter.

Information relevant to food safety which is contained in these records or documentation must accompany slaughter animals to the slaughterhouse or where appropriate animal products to processing factories in order to inform the competent authority and the receiving food operator about the health status of the herd.

CHAPTER III

**Requirements for products of plant origin**

1. In the codes of good practice, actions to be taken in order to ensure the hygiene of food shall be described. This includes, where appropriate:

   — the correct and appropriate use of plant-protection products and fertilisers,

   — appropriate production, handling, storage and transport methods,

   — practices and measures to avoid contamination with biological, chemical or physical hazards such as mycotoxins, heavy metals, radioactive material, etc.

   — the use of water in primary production,

   — the use of organic waste in primary production,

   — the cleaning and where necessary disinfection of machinery, equipment and vehicles used for transport.

2. Farmers, where necessary assisted by those responsible for the hygiene at the farm (agronomists, farm technicians, etc.), shall keep records or documentation containing information relevant to health protection, and in particular on:

   — the correct and appropriate use of plant-protection products and fertilisers,

   — the results of analyses carried out on samples taken on products or of other analysis made.

*ANNEX II*

## GENERAL HYGIENE REQUIREMENTS APPLYING TO ALL FOOD BUSINESSES (EXCEPT PRIMARY PRODUCTION)

### *Introductory remarks*

Chapters V to XII of this Annex apply throughout all stages after primary production during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the final consumer.

The remaining Chapters of the Annex apply as follows:

— Chapter I to all food premises except those covered by Chapter III,

— Chapter II to all rooms where food is prepared, treated or processed except those covered by Chapter III and excluding dining areas,

— Chapter III to those premises listed in the heading to the Chapter,

— Chapter IV to all transportation.

### CHAPTER I

### General requirements for food premises including outside areas and sites (other than those specified in Chapter III)

1. Food premises must be kept clean and maintained in good repair and condition.

2. The layout, design, construction, siting and size of food premises shall:

   (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and have adequate working space to allow for the hygienic performance of all operations;

   (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;

   (c) permit good food hygiene practices, including protection against cross-contamination between and during separate operations from foodstuffs, wrapping and packaging materials, equipment, materials, water, air supply or personnel and external sources of contamination such as pests;

   (d) where it is necessary for the purposes of achieving the objectives of this Regulation, provide suitable temperature-controlled storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and recorded.

3. An adequate number of washbasins must be available, suitably located and designated for cleaning hands. An adequate number of flush lavatories must be available and connected to an effective drainage system. Lavatories must not open directly into rooms in which food is handled.

4. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary to avoid an unacceptable risk of contamination of food, the facilities for washing food must be separate from the hand-washing facility.

5. There must be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area must be avoided. Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6. Sanitary conveniences shall be provided with adequate natural or mechanical ventilation.

7. Food premises must have adequate natural and/or artificial lighting.

8. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of foodstuffs. Where drainage channels are fully or partially open, they must be so designed to ensure that waste does not flow from a contaminated area towards and into a clean area or area where foods likely to present a high risk to the final consumer are handled.

9. Where required for the purposes of hygiene, adequate changing facilities for personnel must be provided as necessary.

CHAPTER II

**Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in Chapter III)**

1. In rooms where food is prepared, treated or processed (excluding dining areas) the design and layout shall permit good food hygiene practices, including protection against cross-contamination between and during operations, and in particular:

   (a) floor surfaces must be maintained in a sound condition and be easy to clean and, if necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors must allow adequate surface drainage;

   (b) wall surfaces must be maintained in a sound condition and be easy to clean and, if necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;

   (c) ceilings and overhead fixtures must be constructed to prevent the accumulation of dirt and reduce condensation, the growth of undesirable moulds and the shedding of particles;

   (d) windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must where necessary be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination of foodstuffs, windows must remain closed and fixed during production;

   (e) doors must be easy to clean and, where necessary, disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

   (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food must be maintained in a sound condition and be easy to clean and, if necessary, disinfect. This will require the use of smooth, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Adequate facilities must be provided for the cleaning and disinfecting of working utensils and equipment where this is required for the purposes of achieving the objectives of this Regulation. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.

3. Adequate provision must be made for any necessary washing of food where this is required to achieve the objectives of this Regulation. Every sink or other such facility provided for the washing of food must have an adequate supply of hot and/or cold potable water as required and be kept clean.

CHAPTER III

**Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling house but where foods are prepared for purposes other than private and domestic consumption, premises used occasionally for catering purposes, and vending machines**

1. Premises and vending machines shall be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contaminating foodstuffs and harbouring pests, so far as is reasonably practicable.

2. In particular and where necessary:

   (a) appropriate facilities must be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);

   (b) surfaces in contact with food must be in a sound condition and be easy to clean and, if necessary, disinfect. This will require the use of smooth, washable, non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision must be made for the cleaning and, if necessary, disinfecting of working utensils and equipment;

(d) where foodstuffs are cleaned as part of the food business's operations adequate provision must be made for this to be undertaken hygienically;

(e) an adequate supply of hot and/or cold potable water must be available;

(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) must be available;

(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available;

(h) foodstuffs must be so placed as to avoid the risk of contamination so far as is reasonably practicable.

CHAPTER IV

**Transport**

1. Conveyances and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair and condition in order to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs.

   Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or must be marked 'for foodstuffs only'.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there must be effective separation of products to protect against the risk of contamination.

4. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there must be effective cleaning between loads to avoid the risk of contamination.

5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimise the risk of contamination.

6. Where it is necessary for the purposes of achieving the objectives of this Regulation, conveyances and/or containers used for transporting foodstuffs must be capable of maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored.

CHAPTER V

**Equipment requirements**

All articles, fittings and equipment with which food comes into contact shall be kept clean and:

(a) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination of the food;

(b) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept thoroughly cleaned and, if necessary, disinfected, sufficient for the purposes intended;

(c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

CHAPTER VI

**Food waste**

1. Food waste and other refuse must not be allowed to accumulate in food rooms except so far as is unavoidable for the proper functioning of the business.

2. Food waste, non-edible by-products and other refuse must be deposited in closable containers unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers must be of an appropriate construction, kept in sound condition, be easy to clean and if necessary disinfect.

3. Adequate provision must be made for the removal and storage of food waste and other refuse. Refuse stores must be designed and managed in such a way as to enable them to be kept clean and to protect against access by pests.

   Wastewater must be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and must not constitute a source of contamination of the food, either directly or indirectly.

CHAPTER VII

**Water supply**

1. There must be an adequate supply of potable water as specified in Council Directive 98/83/EC relating to the quality of water intended for human consumption [1]. This potable water must be used whenever necessary to ensure that foodstuffs are not contaminated.

2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it must circulate in a separate system and be identified as such. Non-potable water shall not connect with, or allow reflux into, potable water systems.

3. Water which is recycled either to be used in processing or as an ingredient must not present a risk of contamination to the food from microbiological, chemical or physical hazards, and shall be of the same standard as potable water under Directive 98/83/EC, unless the competent authorities in the Member States are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.

4. Ice which comes into contact with food or which may lead to any contamination of food must be made from water which meets the specifications referred to in Directive 98/83/EC. It must be made, handled and stored under conditions which protect it from all contamination.

5. Steam used directly in contact with food must not contain any substance which presents a hazard to health or is likely to contaminate the food.

CHAPTER VIII

**Personal hygiene**

1. Every person working in a food-handling area shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where necessary for the purposes of achieving the objectives of this Regulation, protective clothing.

2. No person suffering from, or known to be a carrier of a disease likely to be transmitted through food or while afflicted for example with infected wounds, skin infections, sores or diarrhoea shall be permitted to enter any food-handling area in any capacity if there is any likelihood of directly or indirectly contaminating food with pathogenic micro-organisms. Any person so affected and employed in a food business and who is likely to come into contact with food shall immediately report illness or symptoms to the food business operator.

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[1] OJ L 330, 5.12.1998, p. 32.

CHAPTER IX

**Provisions applicable to foodstuffs**

1. No raw materials or ingredients shall be accepted by a food business if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances that, after normal sorting and/or preparatory or processing procedures hygienically applied by food businesses, they would still be unfit for human consumption.

2. Raw materials and ingredients stored in a food business shall be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.

3. All food which is handled, stored, packaged, displayed and transported must be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state. Adequate procedures must be in place to ensure pests are controlled.

4. Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not result in a risk to health. The cold chain must not be interrupted. However, limited periods outside temperature control are permitted to accommodate the practicalities of handling during preparation, transport, storage, display and service of food provided that it does not result in a risk to health. For processed foodstuffs food businesses manufacturing, handling and wrapping processed foodstuffs must have suitable rooms large enough for the separate storage of raw materials from processed material, with sufficient separate refrigerated storage to prevent contamination.

5. Where foodstuffs are to be held or served at chilled temperatures they must be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which would not result in a risk to health.

6. The thawing of foodstuffs shall be undertaken in such a way as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins in the foods. During thawing foods shall be subjected to temperatures which would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it must be adequately drained. Following thawing, food must be handled in such a manner as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins.

7. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labelled and stored in separate and secure containers.

8. Raw materials used for the manufacture of processed products must have been produced and marketed or imported in accordance with this Regulation.

CHAPTER X

**Provisions applicable to the wrapping and packaging of foodstuffs**

1. Measures shall be taken to ensure that wrapping and packaging materials are not a source of contamination to foodstuffs. Wrapping and packaging materials must be manufactured transported and supplied to food businesses in such a manner that they are protected from any contamination that may present a risk to health.

2. Wrapping materials must be stored in such a manner that they are not exposed to a risk of contamination, in particular contamination arising from food, the storage environment, cleaning substances and pests.

3. In food businesses where packing operations are carried out in the presence of exposed products measures must be taken to avoid contamination of these products. In particular, the room where packaging operations are undertaken must be of sufficient size, construction and design to allow for hygienic operations. Packaging materials must be assembled prior being brought into the packaging area and used without delay. Where packaging materials are to be lined with a wrapping material this must be carried out hygienically.

4. Wrapping and packaging material must only be re-used for foodstuffs if it is made of materials that are easy to clean and where necessary for the purposes of food hygiene, disinfect.

CHAPTER XI

**Special conditions for certain processing operations**

1. *Processing by heat treatment*

   — the food must be processed in accordance with a scheduled heat treatment possibly associated with other methods to control microbiological hazards; equipment for the heat-treatment must be fitted with all control devices necessary to ensure that an appropriate heat treatment is applied,

   — if the heat treatment, possibly combined with other hurdles is not sufficient to ensure the stability of the products, a rapid cooling to the specified storage temperature must be applied after heating so that the critical temperature zone for spore germination and subsequent growth is passed through as rapidly as possible,

   — if the heat treatment is applied before wrapping, measures must be taken to prevent recontamination of the food after heating and before filling,

   — where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness must be confirmed before filling,

   — where the heat treatment is applied to foodstuffs in hermetically sealed containers it must be ensured that the water used for cooling the containers after heat treatment is not a source of contamination for the foodstuff. Chemical additives to prevent corrosion of equipment and containers must be used in accordance with good practices,

   — in the case of a continuous heat treatment of liquid food, the mixture of heat-treated liquid with incompletely heated liquid must be adequately prevented.

2. *Smoking*

   — fumes and heat must not affect other operations,

   — materials used for smoke production must be stored and used in such a way as to avoid contamination of foodstuffs,

   — the combustion for smoke production of wood which is painted, varnished, glued or has undergone any chemical preservation is prohibited.

3. *Salting*

   Salts used for the treatment of foodstuffs must be clean and must be stored in such a way as to prevent contamination. Salts may be re-used after cleaning where HACCP procedures have demonstrated that there is no risk of contamination.

CHAPTER XII

**Training**

Food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

Food business operators shall ensure that those responsible for the development and maintenance of the HACCP system in a food business have received adequate training in the principles of HACCP.

# Proposal for a Regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

(2000/C 365 E/03)

**(Text with EEA relevance)**

*COM(2000) 438 final — 2000/0179(COD)*

*(Submitted by the Commission on 14 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) European Parliament and Council Regulation . . . (on the hygiene of foodstuffs) lays down the basic hygiene rules to be respected by food operators in order to ensure food safety.

(2) Certain food may present specific hazards to human health requiring the setting of specific hygiene rules in order to ensure food safety.

(3) This is in particular the case for food of animal origin in which microbiological and chemical hazards have frequently been reported.

(4) In the context of the common agricultural policy, specific health rules affecting the production and placing on the market of products included in the list contained in Annex I to the Treaty have already been established.

(5) These health rules have ensured that barriers to trade for the products concerned were removed, thus contributing to the creation of the internal market, whilst ensuring a high level of protection of public health.

(6) These specific rules are contained in a large number of Directives and in particular in:

— Council Directive 64/433/EEC of 26 June 1964, on health conditions for the production and marketing of fresh meat [1], as last amended by Directive 95/23/EC [2],

— Council Directive 71/118/EEC of 15 February 1971, on health problems affecting the production and placing on the market of fresh poultry meat [3], as last amended by Directive 97/79/EC [4],

— Council Directive 77/96/EEC of 21 December 1976, on the examination for trichinae (*Trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine [5], as last amended by Directive 94/59/EC [6],

— Council Directive 77/99/EEC of 21 December 1976, on health problems affecting the production and marketing of meat products and certain other products of animal origin [7], as last amended by Directive 97/76/EC [8],

— Council Directive 89/437/EEC of 20 June 1989, on hygiene and health problems affecting the production and the placing on the market of egg products [9], as last amended by Directive 96/23/EC,

— Council Directive 91/492/EEC of 15 July 1991, laying down the health conditions for the production and the placing on the market of live bivalve molluscs [10], as last amended by Directive 97/79/EC,

— Council Directive 91/493/EEC of 22 July 1991, laying down the health conditions for the production and the placing on the market of fishery products [11], as last amended by Directive 97/79/EC,

— Council Directive 91/495/EEC of 27 November 1990, concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat [12], as last amended by the act of accession of Austria, Finland and Sweden,

[1] OJ 121, 29.7.1964, p. 2101/64.
[2] OJ L 243, 11.10.1995, p. 7.
[3] OJ L 55, 8.3.1971, p. 23.
[4] OJ L 24, 30.1.1998, p. 31.
[5] OJ L 26, 31.1.1977, p. 8.
[6] OJ L 315, 8.12.1994, p. 18.
[7] OJ L 26, 31.1.1977, p. 85.
[8] OJ L 10, 16.1.1998, p. 25.
[9] OJ L 212, 22.7.1989, p. 87.
[10] OJ L 168, 24.9.1991, p. 1.
[11] OJ L 268, 24.9.1991, p. 15.
[12] OJ L 268, 24.9.1991, p. 41.

— Council Directive 92/45/EEC of 16 June 1992, on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat [1], as last amended by Directive 97/79/EC,

— Council Directive 92/46/EEC of 16 June 1992, laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products [2], as last amended by Directive 96/23/EC,

— Council Directive 92/48/EEC of 16 June 1992, laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC [3],

— Council Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC [4], as last amended by Directive 97/79/EC,

— Council Directive 94/65/EC of 14 December 1994, laying down the requirements for the production and placing on the market of minced meat and meat preparations [5].

(7) With regard to public health, these Directives contain common principles such as those related to the responsibilities of manufacturers of products of animal origin, the obligations of the competent authorities, the technical requirements for the structure and operation of establishments handling products of animal origin, the hygiene requirements which must be complied with in these establishments, the procedures for the approval of establishments, the conditions for storage and transport, the health marking of the products, etc.

(8) Many of these principles are the same as the principles laid down in Regulation . . . (on the hygiene of foodstuffs) which serve as a common basis for all food.

(9) This common basis allows simplifying the Directives referred to above.

(10) These specific rules can be further simplified by eliminating possible inconsistencies which have arisen at the time of their adoption.

(11) With the introduction of the HACCP procedure, food operators must develop methods to control and reduce or eliminate biological, chemical or physical hazards.

(12) The above elements lead to a complete recasting of the specific hygiene rules and to more transparency.

(13) The principle objective of the recasting of the general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.

(14) It is therefore necessary to maintain and, where required to ensure consumer protection, tighten detailed hygiene rules for products of animal origin.

(15) The primary production, the transport of animals, the slaughter and processing facilities up to the point of sale at the retailers level must be considered as interacting entities where animal health, animal welfare and public health are intertwined.

(16) This requires adequate communication between the different stakeholders along the food chain.

(17) Microbiological criteria, targets and/or performance standards may be laid down in accordance with the appropriate procedures foreseen for the purpose in Regulation . . . (on the hygiene of foodstuffs); awaiting the setting of new microbiological criteria, the criteria fixed in the Directives referred to above shall continue to apply.

(18) In the case of establishments with a limited production capacity for handling food of animal origin and which are the subject of particular constraints or serving the local market only, Member States must be given the tools necessary to define specific hygiene rules for such establishments provided that the objectives of food safety are not compromised and taking into account that in certain cases the local market may exceed national borders.

(19) Imported food of animal origin must be of at least the same or an equivalent health standard as that produced within the Community, and uniform procedures to ensure that this objective is attained must be introduced.

(20) The present recast means that the existing hygiene rules can be repealed; this is achieved through Council Directive . . ./. . ./EC repealing certain Directives on the hygiene of foodstuffs and on the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC.

[1] OJ L 268, 14.9.1992, p. 35.
[2] OJ L 268, 14.9.1992, p. 1.
[3] OJ L 187, 7.7.1992, p. 41.
[4] OJ L 62, 15.3.1993, p. 49.
[5] OJ L 368, 31.12.1994, p. 10.

(21) The products covered by this Regulation are included in Annex I to the Treaty.

(22) Scientific advice underpins Community legislation on food hygiene; to this end, the scientific committees in the field of consumer protection and food safety set up by Commission Decision 97/579/EC of 23 July 1997 [1] and the Scientific Steering Committee set up by Commission Decision 97/404/EC of 10 June 1997 [2] should be consulted wherever necessary.

(23) In order to take account of technical and scientific progress, a procedure should be available to adopt certain requirements called for in the present Regulation; equally, a procedure should be available enabling, where necessary, a smooth transition to the required health level.

(24) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Scope**

This Regulation lays down the specific hygiene rules to ensure the hygiene of food of animal origin.

*Article 2*

**Definitions**

For the purpose of this Regulation, the definitions laid down in Regulation . . . (on the hygiene of foodstuffs) shall apply. In addition, the definitions laid down in Annex I to the present Regulation shall apply.

*Article 3*

**General obligation**

In addition to the requirements laid down in Regulation . . . (on the hygiene of foodstuffs), food business operators shall ensure that food of animal origin is obtained and marketed in accordance with Annex II to the present Regulation.

*Article 4*

**Imports from third countries**

Food of animal origin imported from third countries shall comply with the requirements laid down in Annex III to the present Regulation.

*Article 5*

**Amending of Annexes and implementing measures**

In accordance with the procedure referred to in Article 6,

1. Provisions in the Annexes to this Regulation may be repealed, amended, adapted or supplemented in order to take account of the development of codes to good practice, the implementation of food safety programmes by food operators, new risk assessments and the possible setting of food safety targets and/or performance standards.

2. Implementing measures to ensure the uniform implementation of the Annexes may be taken.

*Article 6*

**Standing Committee procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee, instituted by Council Decision 68/361/EEC [4].

2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 3 months.

*Article 7*

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2004.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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[1] OJ L 237, 28.8.1997, p. 18.

[2] OJ L 169, 27.6.1997, p. 85.

[3] OJ L 184, 17.7.1999, p. 23.

[4] OJ L 225, 18.10.1968, p. 23.

*ANNEX I*

**DEFINITIONS**

1. **Meat**

1.1. *meat:* all parts of animals which are fit for human consumption;

1.1.1. *meat of domestic ungulates:* meat of domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds;

1.1.2. *poultry meat:* meat of farmed birds including birds which are not considered as domestic but which are farmed as domestic animals (farmed game birds);

1.1.3. *meat of lagomorphs:* meat of rabbits, hares and rodents farmed for human consumption;

1.1.4. *wild game meat:* meat of:

— wild land mammals which are hunted, including mammals living in enclosed territory under conditions of freedom similar to those of wild game,

— wild birds which are hunted;

1.1.5. *farmed game meat:* meat of farmed even-toed ungulate game mammals (including Cervidae and Suidae) and of farmed ratites;

1.2. *large wild game:* wild mammals of the Orders Artiodactyla, Perissodactyla and Marsupialia, as well as other mammal species classified under national hunting legislation as large game;

1.3. *small wild game:* wild game birds and wild game mammals not classified as large game;

1.4. *carcase (domestic ungulates):* the whole body of a slaughtered domestic ungulate after bleeding, evisceration and removal of the limbs at the carpus and the tarsus, removal of the head, tail and where appropriate the udder, and in addition, in the case of bovine animals, sheep, goats and solipeds, after flaying;

1.5. *carcase (poultry):* the whole body of a bird after bleeding, plucking and evisceration; however, removal of the heart, liver, lungs, gizzard, crop and kidneys, sectioning of the legs at the tarsus and removal of the head, oesophagus or trachea are optional;

1.6. *New-York dressed poultry:* poultry carcases for which the evisceration has been deferred;

1.7. *fresh meat:* meat, including meat which is vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any preserving process other than chilling, freezing or quick-freezing to ensure preservation;

1.8. *offals:* meat other than that of the carcase even if it remains naturally connected to the carcase;

1.9. *viscera:* offal from the thoracic, abdominal and pelvic cavities, including the trachea and oesophagus, and in birds the crop;

1.10. *slaughterhouse:* an establishment for slaughtering animals, the meat of which is intended for sale for human consumption, including any place available in connection therewith for the confinement of animals while awaiting slaughter there;

1.11. *cutting plant:* an establishment used for boning and/or cutting up carcases, parts of carcases and other edible parts of animals including premises adjacent to sale points where these operations are carried out for supplying the consumer or other sale points;

1.12. *game collection centre:* an establishment where killed wild game is kept prior to being transported to a game handling establishment;

1.13. *game handling establishment:* an establishment for the skinning of game and the further handling of game meat obtained after hunting;

1.14. *minced meat:* boned meat which has been reduced into fragments or passed through a spiral screw mincer;

1.15. *mechanically separated meat:* product resulting from the mechanical separation of meat left on the bones after boning, so that the cellular structure of the meat is broken;

1.16. *meat preparations:* fresh meat including minced meat which has had foodstuffs, seasonings or additives added to it or which has undergone a treatment insufficient to modify the internal cellular structure of the meat and thus to eliminate the characteristics of the fresh meat.

2. **Live bivalve molluscs**

2.1. *bivalve molluscs:* filter-feeding lamellibranch molluscs, and by extension, echinoderms, tunicates and marine gastropods;

2.2. *marine biotoxins:* poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxins;

2.3. *conditioning:* the storage of live bivalve molluscs coming from class A areas in tanks or any other installation containing clean sea water or in natural sites to remove sand, mud or slime and to improve organoleptic qualities;

2.4. *gatherer:* any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;

2.5. *production area:* any sea, estuarine or lagoon area containing natural beds of bivalve molluscs or sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken;

2.6. *relaying area:* any sea, estuarine or lagoon area approved by the competent authority, with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs;

2.7. *dispatch centre:* any approved on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption;

2.8. *purification centre:* an approved establishment with tanks fed by clean sea water in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;

2.9. *relaying:* an operation whereby live bivalve molluscs are transferred to approved sea, lagoon or estuarine areas under the supervision of the competent authority for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;

2.10. *faecal coliform:* facultative aerobic, gram-negative, non-sporeforming, cytochrome oxidase negative, rod-shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhibiting properties, at 44 °C ± 0,2 °C within 24 hours;

2.11. *E. coli:* faecal coliform which also forms indole from tryptophan at 44 °C ± 0.2 °C within 24 hours;

2.12. *clean seawater:* sea water, brackish water or seawater preparations made from fresh water, free from microbiological contamination, objectionable substances and/or toxic marine plankton in such quantities likely to adversely affect the health quality of bivalve molluscs and fishery products.

3. **Fishery products**

3.1. *fishery products:* all seawater or freshwater animals, wild or farmed, other than live bivalve molluscs, aquatic mammals and frogs, or parts of these animals including their roes and livers;

3.2. *aquaculture products:* all fishery products born and raised in controlled conditions until placed on the market as a foodstuff as well as seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;

3.3. *factory vessel:* any vessel, fishing or not, on which fishery products undergo one or more of the following operations followed by wrapping: filleting, slicing, skinning, mincing, or processing; fishing vessels in which only crustaceans and molluscs are cooked on board are not deemed to be factory-vessels;

3.4. *freezer vessel:* any vessel, fishing or not, on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins. Where necessary, these operations are followed by wrapping and/or packaging;

3.5. *mechanically recovered fish flesh:* flesh obtained by mechanical means from gutted whole fish or bones after filleting;

3.6. *clean seawater:* see definition at point 2.12;

3.7. *clean river or lake water:* river or lake water free from microbiological contamination or any objectionable substances in quantities likely to adversely affect the health quality of fishery products.

4. **Eggs**

4.1. *eggs:* eggs of birds in shell, fit for direct consumption or for the preparation of egg products, other than broken, incubated or cooked eggs;

4.2. *liquid egg:* untreated egg contents after removal of the shell;

4.3. *egg production farm:* farm for the production of eggs intended for human consumption;

4.4. *cracked eggs:* eggs with a damaged but unbroken shell, with intact membranes.

5. **Milk**

5.1. *milk:* the lactic secretion of the mammary gland free of colostrum;

5.2. *raw milk:* milk which has not been heated beyond 40 °C; treatments such as homogenisation and standardisation which have an effect on the quality of the milk may be carried out;

5.3. *milk production holding:* a holding in which one or more cows, ewes, goats, buffaloes or females of other species are kept to supply milk;

5.4. *dairy establishment:* an establishment for the processing of milk, or for the further processing of already processed milk.

6. **Frogs' legs and snails**

6.1. *frogs' legs:* posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species Rana (family Ranidae);

6.2. *snails:* terrestrial gastropods of the species Helix pomatia Linné, Helix aspersa Muller, Helix lucorum and species of the family Achatinidae.

7. **Processed products**

7.1. *processed product:* foodstuff resulting from the application to unprocessed products of a treatment such as heating, smoking, curing, maturing, drying, marinating, etc., or a combination of these processes and/or products; substances necessary for their manufacture or for giving specific characteristics to the products may be added;

7.2. *meat products:* products resulting from the application of a treatment to meat;

7.3. *processed fish products:* fishery products to which a treatment has been applied;

7.4. *egg products:* products resulting from the application of a treatment to eggs or to the various components or mixtures thereof after removal of the shell and membranes. They may be partially supplemented by other foodstuffs or additives. They may be liquid, concentrated, dried, crystallised, frozen, quick-frozen or coagulated.

7.5. *milk products:* products resulting from the application to raw milk of a treatment, such as heat-treated drinking milk, milk powder, whey, butter, cheese, yoghurt (whether or not with acid, salt, spices or fruits added) and reconstituted drinking milk;

7.6. *rendered animal fat:* fat derived from rendering meat, including bones, and intended for human consumption;

7.7. *greaves:* the protein-containing residue of rendering, after partial separation of fat and water;

7.8. *gelatine:* natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry);

7.9. *treated stomachs, bladders and intestines:* stomachs, bladders and intestines which have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.

8. **Other definitions**

8.1. *composite product:* a foodstuff containing products, whether unprocessed or processed, of animal and plant origin;

8.2. *re-wrapping:* the removal of the original wrapping from the product for replacing it by a new wrapping, possibly after having applied to the unwrapped product physical operations such as cutting or slicing;

8.3. *wholesale market:* means a food business which includes several separate units which share common installations and sections where foodstuffs are sold to food businesses and not to the final consumer.

*ANNEX II*

**SPECIFIC REQUIREMENTS**

***Preface***

1. This Annex applies to unprocessed and processed products of animal origin. Composite products are not subject to the requirements of the present Annex. However, it must be ensured that possible hazards resulting from the use of ingredients of animal origin are identified and controlled, and where necessary eliminated or reduced to acceptable levels.

2. Unless specified otherwise, the requirements laid down in this Annex shall not apply to the point of retail trade.

3. Where approval of establishments is required under the present Annex, the following shall apply:

   (a) approved establishments shall be given an approval number to which codes shall be added to indicate the types of products of animal origin manufactured. For wholesale markets, the approval number may be completed with a secondary number indicating units or groups of units selling or manufacturing products of animal origin;

   (b) Member States shall maintain up-to-date lists of approved establishments with their respective approval numbers.

   In addition to the above, the approval is also required for wholesale markets where unprocessed or processed products of animal origin are handled.

4. Where required under the present Annex, products of animal origin shall carry an oval health mark in accordance with the following rules:

   (a) the health mark shall be applied during or immediately after manufacture in the establishment in such a way that it cannot be re-used;

   (b) the health mark must be legible, indelible and the characters must be easily decipherable; it must be clearly displayed for the controlling authorities;

   (c) the health mark shall carry the following information:

      — the name of the country of dispatch, which may be written out in full or shown as an abbreviation as follows:

        A, B, DK, D, EL, E, F, FIN, IRL, I, L, NL, P, S, UK,

      — the approval number of the establishment;

   (d) the health mark may, depending on the presentation of different products of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The health mark may also be an irremovable tag made of a resistant material.

      For products of animal origin which are placed in transport containers or large packages and intended for further handling, processing or wrapping in another establishment, the health mark may be applied to the external surface of the container or packaging. In this event, the recipient food operator must maintain a record of the quantities, type, origin and the destination of the products of animal origin;

   (e) the health marking of individual products of animal origin contained in a retail sale unit is not necessary if the health mark is applied to the external surface of that retail sales unit;

   (f) when the health mark is applied directly to products of animal origin, the colours used shall be authorised in accordance with Community rules on the use of colouring substances in foodstuffs;

   (g) if products of animal origin are unwrapped and subsequently re-wrapped, handled or further processed in another establishment, the latter establishment must be approved and apply its own health mark to the product.

   Products to which the above health mark must not be applied shall carry a mark that allows the origin of the products to be traced and that is distinctly different from the oval health mark.

5. Any substance other than potable water applied to products for hazard reduction, as well as their conditions for use, must be approved in accordance with the procedure referred to in Article 6, after the opinion of the Scientific Committee. The implementation of this paragraph shall be without prejudice to the correct implementation of the requirements of the present Regulation.

6. Where necessary, special conditions may be granted by the competent authority in particular in order to take account of traditional production methods.

7. The present Annex shall apply without prejudice to the relevant animal health rules and without prejudice to more stringent rules laid down for the prevention and control of certain transmissible spongiform encephalopathies.

## SECTION I

### Meat of domestic ungulates

The animals, or where appropriate each batch of animals sent for slaughter must be identified so that its origin can be traced.

Animals may not come from a holding or an area subject to a movement prohibition for reasons of animal health unless permitted by the competent authority.

## CHAPTER I

### CONDITIONS FOR SLAUGHTERHOUSES

Slaughterhouses must be constructed and equipped in accordance with the following conditions:

1. They must have adequate and hygienic lairage facilities or, climate permitting, waiting pens which are easy to clean and disinfect. These facilities must be equipped for watering the animals and feeding them if necessary. The drainage of the wastewater must not compromise food safety.

   Where considered necessary by the competent authority, they must also have separate lockable premises or climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals.

   The size of the lairage facilities must enable to ensure the respect of the welfare of the animals. Their lay-out must facilitate ante-mortem inspections including the identification of the animals or groups of animals.

2. Have a slaughter room and where appropriate a sufficient number of rooms appropriate to the operations being carried out and be constructed in such a way as to avoid contamination of the meat by ensuring that:

   (a) there is a distinctly separated area for stunning and bleeding;

   (b) in the case of pig slaughtering, there is a separation of scalding, depilation, scraping and singeing operations of pigs from other operations;

   (c) there are installations ensuring that there is no contact between the meat and the floors, walls or equipment;

   (d) where slaughter lines are operated, these are designed to allow a constant progress of the slaughter process and avoid cross-contamination between the different parts of the slaughter line;

   where different slaughter lines are operated in the same premises, adequate separation of these lines is ensured in order to prevent cross-contamination;

   (e) the following operations are carried out separately from the operations during which meat is obtained:

   — emptying stomachs and intestines; in slaughterhouses with a limited throughput, the competent authority may allow the cleaning of stomachs and intestines in the slaughter room at times when no slaughtering is taking place,

   — further handling of guts and tripe, if this is carried out in the slaughterhouse,

   — preparation and cleaning of other offal; skinned heads must be handled at a sufficient distance from meat and other offal, if these operations are carried out in the slaughterhouse and do not take place at the slaughter line;

   (f) there is a separate place for packaging offal if this is done in the slaughterhouse;

   (g) there is an appropriate area, sufficiently protected, for dispatching meat.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat shall be provided with taps that are non-hand operable.

5. Lockable premises must be provided for the refrigerated storage of detained meat and for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning and disinfection of means of transport of livestock. These places and facilities are not compulsory if officially authorised places and facilities exist nearby.

7. They must have lockable premises reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorised by the competent authority for this purpose, or at the end of the normal slaughter period. The premises must be cleaned and disinfected under official supervision before slaughter is resumed.

8. If manure and stomach or gut content is stored in the slaughterhouse precincts, they must have a special area or place for that purpose.

CHAPTER II

**CONDITIONS FOR CUTTING PLANTS**

Cutting plants must:

1. Be constructed so as to allow constant progress of the operations or ensure separation between the different production batches.

2. Have rooms for the separate storage of packed and exposed meat, unless stored at different times.

3. Have cutting rooms equipped to ensure that the cold chain is not interrupted during cutting operations.

4. Have equipment for washing hands provided with taps that are non-hand operable to be used by the staff engaged in handling exposed meat.

5. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

CHAPTER III

**SLAUGHTER HYGIENE**

1. After arrival in the slaughterhouse, the slaughter of the animals shall not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter. Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of animals that have undergone emergency slaughter outside the slaughterhouse, farmed game slaughtered at the place of production and wild game.

   Animals which have died during transport or in the lairages shall not be used for human consumption.

2. The state of cleanliness of the animals must be such as not to present an unnecessary risk of contaminating the meat during slaughter operations.

3. Before slaughter, animals must be presented to the competent authority in order to be submitted to an ante-mortem inspection. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the ante-mortem inspection is carried out under suitable conditions.

4. Slaughter animals brought into the slaughter hall must be slaughtered without undue delay.

5. Stunning, bleeding, skinning, dressing and evisceration must be carried out without undue delay in such a way that contamination of the meat is avoided. It must in particular be ensured that:

   — the trachea and oesophagus remain intact during bleeding, except in the case of ritual slaughter,

   — during the removal of hides and fleece, contact between the outside of the skin and the carcase is prevented, and that operators and equipment coming into contact with the outer surface of hides and fleece do not touch the meat,

   — measures are taken to prevent the spillage of digestive tract contents during evisceration and that evisceration is completed as soon as possible after stunning,

   — removal of the udder does not result in contamination of the carcase with milk.

6. Skinning must be complete; however, the skinning of the head is not required:

   — in the case of heads of calves and ovines, provided that such heads are handled so as to avoid contamination of meat,

— if such heads, including tongues and brains, are not intended for human consumption.

When not skinned, pigs must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimised. Only approved additives may be used for this operation provided that pigs are thoroughly rinsed afterwards with potable water.

7. The carcases must not contain visible faecal contamination. Any visible contamination must be removed by trimming.

8. Carcases and offal shall not come into contact with floors, walls or work stands.

9. Slaughtered animals must be presented to the competent authority in order to be submitted to a post-mortem inspection. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the post-mortem inspection is carried out under suitable conditions.

Parts of the slaughtered animals that have been removed before the post-mortem inspection is performed, must remain identifiable as belonging to a given carcase. However, provided it shows no pathological symptom or lesion, the penis may be discarded immediately.

Both kidneys must be removed from their fatty covering and peri-renal capsule.

If the blood or offals of several animals are collected in the same container before completion of the post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcase of one or more of the animals concerned has been declared unfit for human consumption.

Carcases and offal shall not come into contact with each other before post-mortem inspection is finalised.

10. After post-mortem inspection:

— the tonsils of bovine animals under six weeks and pigs must be removed hygienically,

— the parts unfit for human consumption must be removed at once from the clean sector of the establishment,

— meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption,

— viscera or parts of viscera which have not been removed from the carcase before post-mortem inspection, except for the kidneys or unless specified elsewhere, must be removed entirely if possible and as quickly as possible.

11. After completion of slaughter and post-mortem inspection procedures, the meat must be stored in accordance with the requirements laid down in Chapter IX of the present Section.

12. Where establishments are approved for the slaughter of different animal species or for the handling of carcases of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcases of farmed game slaughtered at the farm and for wild game must be available.

## CHAPTER IV

## HYGIENE DURING CUTTING AND BONING

1. Carcases of domestic ungulates may be cut into half-carcases, and half-carcases into quarters or a maximum of three pieces in approved slaughterhouses. Further cutting and boning must be carried out in a cutting plant.

2. The work on meat must be organised in such a way as to prevent the growth of pathogenic micro-organisms or the formation of toxins or other pathogenic substances, and in particular:

(a) Meat intended for cutting must be brought into the work rooms progressively as needed.

(b) During cutting, boning, slicing, dicing, wrapping and packaging, the cooling of the meat must not be interrupted.

Where meat is boned and cut prior to reaching the temperatures for storage and transport provided for in Chapter IX of the present Section, such meat must be transferred directly from the slaughter premises to the cutting room, or after a waiting period in the cold store. As soon as it is cut and where appropriate packaged, the meat must be chilled to 7 °C for carcase meat and 3 °C for offals.

(c) Where the premises are approved for the cutting of meat of different species, precautions must be taken to avoid cross-contamination, where necessary by separation of the operations of the different species in either space or time.

CHAPTER V

**SPECIAL CONDITIONS**

Member States may adapt the requirements laid down in Chapters I and II with a view to accommodate the needs of establishments situated in regions suffering from special geographical constraints or affected by supply difficulties, or those serving the local market. Hygiene shall not be compromised. The Member States shall inform the Commission of the details of such special conditions.

Establishments serving the local market shall mean slaughterhouses and cutting plants marketing their meat in the vicinity of the place where such slaughterhouses and cutting plants are situated.

CHAPTER VI

**CASUALTY AND EMERGENCY SLAUGHTER**

1. Meat from animals that have undergone emergency slaughter following serious physiological or functional problems is not authorised for human consumption.

2. Meat from animals that have undergone emergency slaughter outside the slaughterhouse following an accident is authorised for human consumption on the local market if the following requirements are fulfilled:

   — the animal is examined by a veterinarian before slaughter; however, the animal may be slaughtered before examination by a veterinarian when required for welfare reasons,

   — the animal is slaughtered after stunning, bled and possibly eviscerated on the spot; the veterinarian may authorise shooting in special cases,

   — the slaughtered and bled animal is transported as quickly as possible after slaughter under satisfactory hygiene conditions to a slaughterhouse approved for that purpose. Where the slaughtered animal cannot be brought to such a slaughterhouse within an hour, it must be transported in a container or means of transport in which the ambient temperature is maintained between 0 °C and 4 °C. Evisceration must be carried out as soon as possible. If an excessively long period elapses between slaughter and evisceration, the official veterinarian may require that special checks are carried out at post-mortem inspection. If evisceration is carried out on the spot, the viscera must accompany the carcase to the slaughterhouse,

   — during transport to the slaughterhouse, the slaughtered animal and where appropriate the viscera are transported hygienically and are accompanied by a certificate issued by the veterinary surgeon who has ordered slaughter attesting to the outcome of the ante-mortem inspection, the time of slaughter and the nature of any treatment administered to the animal and, if appropriate, the result of the inspection of the viscera,

   — the slaughtered animal is declared wholly or partly fit for human consumption after having been submitted to a detailed post-mortem examination, where necessary supplemented by a bacteriological and residue examination,

   — the meat is not provided with the health mark but with an identification mark approved by the competent authority.

3. Meat from animals that have undergone emergency slaughter following an accident in a slaughterhouse may be marketed if the animals have been submitted to an examination before slaughter, if no other serious lesions than those which occurred immediately before slaughter have been found and if it has been declared wholly or partly fit for human consumption after having been submitted to a detailed post-mortem examination.

CHAPTER VII

**APPROVAL AND REGISTRATION OF ESTABLISHMENTS**

Slaughterhouses, cutting plants and cold stores must be approved by the competent authority and be given an approval number. However, low capacity establishments distributing their products on the local market only may be registered. Such establishments shall not apply the health mark referred to in Chapter VIII.

CHAPTER VIII

**HEALTH MARKING**

1. Marking of meat must be carried out under the responsibility of an official veterinarian, who for this purpose, must supervise the marking and keep under his control the health stamp to be applied to the meat which must be handed over to auxiliaries or designated plant employees at the time of marking and for the length of time required for this purpose.

Health marks may not be removed unless the meat is further worked upon in another separate approved establishment where the original mark must be replaced by that establishment's own number.

2. After completion of the post-mortem inspection, carcases, half carcases, quarters and carcases cut into three pieces must be stamped in ink or hot-branded on their external surface so as to ensure that the slaughterhouse of origin is easily identifiable.

3. Livers must be hot-branded, unless wrapped or packaged.

4. In the case of cut meat and packaged cut offal obtained in a cutting plant the mark must be applied to a label fixed to the packaging, or printed on the packaging. However, when cut meat or offal is wrapped, the label may be affixed to the wrapping in such a way that the label is destroyed when the wrapping is opened.

5. The health mark may include an indication of the official veterinarian who carried out the health inspection of the meat.

## CHAPTER IX

## STORAGE, TRANSPORT AND MATURATION

1. Except where warm cutting and boning is practised, meat must be chilled after post-mortem inspection to an internal temperature of not more than 7 °C for carcase meat and 3 °C for offals along a chilling curve which ensures a constant decrease of the temperature. During the chilling operations, there must be adequate ventilation in order to prevent condensation on the surface of the meat.

   For technical reasons relating to maturation of the meat, a derogation may be granted on a case-by-case basis for the transportation of meat to cutting plants or butcher shops located in the immediate vicinity of a slaughterhouse, provided that such transport takes not more than one hour.

2. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

3. Exposed meat must be stored in a separate room from packaged meat, unless stored at different times.

4. Carcases, half-carcases, half-carcases cut into no more than three wholesale cuts, and quarters may be transported at temperatures higher than those referred to in point 1, under conditions to be set in accordance with the procedure referred to in Article 6 after consultation of the Scientific Committee.

5. Meat must not come into contact with the floor. Containers must not be placed directly on the floor.

6. Packaged meat must not be transported with unpacked meat unless adequate physical separation is provided. Stomachs may not be transported unless scalded or cleaned, nor may heads and feet unless they are skinned or scalded and depilated.

## CHAPTER X

## ADDITIONAL GUARANTEES

In respect of salmonella, the following rules shall apply to beef and veal meat and meat of porcine animals intended for Sweden and Finland:

(a) The consignments must have been subjected to a microbiological test by sampling in the establishment of origin.

(b) With regard to meat of bovine and porcine animals, the test provided for in (a) must not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect.

(c) The test provided for in (a) must not be carried out for meat originating in an establishment which is subject to an operational programme recognised by the Commission, in accordance with the procedure referred to in Article 6, as equivalent to that approved for Sweden and Finland.

The operational programmes of the Member States may be amended and updated by the Commission in accordance with the procedure referred to in Article 6.

SECTION II

**Poultrymeat**

The requirements of this section apply, by analogy, to meat from lagomorphs.

Ratites must be handled in accordance with the requirements set out below but with appropriate accommodation adapted to the size of the animals to ensure the respect of hygiene.

CHAPTER I

**TRANSPORT OF BIRDS TO THE SLAUGHTERHOUSE**

1. During the collection of birds at the farm and during transport, birds must be handled carefully without causing unnecessary distress. Only birds which do not show symptoms of disease or other deficiencies may be transported. Where appropriate, birds showing symptoms of disease or originating in flocks that are known to be contaminated with agents of public health importance must be transported under the control of the competent authority.

2. Equipment used for collecting live birds must be cleaned and disinfected before re-use. Crates for delivering poultry to the slaughterhouse must be made of non-corrodible material and be easy to clean and disinfect.

3. Upon arrival at the slaughterhouse, birds must be rested before slaughter.

CHAPTER II

**CONDITIONS FOR SLAUGHTERHOUSES**

Slaughterhouses must:

1. Have a room or covered space for the reception of the animals and for their inspection before slaughter.

2. Be constructed in such a way as to avoid the contamination of the meat, ensuring in particular that:

   — there is a slaughter room for stunning and bleeding on the one hand, and plucking and any scalding on the other, to be carried out in separate places,

   — there is a room for evisceration and further dressing which is large enough for evisceration to be carried out in a place sufficiently far from the other work stations, or separated from them by a partition, to prevent contamination,

   — slaughter lines are designed to allow a constant progress of the slaughter process and to avoid cross contamination between different parts of the slaughter line as well as contact between carcases and walls, equipment, etc.,

   — there is an appropriate area, sufficiently protected, for dispatching meat.

3. Have refrigeration facilities of sufficient capacity in relation to the volume of production.

4. Have lockable premises for the refrigerated storage of detained meat.

5. Have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

6. Have equipment for washing hands used by the staff engaged in handling exposed meat provided with taps that are non-hand operable.

7. There must be a separate place with appropriate facilities for the cleaning and disinfection of means of transport and, where appropriate, transport equipment such as crates. These places and facilities are not compulsory if officially authorised places and facilities exist nearby.

CHAPTER III

**CONDITIONS FOR CUTTING PLANTS**

Cutting plants must:

1. Be constructed so as to allow constant progress of the operations or ensure separation between the different batches.

2. Have rooms for the separate storage of packed and exposed meat, unless stored at different times.

3. Have cutting rooms equipped to ensure that the cold chain is not interrupted during cutting operations.

4. The equipment for washing hands used by staff handling exposed meat shall be provided with taps that are non-hand operable.

5. Have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

If the following operations are undertaken in a cutting plant:

— the evisceration of geese and ducks reared for the production of 'foie gras', which have been stunned, bled and plucked on the fattening farm,

— the evisceration of 'New York dressed' poultry,

separate rooms must be available for that purpose unless these operations are separated in time from the cutting operations and proper cleaning and infection procedures are in place.

CHAPTER IV

**SLAUGHTER HYGIENE**

1. Crates for delivering live poultry must be cleaned and disinfected each time they are emptied.

2. Only live animals intended for slaughter may be brought into the slaughter premises with the exemption of farmed ratites slaughtered at the place of production, 'New York dressed' poultry slaughtered at the farm, small wild game and geese and ducks reared for the production of 'foie gras' which have been stunned, bled and plucked on the fattening farm.

   Animals that have died during transport or before slaughter shall not be used for human consumption.

3. Where provided for in Community legislation, animals must before slaughter be presented to the competent authority in order to be submitted to an ante-mortem inspection. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the ante-mortem inspection is carried out under suitable conditions.

4. Where establishments are approved for the slaughter of different animal species or for the handling of farmed ratites and small wild game, precautions must be taken to prevent cross contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcases of farmed ratites slaughtered at the farm and for small wild game must be available.

5. Animals brought into the slaughter room must be immediately slaughtered after stunning, save in case of slaughter according to religious rite.

6. Stunning, bleeding, skinning or plucking, dressing and evisceration must be carried out without delay in such a way that contamination of the meat is avoided. It must in particular be ensured that measures are taken to prevent the spillage of digestive tract contents during evisceration.

7. Slaughtered animals must be submitted to a post-mortem inspection under the supervision of the competent authority. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the post-mortem inspection is carried out under suitable conditions ensuring in particular that slaughtered poultry can be inspected properly.

8. Viscera or parts of viscera which have not been removed from the carcase before post-mortem inspection must, except for the kidneys, be removed entirely, if possible, and as quick as possible after inspection has been completed.

9. After inspection and evisceration, slaughtered birds must be cleaned and chilled to a temperature of not more than 4 °C as soon as possible, unless the meat is cut while warm.

   'New York dressed' poultry obtained at the farm of production may be kept for up to 15 days at a temperature which must not exceed 4 °C; they must, at the latest at the end of this period, be eviscerated in a slaughterhouse or in a cutting plant. Such poultry must be accompanied by a certificate signed by the competent authority stating that the uneviscerated carcases are of birds which were examined before slaughter on the farm of origin and were found to be healthy at the time of examination.

10. When poultry carcases are subjected to an immersion chilling process, account must be taken of the following:

    (a) every precaution must be taken to avoid cross-contamination of carcases taking into account parameters such as carcase weight, water temperature, volume and direction of water flow and chilling time;

    (b) equipment must be entirely emptied, cleaned and disinfected whenever this is necessary;

    (c) calibrated control equipment must continuously record the following:

    — the water consumption during spray-washing before immersion,

    — the temperature of the water of the tank or tanks at the points of entry and exit of the carcases,

    — the water consumption during immersion,

    — the total weight of the immersed carcases.

11. Sick or suspect birds or birds slaughtered in application of disease eradication or control programmes must not be slaughtered in the establishment except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the premises must be cleaned and disinfected before being used again.

## CHAPTER V

## HYGIENE DURING CUTTING AND BONING

The work on meat must be organised in such a way as to prevent the growth of pathogenic micro-organisms or the formation of toxins or other pathogenic substances, and in particular:

1. Meat intended for cutting must be brought into the work rooms progressively as needed.

2. During cutting, boning, slicing, dicing, wrapping and packaging, the cooling of the meat must not be interrupted.

   Where meat is boned and cut prior to reaching 4 °C, such meat must be transferred directly from the slaughter premises to the cutting room in a single operation, or after a waiting period in the cold store. Cutting must be carried out immediately after transfer.

3. As soon as it is cut, and where appropriate wrapped and packaged, the meat must be chilled to 4 °C.

4. Where the premises are approved for the cutting of meat of different species or for handling 'New York dressed' poultry and small wild game, precautions must be taken to avoid cross-contamination, where necessary by separation of the operations of the different species in either space or time.

## CHAPTER VI

## SPECIAL CONDITIONS

1. Member States may adapt the requirements laid down in Chapters II and III with a view to accommodate the needs of establishments situated in regions suffering from special geographical constraints or affected by supply difficulties, or those serving the local market. Hygiene shall not be compromised. The Member States shall inform the Commission of the details of such special conditions.

   Establishments serving the local market shall mean farms with an annual production of under 10 000 birds supplying fresh poultry meat coming from their holdings in small quantities:

   — either directly to the final consumer at the holding or at the weekly markets in the vicinity of their holdings or

   — to retailers with a view to direct sale to the final consumer, provided that such retailers pursue their activities in the same or neighbouring locality as that of the producer.

2. Member States may:

   — allow the further handling in establishments approved for that purpose of farmed game birds and small farmed game animals which are slaughtered and bled at the farm,

   — grant a derogation from the slaughter and evisceration provisions in the case of the production of partially eviscerated or non-eviscerated farmed game birds.

3. Slaughter, bleeding and plucking of poultry reared and slaughtered for the production of 'foie gras' may be carried out at the farm, provided these operations are carried out in a separate room fully complying with hygiene rules. The uneviscerated carcases must be transported immediately, under respect of the cold chain principles, to a slaughterhouse or cutting plant with a special room where the carcases must be eviscerated within 24 hours under the supervision of the competent authority. During transport, such poultry carcases must be accompanied by a certificate signed by the official veterinarian giving information about the health status of the flock of origin and the hygiene at the farm of production.

4. Where the competent authority authorises the slaughter of animals at the farm in accordance with point 3, the following conditions shall apply:

— the farm must undergo regular veterinary inspection and not be placed under any animal- or public-health restriction,

— the competent authority must be informed in advance of the date of slaughter of birds,

— the holding must have facilities for concentrating the birds to allow an ante-mortem inspection of the group to be made,

— the holding must have premises suitable for the hygienic slaughter and further handling of the birds,

— animal welfare requirements must be complied with.

CHAPTER VII

**APPROVAL AND REGISTRATION OF ESTABLISHMENTS**

Slaughterhouses, cutting plants and cold stores must be approved by the competent authority and be given an approval number. However, low capacity establishments referred to in Chapter VI distributing their products on the local market only may be registered.

CHAPTER VIII

**ADDITIONAL GUARANTEES**

In respect of salmonella, the following rules shall apply to meat of domestic fowl, turkey, guinea fowl, ducks and geese intended for Sweden and Finland:

(a) The consignments must have been subjected to a microbiological test by sampling in the establishment of origin.

(b) The test provided for in (a) must not be carried out for meat originating in an establishment which is subject to an operational programme recognised by the Commission, in accordance with the procedure referred to in Article 6, as equivalent to that approved for Sweden and Finland.

The operational programmes of the Member States may be amended and updated by the Commission in accordance with the procedure referred to in Article 6.

SECTION III

**Meat of farmed game**

1. The provisions for meat of domestic ungulates shall apply to the production and marketing of meat of farmed even-toed game mammals (Cervidae and Suidae).

2. The provisions for poultry meat shall apply to the production and marketing of meat from ratites.

3. Notwithstanding paragraphs 1 and 2, the competent authority may authorise the slaughter of farmed game at the place of origin where it cannot be transported, in order to avoid any risk for the handler or to protect the welfare of the animals. This authorisation may be granted if:

— the herd undergoes regular veterinary inspection and is not under any animal- or public-health restriction,

— a request is submitted by the owner of the animals,

— the competent authority is informed in advance of the date of slaughter of the animals,

— the holding has facilities for concentrating the animals to allow an ante-mortem inspection of the group to be made,

— the holding has premises suitable for the slaughter, sticking and bleeding, and where ratites are to be plucked, plucking of the animals,

— slaughter by sticking and bleeding is preceded by stunning in accordance with Directive 93/119/EC; slaughter by shooting may be allowed,

— slaughtered and bled animals are transported suspended, under satisfactory conditions of hygiene, to an approved establishment as soon as possible after slaughter. Where animals slaughtered at the place of rearing cannot be brought within one hour to an approved establishment, they must be transported in a container or means of transport in which the ambient temperature is maintained at between 0 °C and 4 °C. Evisceration must be carried out as soon as possible after stunning and bleeding,

— during transport to the approved establishment, slaughtered animals are accompanied by a certificate issued and signed by the official veterinarian attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the time of slaughter.

4. All operations for the slaughter of reindeer destined for intra-Community trade may be carried out in mobile slaughter units in accordance with the provisions for meat of domestic ungulates. In accordance with the procedure referred to in Article 6, and after the opinion of the Scientific Committee, the conditions under which mobile slaughterhouses can be used for the slaughter of other species shall be laid down.

## SECTION IV

## Wild game meat

This Section does not apply to trophies or killed wild game transported by travellers, in so far as this involves a small quantity of small wild game or only one whole item of large wild game and where the circumstances indicate that the game is not intended for commercial purposes, and provided that it does not come from an area or region subject to animal health restrictions or restrictions because of the presence of residues.

### CHAPTER I

### TRAINING OF HUNTERS IN HEALTH AND HYGIENE

1. Persons responsible for hunting wild game and for placing it on the market for human consumption must have sufficient knowledge of wild game hygiene and pathology in order to undertake an initial examination of wild game on the spot.

   For that purpose, Member States shall organise training and education schemes for hunters, game managers, game keepers, etc. which must cover at least the following subjects:

   — normal anatomy, physiology and behaviour of wild game animals,

   — abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption,

   — the hygiene rules and proper techniques for handling, transportation, evisceration, etc. of wild game animals after killing,

   — legislation, regulations and administrative provisions on the health and hygiene conditions governing the placing on the market of wild game.

   Such schemes shall if possible be set up and run in collaboration with officially recognised hunters' organisations in order to guarantee that there is a permanent effort of instructing and educating hunters about possible public-health risks due to meat from wild game.

2. Hunters, or in a hunting team at least one person shall have the qualifications referred to above for performing a health check on hunted animals

### CHAPTER II

### KILLING, EVISCERATION AND TRANSPORT OF WILD GAME TO AN APPROVED ESTABLISHMENT

1. After killing, large wild game must be drawn and have their stomachs and intestines removed; small wild game may be totally or partially eviscerated on the spot or in a game handling establishment.

2. Hunted animals must be examined by the hunter, a qualified person as referred to in Chapter I point 2 or where appropriate a veterinarian as soon as possible after killing and opening in order to detect characteristics which may indicate that the meat presents a health risk.

(a) Where no such characteristics are found or where there is no suspicion of environmental contamination, the game may be either released for direct private consumption or else be transported as soon as possible to a game collecting centre or game handling establishment. In a game collection centre, any intervention on the game is forbidden. In the game handling establishment, the game shall be presented for inspection to the competent authority. Unless the game carcase is accompanied by a certificate from a qualified hunter or person as referred to in Chapter I point 2, stating that the game did not show abnormal characteristics and that there is no suspicion of environmental contamination, the thoracic viscera of large wild game, even if detached from the carcase, the kidneys and, where appropriate, the liver and the spleen, must accompany the carcase and be identified in such a way that the inspection of the viscera can be carried out together with the rest of the carcase; the head may have been removed as a trophy.

(b) If any abnormal behaviour before killing or pathological changes are detected during the examination or when environmental contamination is suspected, the carcase together with the viscera must be transported to the game handling establishment to be submitted to a complete post-mortem inspection and the competent authority must ensure that the hunter informs the official veterinarian thereof. The official veterinarian must submit the carcase to the tests necessary in order to make a diagnosis about the nature of the defect. After making a diagnosis, the official veterinarian determines if the carcase is fit for human consumption.

It must be ensured that species that may be contaminated by *trichinella spiralis* are submitted in an officially recognised laboratory to an examination to detect the possible presence of that parasite before release for human consumption. Hunters or the qualified person referred to in Chapter I point 2 shall be held responsible for any decision taken by them with regard to the examination of wild game for the possible presence of a health risk.

Where a hunter is not qualified or when in a hunting team there is no qualified person as referred to in Chapter I point 2, the hunted animal together with its viscera shall be presented for inspection by the competent authority in a game handling establishment.

3. Carcases and viscera must be moved within 12 hours after killing to a game handling establishment or a collection centre, where they must be chilled to the required temperature. If the game is brought to a collection centre first, it must be transported within 12 hours after arrival in the collection centre to a game handling establishment or in remote regions where climatological conditions so permit, within a period to be fixed by the competent authority. During transport to the game collection centre and the game handling establishment, heaping and stacking shall be prohibited.

4. Wild game carcases must be chilled to a temperature of not more than 7 °C for large game and not more than 4 °C for small game.

5. Where unskinned large game is marketed:

(a) their viscera must have undergone post-mortem inspection in a wild game handling establishment;

(b) it must be accompanied by a health certificate signed by the official veterinarian to certify that the result of the post-mortem inspection was satisfactory;

(c) it must have been cooled to a temperature not exceeding:

— + 7 °C and be kept below this temperature for a maximum period of 7 days from the post-mortem inspection, or

— + 1 °C and kept below this temperature for a maximum period of 15 days from the post-mortem inspection;

(d) it must be stored and handled separately from other food.

Meat from such unskinned wild game cannot bear the health mark unless, after skinning in a game handling establishment, it has undergone post-mortem inspection and has been declared fit for human consumption.

CHAPTER III

**HYGIENE PROVISIONS IN GAME HANDLING ESTABLISHMENTS**

1. Wild game meat must be prepared in an approved game handling establishment.

2. Evisceration must be carried out without undue delay, upon arrival at the wild game handling establishment, if it has not been carried out on the spot. The lungs, heart, kidneys, mediastinum and where appropriate the liver and spleen may either be detached or left attached to the carcase by their natural connections.

3. During cutting, boning, wrapping and packaging the internal temperature of the wild game must be kept at a temperature of + 7 °C or lower in the case of large wild game, or 4 °C or lower in the case of small wild game.

CHAPTER IV

**REGISTRATION AND APPROVAL OF ESTABLISHMENTS**

1. Game collection centres shall be registered.

2. Game handling establishments shall be approved.

SECTION V

**Minced meat, meat preparations and mechanically separated/recovered meat**

This Section does not apply to the production and marketing of minced meat intended for the processing industry; such meat remains subject to the requirements for fresh meat.

CHAPTER I

**ESTABLISHMENTS OF PRODUCTION**

1. Production rooms must be equipped to ensure that the cold chain is not interrupted during the operations.

2. It must be ensured that the products are microbiologically safe.

3. Establishments shall be approved by the competent authority.

CHAPTER II

**MINCED MEAT**

1. Requirements for the raw materials:

   (a) minced meat must have been prepared from skeletal muscle (including the adherent fatty tissues);

   (b) frozen or deep-frozen meat used for the preparation of minced meat must have been boned before freezing and have been stored for a limited period after boning;

   (c) the competent authority may authorise the boning of meat on the spot immediately before mincing where this operation is carried out in satisfactory conditions of hygiene and quality;

   (d) where it has been prepared from chilled meat, such meat must be used:

      — within no more than 6 days after slaughter of the animals, or

      — within no more than 15 days after slaughter of the animals in the case of boned, vacuum-packed beef and veal;

   (e) in all cases, meat with organoleptic deficiencies shall be excluded from the production of minced meat;

   (f) minced meat shall not be obtained from:

      — scrap cuttings and scrap trimmings (other than whole muscle cuttings) or from mechanically separated meat,

— meat from the following parts of bovine animals, pigs, sheep or goats: meat of the head with the exception of the masseters, the non-muscular part of the linea alba, the region of the carpus and the tarsus, and bone scrapings. The muscles of the diaphragm — after removal of the serosa – and of the masseters may be used only after being examined for cysticercosis,

— meat containing bone fragments or skin.

Pig meat or horse meat used for minced meat production must have been obtained in accordance with the requirements regarding trichina examination.

2. The mincing operations must be performed within one hour from the time when the meat enters the preparation room. A longer time limit may be granted in individual cases where the addition of salt justifies this on technical grounds, or where hazard analysis demonstrates that there is no increased hazard to human health.

When the duration of these operations exceeds the time limit referred to above, the fresh meat may not be used until the internal temperature of the meat has been reduced to a maximum of 4 °C.

3. Immediately after production, minced meat must be hygienically wrapped and/or packaged and after that be cooled to and stored at a temperature not exceeding 2 °C.

4. Minced meat may be deep-frozen only once.

5. Minced meat to which not more than 1 % of salt has been added shall be subject to the same requirements. If more than 1 % salt is added, the product is considered to be a meat preparation.

6. In order to take account of particular habits of consumption, and on condition that the products of animal origin do not present a hazard to human health, Member States may grant derogations from points 1 to 5. In this case, the minced meat must not be given the Community health mark.

## CHAPTER III

## MEAT PREPARATIONS

1. Meat preparations obtained from minced meat must fulfil the conditions laid down for minced meat.

2. The addition of seasonings to whole poultry carcases may be authorised in a specific room that is clearly separate from the slaughter room.

3. Where the meat has been frozen or deep-frozen, it must be used within a time period sufficiently short after slaughter.

4. Boning of meat on the spot immediately before preparation may be authorised, provided this operation is carried out in satisfactory conditions of hygiene.

5. Meat preparations may be deep-frozen only once.

6. After their production, wrapping and packaging, meat preparations must be cooled as quickly as possible to an internal temperature of maximum 4 °C.

In the deep-frozen form, an internal temperature below - 18 °C must be reached, in accordance with Article 1(2) of Directive 89/108/EEC.

## CHAPTER IV

## MECHANICALLY SEPARATED MEAT (MSM)

MSM must have been obtained under the following conditions:

1. Raw materials

(a) The raw materials used for the production of MSM must comply with the requirements for fresh meat.

(b) The use of the following is not allowed for the production of MSM:

— for poultry: feet, neckskin, neckbones and head,

— for other animals: the bones of the head, feet, tails (except bovine tails), femur, tibia, fibula, humerus, radius and ulna, the vertebral column of bovine, ovine and caprine animals.

(c) Chilled raw material for deboning from an on-site slaughterhouse must not be older than 7 days.

Chilled raw material for deboning from another slaughterhouse must not be older than 5 days.

Flesh-bearing bones from frozen carcases may be used.

2. Conditions for the production of MSM:

(a) Mechanical separation must take place without undue delay after deboning. Otherwise, the flesh-bearing bones obtained after boning must:

— either be chilled at 2 °C and stored at a room temperature not exceeding 2 °C,

— or be frozen after boning so as to reach a temperature of - 18 °C within 24 hours. Such bones must be used within three months after freezing. However, refreezing of flesh-bearing bones obtained from frozen carcases is not allowed.

(b) During mechanical separation, the room temperature may not exceed 12 °C.

(c) If not used within one hour after it has been obtained, the MSM must be chilled immediately to a temperature of not more than 2 °C.

After chilling, it can be processed within 24 hours, or else it must be frozen within 12 hours after production.

If the MSM is frozen, the freezing layers must reach a core temperature of - 18 °C or less within six hours. Frozen MSM shall not be stored for more than three months. Frozen MSM must be kept below - 18 °C during transport and storage.

MSM may be transported from the separation unit to a processing establishment. The cold chain may not be interrupted during transport, the product remaining at 2 °C or below.

3. Use of MSM

MSM may only be used in heat-treated meat products in which the temperature increases to + 70 °C during 30 minutes or any other time/temperature combination providing the same security.

## SECTION VI

## Meat products

### CHAPTER I

### REQUIREMENTS FOR RAW MATERIALS

The following items may not be used in the preparation of processed meat products:

(a) genital organs of both female and male animals, except testicles;

(b) urinary organs, except the kidneys and the bladder;

(c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;

(d) eyes and eyelids;

(e) the external auditory meatus;

(f) corneal tissue;

(g) in poultry, the head — except the comb and the ears, the wattles and caruncles — the oesophagus, the crop, the intestines and the genital organs.

### CHAPTER II

### APPROVAL OF ESTABLISHMENTS

Establishments for the manufacture of meat products must be approved by the competent authority. However, low capacity establishments distributing their products on the local market only may be registered.

SECTION VII

**Live bivalve molluscs**

The provisions on purification shall not apply to echinoderms, tunicates and marine gasteropods.

It shall be ensured that live bivalve molluscs harvested from the wild and destined for direct human consumption, comply with the standards set out in Chapter IV of this Section.

CHAPTER I

**SPECIAL HYGIENE CONDITIONS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS**

A. *Conditions for production areas*

1. Live bivalve molluscs shall only be harvested from areas the location and boundaries of which are fixed and classified by the competent authority as follows:

   (a) *Class A areas:* areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the requirements of Chapter IV of this Section.

   (b) *Class B areas:* areas from which live bivalve molluscs may be collected, but only placed on the market for human consumption after treatment in a purification centre or after relaying.

   (c) *Class C areas:* areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period (at least two months).

   The criteria for the classification of class B or C areas will be laid down by the Commission in accordance with the procedure referred to in Article 6, after obtaining the opinion of the appropriate Scientific Committee.

   After purification or relaying, molluscs from class B or C areas must meet all of the requirements of Chapter IV of this Section.

   However, live bivalve molluscs from such areas which have not been submitted to purification or relaying may be sent to a processing establishment where they must be subjected to a treatment intended to inhibit the development of pathogenic micro-organisms. Such treatment must be approved by the Commission in accordance with the procedure referred to in Article 6, after obtaining the opinion of the appropriate Scientific Committee.

2. Any production and harvesting of bivalve molluscs in areas considered unsuitable for these activities for health reasons or in areas not classified in one of the categories referred to in point 3 shall be prohibited. Operators shall inform themselves with the competent authority about the areas that are suitable for production and harvesting.

3. The provisions laid down in point 1 apply, with regard to pectinids, only to products of aquaculture, or, where data are available permitting the classification of fishing grounds, to wild pectinids. However, if no classification of fishing grounds is possible, the requirements of Chapter IV apply to pectinids harvested from the wild.

B. *Conditions for harvesting and transporting live bivalve molluscs to a dispatch or purification centre, relaying area or processing plant*

1. Harvesting techniques and further handling must not cause additional contamination and excessive damage to the shells or tissues of live bivalve molluscs and must not result in changes significantly affecting their suitability for treatment by purification, processing or relaying. They must in particular:

   — be adequately protected from crushing, abrasion or vibration,

   — not be exposed to extremes of hot or cold temperatures,

   — not be re-immersed in water which could cause additional contamination.

2. The means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

3. A registration document for the identification of batches of live bivalve molluscs during transport from the production area to a dispatch centre, purification centre, relaying area or processing establishment is to be issued by the competent authority at the request of the gatherer. For each batch, the gatherer must complete legibly and indelibly the relevant sections of the registration document, the form for which is laid down in accordance with the procedure referred to in Article 6. This document must be produced in at least one of the languages of the country of destination.

The registration documents must be sequentially numbered. The competent authority must keep a register containing the numbers of registration documents together with the names of the persons collecting live bivalve molluscs to whom the documents have been issued. The registration document for each batch of live bivalve molluscs must be date-stamped upon delivery of a batch to a dispatch centre, purification centre, relaying area or processing establishment. It must be kept by operators of such centres, areas or establishments for at least twelve months, or, upon request of the competent authority, for a longer period. In addition, the gatherer is also obliged to keep it for the same period.

However, if gathering is carried out by the same staff operating the dispatch centre, purification centre, relaying area or processing establishment of destination, the registration document may be replaced by a standing transport authorisation granted by the competent authority.

4. If a production or relaying area is closed temporarily, the competent authority must refrain from issuing registration documents for that area and immediately suspend the validity of all registration documents already issued.

C. *Conditions for relaying live bivalve molluscs*

For relaying live bivalve molluscs, the following conditions must be met:

1. Only areas approved by the competent authority for relaying live bivalve molluscs may be used. The boundaries of the sites must be clearly identified by buoys, poles or other fixed means; there must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to ensure that the quality of the waters is not adversely affected.

2. Conditions for relaying must ensure optimal conditions for purification. It must in particular be ensured that:

   — techniques for handling live bivalve molluscs intended for relaying permit the resumption of filter-feeding activity after immersion in natural waters,

   — live bivalve molluscs are not be relayed at a density which prevents purification,

   — live bivalve molluscs are immersed in sea water at the relaying area for an appropriate period which is fixed depending on the water temperature. This period must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted under Chapter IV of this Section,

   — the minimum water temperature for effective relaying is, where necessary, determined and publicised by the competent authority for each species of live bivalve molluscs and each approved relaying area,

   — to prevent mixing of batches, sites within a relaying area are well separated.

3. Permanent records of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying must be kept by the operators of relaying areas for inspection by the competent authority.

4. After harvesting from a relaying area, batches must be accompanied by a registration document during transport from the relaying area to the approved dispatch centre, purification centre or processing establishment, the form for which is to be laid down in accordance with the procedure referred to in Article 6, except where the same staff operates both the relaying area and the dispatch centre, purification centre or processing establishment. This document must be produced in at least one of the languages of the country of destination.

## CHAPTER II

## DISPATCH AND PURIFICATION CENTRES

A. *Premises*

1. The location of premises must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

2. When sea water is used, facilities for the supply of clean sea water must be available.

B. *Special conditions for purification centres*

In addition to the conditions laid down under A, purification centres must meet the following conditions:

— the internal surfaces of the purification tanks and any water storage containers must be smooth, durable and impermeable, easy to clean by scrubbing or the use of pressurised water,

— the purification tanks must be constructed so as to allow complete draining of water,

— the purification tanks must be supplied with a sufficient flow of clean sea water and sufficient water outlet capacity for the volume of products to be purified,

— if the purification centre does not have a directly pumped clean water supply, it must have equipment making it possible to purify the sea water.

CHAPTER III

**HYGIENE CONDITIONS IN DISPATCH AND PURIFICATION CENTRES**

A. *Hygiene conditions to be met in purification centres*

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using pressurised clean sea water or potable water.

2. The purification tanks must be supplied with a sufficient flow of sea water per hour and per tonne of live bivalve molluscs treated; the distance between the sea water intake point and the waste water outlets must be sufficient to avoid contamination.

3. Operation of the purification system must allow live bivalve molluscs to rapidly resume filter-feeding activity, eliminate sewage contamination, not become re-contaminated and be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.

4. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre; the live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards of Chapter IV of this Section to be met.

5. Should a purification tank contain several species of bivalve molluscs, the length of the treatment must be based on the time required by the species needing the longest period of purification.

6. Containers used to hold live bivalve molluscs in purification systems must have a construction which allows sea water to flow through; the depth of layers of live bivalve molluscs must not impede the opening of shells during purification.

7. After completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean sea water.

8. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.

9. Purification centres must accept only batches of live bivalve molluscs which are accompanied by a registration document, the form for which is to be drawn up in accordance with the procedure referred to in Article 6.

10. Purification centres sending batches of live bivalve molluscs to dispatch centres must provide a registration document, the form for which is to be drawn up in accordance with the procedure referred to in Article 6.

11. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

B. *Hygiene conditions to be met in dispatch centres*

1. Handling of molluscs such as packing or calibration procedures must not cause contamination of the product or affect the viability of the molluscs.

2. Any washing or cleaning of live bivalve molluscs must be carried out using pressurised clean sea water or potable water; cleaning water may not be recycled.

3. Dispatch centres must accept only batches of live bivalve molluscs which are accompanied by the registration document referred to under point I.B(4) and come from an approved production area (class A), relaying area or purification centre.

4. Molluscs must be kept away from places to which domestic animals have access.

5. Dispatch centres situated aboard vessels are subject to the conditions laid down in points 1, 2 and 4. The molluscs must come from an approved production area (class A). The conditions laid down in Chapter II(A) apply *mutatis mutandis* to such dispatch centres, although special conditions may be laid down by the Commission in accordance with the procedure referred to in Article 6.

CHAPTER IV

**HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS**

Live bivalve molluscs placed on the market for human consumption must comply with the following requirements:

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and, except for Pectinidae, normal amounts of intravalvular liquid.

2. They must respect microbiological criteria or be produced in conformity with microbiological guidelines to be established in accordance with the procedure referred to in Article 6 of the present Regulation.

3. They must not contain toxic or objectionable compounds occurring naturally or added to the environment in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI).

4. The upper limits for radionuclide levels must not exceed the limits for foodstuffs as laid down by the Community.

5. Limits for marine biotoxines:

   (a) the total Paralytic Shellfish Poison (PSP) content in the edible parts of the molluscs (the whole body or any part edible separately) must not exceed 80 micrograms per 100 g of mollusc flesh in accordance with a method recognised by the Commission deciding in accordance with the procedure referred to in Article 6;

   (b) the total Amnesic Shellfish Poison (ASP) content in edible parts of molluscs (the entire body or any edible part edible separately) must not exceed 20 micrograms of domoic acid per gram using the HPLC method;

   (c) the customary biological testing methods must not give a positive result to the presence of Diarrheic Shellfish Poison (DSP) in the edible parts of the molluscs (the whole body or any part edible separately).

The Commission is to lay down, in cooperation with the relevant Community Reference Laboratory and in accordance with the procedure referred to in Article 6, and after obtaining the opinion of the Scientific Committee:

— limit values and analysis methods for other marine biotoxins, where the need occurs,

— virus testing procedures and virological standards,

— sampling plans as well as the methods and analytical tolerances to be applied in order to check compliance with the health standards. Pending decisions thereon, methods for checking compliance with the health standards must be scientifically recognised,

— other health standards or checks are to be introduced where there is scientific evidence indicating that this should be done in order to protect public health.

CHAPTER V

**WRAPPING OF LIVE BIVALVE MOLLUSCS**

1. Oysters must be wrapped with the concave shell downwards.

2. All wrappings of live molluscs, including vacuum wrapping in sea water, must be closed and remain closed from the dispatch centre until delivery to the consumer or retailer. However, wrappings may be opened and the molluscs be re-wrapped in an approved dispatch or purification centre.

CHAPTER VI

**APPROVAL OF ESTABLISHMENTS**

Dispatch and purification centres shall be approved by the competent authority.

CHAPTER VII

**HEALTH MARKING AND LABELING**

1. The health marking must be waterproof.

2. In addition to the health marking requirements, the following information must be present on the label:

   — the species of bivalve mollusc (common name and scientific name),

— the date of wrapping, comprising at least the day and the month.

By way of derogation from Directive 79/112/EEC, the date of durability may be replaced by the entry 'these animals must be alive when sold'.

3. The label attached to the wrapping of live bivalve molluscs which are not wrapped in individual consumer-size parcels must be kept for at least 60 days by the retailer after splitting up the contents.

CHAPTER VIII

**STORAGE AND TRANSPORT OF LIVE BIVALVE MOLLUSCS**

1. In storage rooms, live bivalve molluscs must be kept at a temperature which does not adversely affect their safety and viability.

2. Re-immersion in or spraying with water of live bivalve molluscs must not take place after they have been wrapped and have left the dispatch centre, except in the case of retail sale at the dispatch centre.

SECTION VIII

**Fishery products**

CHAPTER I

**CONDITIONS FOR FISHERIES VESSELS**

Fishery products caught in their natural environment must have been caught and, where appropriate, handled for bleeding, heading, gutting and the removal of fins, chilled, frozen or processed and/or wrapped/packaged on board vessels in accordance with the rules laid down in this Chapter.

I. **Conditions for the equipment of fisheries vessels**

A. *Conditions applicable to all vessels*

1. Fisheries vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

2. Surfaces with which the fish comes into contact must be of suitable corrosion-resistant material which is smooth and easy to clean. Surface coatings must be durable and non-toxic.

3. Equipment and material used for working on fish must be made of corrosion-resistant material which is easy to clean.

B. *Factory vessels*

1. Factory vessels must have at least:

(a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;

(b) a hygienic system for conveying fishery products from the receiving area to the work area;

(c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and designed and arranged in such a way as to prevent any contamination of the products;

(d) storage areas for the finished products that are large enough and designed so that they are easy to clean; if a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;

(e) a place for storing packaging materials that is separate from the product preparation and processing areas;

(f) special equipment for pumping waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose; if waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;

(g) equipment providing a supply of potable water within the meaning of Council Directive 98/83/EC, or pressurised clean sea water or clean river or lake water. The sea water intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant;

(h) appliances for cleaning and disinfecting hands with taps that must not be manually operated unless a procedure of equal guarantee can be demonstrated, and hygienic means of drying hands.

2. Factory vessels which freeze fishery products must have:

(a) freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of - 18 °C or lower;

(b) refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at - 18 °C or lower. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest.

Whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of - 9 °C or lower.

C. *Freezer vessels and vessels designed and equipped to preserve fishery products for more than 24 hours*

1. Such vessels must be equipped with holds, tanks or containers for the storage of refrigerated or frozen fishery products at the temperatures laid down in this Section. The holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. The freezing and refrigeration equipment is subject to the same conditions as laid down for factory vessels under B(3).

2. The holds shall be designed to ensure that melt water cannot remain in contact with fishery products.

3. Containers used for the storage of products must ensure their preservation under satisfactory conditions of hygiene and, in particular, be clean and allow the drainage of melt water.

4. In vessels equipped for chilling fishery products in cooled sea water, tanks must incorporate devices for achieving a uniform temperature throughout the tanks; a chilling rate must be achieved which ensures that the mix of fish and sea water reaches 3 °C at the most 6 hours after loading and 0 °C at the most after 16 hours.

II. **Hygiene on board fishing vessels**

The following hygiene conditions apply to fishery products on board fishing vessels:

1. When in use, the parts of fishing vessels or containers set aside for the storage of fishery products must be clean and, in particular, must not be capable of being contaminated by fuel or bilge water.

2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either fresh water complying with the parameters set out in Directive 98/83/EC, or where appropriate, clean sea water or clean river or lake water.

3. Fishery products must be handled and stored so as to prevent bruising. The use of spiked instruments is allowed for moving large fish or fish which might injure the handler, provided the flesh of these products is not damaged.

4. Fishery products other than those kept alive must undergo cold treatment as soon as possible after loading. However, when cooling is not possible, fishery products must be landed as soon as possible.

5. When ice is used for chilling products, it must be made from potable water or clean sea water or clean river or lake water. Before use, it must be stored under conditions which prevent its contamination.

6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water, clean sea water or clean river or lake water. In that event, the viscera and parts which may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at the temperature of melting ice or be frozen.

7. Where freezing in brine of whole fish intended for canning is practised, a temperature of - 9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

8. The cooking of crustaceans and molluscs on board must be carried out under the conditions laid down in Chapter III point VI.

## CHAPTER II

## CONDITIONS OF HYGIENE DURING AND AFTER LANDING

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be maintained in a good state of repair and cleanliness.

2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that:

   — unloading and landing operations proceed rapidly,

   — fishery products are placed without delay in a protected environment at the temperature required,

   — equipment and practices that cause unnecessary damage to the edible parts of the fishery products are not authorised.

3. Auction and wholesale markets or parts thereof where fishery products are displayed for sale must:

   (a) at the time of display or storage of fishery products, not be used for other purposes. Vehicles emitting exhaust fumes likely to impair the quality of the fishery products must not be admitted to markets. Persons having access to the premises are not allowed to introduce animals therein;

   (b) when sea water is used, have facilities for the supply of clean sea water.

4. After landing or, where appropriate, after first sale, fishery products must be conveyed without delay to their place of destination, or else stored in cold rooms before being displayed for sale or after being sold and pending transport to their place of destination. In such cases, fishery products must be stored at the temperature approaching that of melting ice.

## CHAPTER III

## SPECIAL CONDITIONS

### I. **Conditions for fresh products**

1. Where chilled, unpacked products are not distributed, dispatched, prepared or processed immediately after reaching an establishment, they must be stored under ice in a cold room. Re-icing must be carried out as often as necessary; the ice used, with or without salt, must be made from potable water or clean sea, river or lake water and be stored hygienically in receptacles provided for the purpose. Wrapped fresh products must be chilled with ice or with a mechanical refrigeration appliance giving similar temperature conditions.

2. Operations such as heading and gutting must be carried out hygienically; the products must be washed thoroughly with potable water or clean sea, river or lake water immediately after these operations.

3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices, and in a place other than used for heading and gutting. Fillets and slices must not remain on the work tables beyond the time necessary for their preparation and must be protected from contamination by suitable wrapping. Fillets and slices must be chilled as quickly as possible after their preparation.

4. Containers used for the dispatch or storage of fresh fishery products must provide adequate drainage of melt water.

II. **Conditions for frozen products**

Establishments where fishery products are frozen must have equipment which satisfies the same requirements for freezing and storage as set out for factory vessels which freeze fishery products.

III. **Conditions for mechanically separated fish flesh**

1. Mechanical separation of gutted fish must take place without undue delay after filleting, using raw materials free from guts. If whole fish are used, they must be gutted and washed beforehand.

2. After production, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

IV. **Conditions concerning endo-parasites harmful to human health**

1. The following fishery products must be frozen at a temperature of not more than - 20 °C in all parts of the product for not less than 24 hours; this treatment must be applied to the raw product or the finished product.

   (a) Fish to be consumed raw or almost raw, e.g. raw herring (maatjes).

   (b) The following species if they are to undergo a cold smoking process in which the internal temperature of the fish is less than 60 °C:

   — herring,

   — mackerel,

   — sprat,

   — (wild) Atlantic and Pacific salmon.

   (c) Marinated and/or salted herring where this process is insufficient to destroy nematode larvae.

2. Where epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites, a derogation from the above treatment may be granted by the Member States. Member States implementing this derogation must inform the Commission and the other Member States thereof.

3. When placed on the market, the fishery products referred to above must be accompanied by a document from the manufacturer stating the type of process they have undergone.

4. Before marketing, fish and fish products must be given a visual examination for the purpose of detecting endo-parasites that are visible. Fish or parts of fish which are obviously contaminated with parasites must be removed and not be used for human consumption.

V. **Cooked crustaceans and molluscs**

Crustaceans and molluscs must be cooked as follows:

(a) any cooking must be followed by rapid cooling. Water used for this purpose must be potable water within the meaning of Directive 98/83/EC or clean sea, river or lake water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached;

(b) shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected according to a schedule drawn up under the HACCP procedures;

(c) after shelling or shucking, cooked products must be frozen immediately, or kept chilled at a temperature which will preclude the growth of pathogens and be stored in appropriate rooms allowing maintenance of the temperatures required.

CHAPTER IV

## HEALTH STANDARDS FOR FISHERY PRODUCTS

### 1. Organoleptic properties of fishery products

Organoleptic examinations of fishery products must be carried out so as to ensure their hygienic quality. Where necessary, freshness criteria are to be issued by the Commission in accordance with the procedure referred to in Article 6, after obtaining the opinion of the Scientific Committee.

### 2. Histamine

The level of histamine in certain fishery products must be within the following limits in nine samples taken from a batch:

— the mean value must not exceed 100 ppm,

— two samples may have a value exceeding 100 ppm but not more than 200 ppm,

— no sample may have a value exceeding 200 ppm.

These limits apply only to fish species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae and Scombraesosidae. However, anchovy which has undergone enzyme maturation treatment in brine may have higher histamine levels but not more than twice the above values. Examinations must be carried out in accordance with reliable methods which are recognised scientifically, such as high performance liquid chromatography (HPLC).

### 3. Total Volatile Nitrogen (TVB-N)

Unprocessed fishery products shall be regarded as unfit for human consumption where, organoleptic assessment having raised doubts as to their freshness, chemical tests reveal that the limits with regard to TVB-N to be fixed in accordance with the procedure referred to in Article 6 have been exceeded.

### 4. Toxins harmful to human health

The placing on the market of the following products is prohibited:

— poisonous fish of the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae,

— fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins.

CHAPTER V

## WRAPPING AND PACKAGING OF FISHERY PRODUCTS

Containers in which fresh fishery products are kept under ice must be water-resistant and provide adequate drainage for melt water.

Frozen blocks prepared on board fisheries vessels must be adequately wrapped before landing.

CHAPTER VI

## STORAGE OF FISHERY PRODUCTS

1. Fresh or thawed fishery products, and cooked and chilled products from crustaceans and molluscs must be maintained at the temperature of melting ice.

2. Frozen fishery products must be kept at a temperature of - 18 °C or below in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of - 9 °C or less.

CHAPTER VII

## TRANSPORT OF FISHERY PRODUCTS

1. During transport, fishery products must be maintained at the required temperature. In particular:

   (a) fresh or thawed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at the temperature of melting ice;

(b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of - 18 °C or below in all parts of the product, with possibly short upward fluctuations of not more than 3 °C.

2. When frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, and where the journey is short, the competent authority may grant a derogation from the conditions laid down in point 1(b).

3. If ice is used to chill the products, adequate drainage must be provided in order to ensure that melting water does not remain in contact with the products.

4. Fishery products to be placed on the market live must be transported in such a way that the hygiene of the product is preserved.

CHAPTER VIII

**APPROVAL AND REGISTRATION OF ESTABLISHMENTS**

Factory vessels, freezer vessels and establishments on land shall be approved by the competent authority. However, establishments on land marketing their products on the local market only may be registered.

Wholesale markets where fishery products are not worked upon but are only displayed for sale and auction halls shall be registered.

SECTION IX

**Milk and milk products**

CHAPTER I

**RAW MILK — PRIMARY PRODUCTION**

I. **Health conditions for milk production**

1. Raw milk must come:

(a) from cows or buffaloes:

(i) belonging to a herd which, under points I and II of Annex A of Directive 64/432/EEC, is officially free of tuberculosis and free or officially free of brucellosis,

(ii) which do not show any symptoms of infectious diseases communicable to humans through milk,

(iii) in a good general state of health and presenting no obvious sign of disease,

(iv) which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder,

(v) which do not have any udder wound likely to affect the milk,

(vi) which have not been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk, unless the milking has complied with an official withdrawal period laid down in Community rules or, if absent, in national rules;

(b) from sheep or goats:

(i) belonging to a holding officially free or free of brucellosis (Brucella melitensis) within the meaning of Article 2(4) and (5) of Directive 91/68/EEC,

(ii) satisfying the requirements of point (a), except point (a)(i);

(c) from females of other species:

(i) belonging, for species susceptible to brucellosis or tuberculosis, to herds regularly checked for these diseases under a control plan approved by the competent authorities,

(ii) satisfying the requirements of point (a) except point (a)(i).

2. Raw milk:

   (a) from animals which do not show a positive reaction to tests for tuberculosis or brucellosis nor any symptoms of these diseases, but belong to a herd which does not meet the requirements of point 1(a)(i) must only be used after having undergone a heat treatment such as to show a negative reaction to the phosphatase test under the supervision of the competent authority;

   (b) from animals which do not show a positive reaction to tests for brucellosis nor any symptom of that disease, but belong to a herd which does not meet the requirements of point 1(b)(i) must be used:

      (i) only for the manufacture of cheese with a maturation period of at least two months, or

      (ii) after having undergone a heat treatment on the spot such as to show a negative reaction to the phosphatase test under the supervision of the competent authority;

   (c) from animals which do not show a positive reaction to tests for tuberculosis or brucellosis nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks required in point 1(c)(i) must be treated to ensure its safety under the supervision of the competent authority;

   (d) from animals showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC cannot be used for human consumption.

3. If goats are kept together with cows, they must be inspected and tested for tuberculosis.

4. The isolation of animals which are infected, or suspected of being infected, with any of the diseases referred to in point 1 must be effective to avoid any adverse effect on the other animals' milk.

II. **Hygiene on milk-production holdings**

A. *Hygiene on milk-production holdings*

1. Movable milking equipment, and premises where milk is stored, handled or cooled must be so located and constructed as to limit the risk of contamination of milk.

2. Where appropriate, premises for the storage of milk must have suitable refrigeration equipment, be protected against vermin and have adequate separation from premises where animals are housed.

B. *Hygiene during milking, collection of raw milk and its transport*

1. Milking must be carried out hygienically, ensuring in particular that:

   — before milking is started, the teats, udder and if necessary adjacent parts are clean,

   — the milk is checked; abnormal milk must be withheld,

   — milk from animals showing clinical signs of udder disease is withheld,

   — animals which have been submitted to a treatment likely to transfer residues of medicinal products to the milk can be identified and their milk is withheld,

   — components in teat dips or sprays do not produce residues in the milk.

2. Immediately after milking, milk must be held in a clean place designed to avoid adverse effects on the milk. If the milk is not processed or collected within 2 hours of milking, it must be cooled to a temperature of 8 °C or lower in the case of daily collection, or 6 °C or lower if collection is not daily.

3. During transport to a dairy establishment, the cold chain must be maintained and at arrival in the dairy establishment the temperature of the milk must not exceed + 10 °C, unless the milk has been collected within 2 hours of milking.

4. For technological reasons concerning the manufacture of certain milk products, Member States may grant derogations from the temperatures laid down in subparagraphs 2 and 3 provided the end-product meets the standards provided for in this Regulation.

C. *Hygiene of premises, equipment and tools*

1. Equipment and instruments or their surfaces which are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and disinfect and be maintained in a sound condition. This will require the use of smooth, washable and non-toxic materials.

2. After use, utensils used for milking, mechanical milking equipment and containers which have been in contact with milk must be cleaned and disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once per day, the containers and tanks used for the transport of raw milk to a dairy establishment must be cleaned and disinfected before re-use.

D. *Staff hygiene*

1. Persons performing milking and/or handling raw milk must wear suitable clean clothes.

2. Persons performing milking must wash their hands immediately before milking and keep them as clean as possible throughout milking. For this purpose, suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

III. **Standards for raw milk**

Awaiting the establishment of standards in the context of a more specific legislation on the quality of milk and milk products, the following standards shall apply and their compliance checked on a representative number of samples taken by random sampling:

Plate count and somatic cell count.

Raw cows' milk must meet the following standards:

| | |
|---|---|
| Plate count 30 °C (per ml) | ≤ 100 000 (1) |
| Somatic cell count (per ml) | ≤ 400 000 (2) |

(1) Rolling geometric average over a two-month period, with at least one sample per month.

(2) Rolling geometric average over a three-month period, with at least one sample per month. Where production levels vary considerably according to season, a Member State may be authorised by the Commission in accordance with the procedure referred to in Article 6 to apply another method of calculating the results for a low lactation period.

Other scientifically validated methods may be used.

For the manufacture of cheese with a period of ageing or ripening of at least 60 days, Member States may grant individual or general derogations.

When the standards to be met by raw milk are exceeded, measures must be taken to correct the situation. When these standards are repeatedly or excessively exceeded, the competent authority must be informed and it shall ensure that appropriate measures are taken.

IV. **Microbiological criteria for raw milk**

Member States shall ensure that raw milk intended for direct consumption or for the manufacture of products whose manufacturing process does not include any treatment capable of eliminating pathogenic micro-organisms, is tested in order to ensure the microbiological safety of the products.

## CHAPTER II

## MILK PRODUCTS

I. **Conditions for establishments**

Where necessary, special conditions may be granted by the competent authority in particular in order to take account of traditional production methods.

II. **Requirements for heat-treated drinking milk**

1. Upon acceptance at a dairy establishment, milk must be cooled to and/or maintained at a temperature not higher than + 6 °C until heat-treated, unless treated within 4 hours of acceptance.

2. Awaiting the establishment of standards in the context of a more specific legislation on the quality of milk and milk products, the following standards shall apply:

   (a) Pasteurised milk must:

   — have been prepared by a treatment involving a high temperature for a short time (at least 71,7 °C for fifteen seconds) or by a pasteurisation process using different time and temperature combinations to obtain an equivalent effect,

— show a negative reaction to the phosphatase test,

— be cooled immediately after pasteurisation to a temperature not exceeding 6 °C as soon as possible,

— be prepared from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned; or from thermised milk as referred to under III(2)(a) which, prior to heat treatment, has a plate count at 30 °C below 100 000 per ml, where cows' milk is concerned.

(b) Ultra high temperature (UHT) milk must:

— be prepared by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (at least 135 °C for at least one second or a process using different time and temperature combinations to obtain an equivalent effect) — the aim being to destroy all residual spoilage micro-organisms and their spores — and be wrapped using aseptic wrapping in opaque containers or containers made opaque by their packaging, of a type such that chemical, physical and sensoric changes are reduced to a minimum,

— be preserved such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of 30 °C; where necessary, provision can also be made for a period of 7 days in a closed container at a temperature of 55 °C,

— be prepared from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned, or from thermised or pasteurised milk which, prior to heat treatment, has a plate count at 30 °C below 100 000 per ml, where cows' milk is concerned.

— Where the UHT milk treatment is applied by direct contact between milk and steam, the steam must be obtained from potable water and must not leave deposits of foreign substances in the milk or affect it adversely.

(c) Sterilised milk must:

— be heated and sterilised in hermetically sealed containers, the seals of which must remain intact,

— be preserved such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of 30 °C; where necessary, provision can also be made for a period of 7 days in a closed container at a temperature of 55 °C,

— be prepared from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned, or from thermised or pasteurised milk which, prior to heat treatment, has a plate count at 30 °C below 100 000 per ml, where cows' milk is concerned.

III. **Requirements for other milk products**

1. Upon acceptance at a dairy establishment, milk must be cooled to and/or maintained at a temperature not higher than + 6 °C until processed. For the manufacture of milk products with raw milk, the operator or manager of the dairy establishment must take all necessary measures to ensure that raw milk is kept at a temperature below + 6 °C awaiting its processing, or is processed immediately after milking is finished. However, for technological reasons concerning the manufacture of certain milk products, the competent authority may authorise the above temperature to be exceeded.

2. Awaiting the establishment of standards in the context of a more specific legislation on the quality of milk and milk products, milk subject to a treatment involving heating and intended for the manufacture of milk products must satisfy the following conditions:

(a) Thermised milk must:

— be obtained from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned,

— be prepared from raw milk which has been heated for at least 15 seconds at a temperature between 57 °C and 68 °C such that after treatment the milk shows a positive reaction to the phosphatase test,

— if it is used for the production of pasteurised, UHT or sterilised milk intended for the manufacture of milk products, comply before treatment with the following standards: plate count at 30 °C below 100 000 per ml;

(b) Pasteurised milk must:

— be prepared by means of a treatment involving a high temperature for a short time (at least 71,7 °C for 15 seconds) or by a pasteurisation process using different time and temperature combinations to obtain an equivalent effect,

— show a negative reaction to the phosphatase test;

(c) UHT milk must be prepared by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (at least 135 °C for at least one second or by a process using different time/temperature combinations to obtain an equivalent effect) – the aim being to destroy all micro-organisms and their spores – be wrapped using aseptic wrapping in opaque containers or containers made opaque by their packaging, of a type such that chemical, physical and organoleptic changes are reduced to a minimum.

CHAPTER III

**WRAPPING AND PACKAGING**

Sealing must be carried out immediately after filling in the establishment where the last heat treatment of the drinking milk and/or liquid-milk products has taken place, by means of sealing devices which ensure the protection of milk against any harmful effects of external origin on its characteristics. The sealing system must be designed in such a way that after opening, the evidence of its opening remains clear and easy to check.

CHAPTER IV

**LABELLING**

Without prejudice to the provisions of Directive 79/112/EEC, labelling must clearly show for inspection purposes:

1. The words 'raw milk' for raw milk intended for direct human consumption.

2. In the case of heat-treated milk and heat-treated liquid milk products:

— the nature of the heat treatment to which the milk has been submitted, e.g. thermised, pasteurised, UHT or sterilised,

— any indication, whether coded or not, making it possible to identify the date of the last heat treatment,

— for pasteurised milk, the temperature at which the product must be stored.

3. In the case of milk products:

— the words 'made with raw milk' or 'made with thermised milk' on milk products manufactured from non-heat-treated milk or from thermised milk and where the manufacturing process does not include any heat treatment,

— on milk products heat-treated at the end of the manufacturing process, the nature of this treatment,

— on pasteurised liquid-milk products, the temperature at which the product must be stored.

CHAPTER V

**HEALTH MARKING**

By way of derogation from the health marking requirements laid down in the preface to the present Annex, the approval number in the health mark may be replaced by a reference to where the approval number of the establishment is shown.

CHAPTER VI

**APPROVAL AND REGISTRATION OF ESTABLISHMENTS**

Dairy establishments shall be approved by the competent authority in accordance with the preface to the present Annex.

Dairy establishments serving the local market may be registered.

SECTION X

## Eggs and egg products

CHAPTER I

### EGGS

1. At the producer's premises and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine. They must be stored and transported at a temperature which is best suited to assure optimal conservation of their hygiene properties.

2. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

3. In respect of salmonella, the following rules shall apply for eggs intended for Sweden and Finland:

   (a) consignments of eggs must originate from flocks which have been subjected to microbiological sampling defined in accordance with the procedure referred to in Article 6;

   (b) the test provided for in (a) is not required for consignments of eggs intended for the manufacture of egg products in an egg product establishment;

   (c) the guarantees provided in (a) are not required for eggs originating in an establishment subject to an operational programme recognised by the Commission in accordance with the procedure referred to in Article 6 as equivalent to that approved for Sweden and Finland. The operational programmes of the Member States may be amended and updated by the Commission in accordance with the same procedure.

CHAPTER II

### EGG PRODUCTS

I. **Conditions for establishments**

Establishments for the manufacture of egg products must have at least:

1. Suitable rooms with appropriate equipment for

   (a) washing and disinfecting dirty eggs, if necessary;

   (b) breaking eggs and collecting their contents and removing the parts of shells and membranes.

2. A separate room for operations other than those referred to in point 1.

Where egg products are pasteurised, this may be done in the room referred to in point 1(b), when the establishment has a closed pasteurisation system. All measures must be taken to prevent contamination of egg products after their pasteurisation.

II. **Raw materials for the manufacture of egg products**

Only non-incubated eggs fit for human consumption may be used in the manufacture of egg products; their shells must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of egg products provided they are delivered directly by the packaging centre or production farm to an approved establishment, where they must be broken as soon as possible.

Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained under the following conditions:

1. The conditions referred to under III points 1 to 4 must be observed.

2. Immediately after production, the products must have been either deep-frozen or chilled to a temperature of not more than 4 °C; in the latter case they must be treated at their place of destination within the 48 hours from the time of breaking of the eggs from which they were obtained, except in the case of ingredients to be de-sugared.

3. The nature of the goods must be indicated as follows: 'non-pasteurised egg products — to be treated at place of destination — date and hour of breaking —'.

III. **Special hygiene requirements for the manufacture of egg products**

All operations must be carried out in such a way as to avoid any contamination during production, handling and storage of egg products, and in particular:

1. Dirty eggs must be washed before breaking.

2. Eggs must be broken in the room provided for that purpose; cracked eggs must be processed without delay.

3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected when processing of hens', turkeys' and guinea fowls' eggs is resumed.

4. Egg contents may not be obtained by the centrifuging or crushing of eggs, nor may centrifuging be used to obtain the remains of egg whites from empty shells for human consumption.

5. After breaking, each particle of egg product must undergo a treatment as quickly as possible to eliminate micro-biological hazards or to reduce them to an acceptable level. A batch which has been insufficiently treated may immediately undergo treatment again in the same establishment, provided that this treatment renders it fit for human consumption; where a batch is found to be unfit for human consumption, it must be denatured.

   A treatment is not required for egg white intended for the manufacture of dried or crystallised albumin intended to undergo a later pasteurisation treatment.

6. If treatment is not carried out immediately after breaking, the egg contents must be stored either frozen or at a temperature not exceeding 4 °C; the storage period at 4 °C must not exceed 48 hours, except for stabilised products (e.g. with salt or sugar) and egg products to be de-sugared.

7. Products which have not been stabilised so as to be kept at room temperature must be cooled to a temperature not exceeding 4 °C; products for freezing must be frozen immediately after treatment.

### IV. **Analytical specifications**

1. The concentration of 3 OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product.

2. The lactic acid content must not exceed 1 000 mg/kg of egg product dry matter (applicable only to the untreated product).

   However, for fermented products, this value should be the one recorded before the fermentation process.

3. The quantity of eggshell remains, egg membranes and any other particles in the egg product must not exceed 100 mg/kg of egg product.

### V. **Labelling of egg products**

Every consignment of egg products leaving an establishment must carry, in addition to the general requirements for health marking, a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

### VI. **Approval and registration of establishments**

The premises of collectors and egg packaging centres shall be registered. Establishments manufacturing egg products shall be approved and given an approval number in accordance with the preface to this Annex

## SECTION XI

## **Frogs' legs**

1. Frogs may only be killed using humane slaughter techniques in an establishment approved for that purpose. Frogs which are found to be dead prior to slaughter must not be prepared for human consumption.

2. A special room must be reserved for the storage and washing of live frogs, and for their slaughter and bleeding. This room must be physically separate from the preparation room.

3. Immediately following preparation, the frogs' legs must be washed fully with running potable water within the meaning of Council Directive 98/83/EC, and immediately chilled to the temperature of melting ice or frozen to a temperature of at least - 18 °C or processed.

4. The frogs' legs must not contain, in their edible parts, contaminants such as heavy metals or organo-halogen substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly human intake.

## SECTION XII

### Snails

1. Snails may only be killed using humane methods in an establishment approved for that purpose. Snails that are found to be dead before being killed must not be used for human consumption.

2. The hepato-pancreas must be removed and must not be used for human consumption.

3. Snails must not contain, in their edible parts, contaminants such as heavy metals or organo-halogen substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly human intake.

## SECTION XIII

### Rendered animal fats and greaves

A. *Standards applicable to establishments collecting or processing raw materials*

1. Centres for collection of raw materials and further transport to processing establishments must be equipped with a cold store for the storage of raw materials at a temperature of 7 °C or below, unless the raw materials are collected and rendered within 12 hours after they were obtained.

2. The processing establishment must be approved and have at least:

   (a) a cold store, unless the raw materials are collected and rendered within 12 hours after they were obtained;

   (b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers;

   (c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.

B. *Hygiene for rendered animal fat, greaves and by-products*

1. Raw materials must come from animals which, following ante-mortem and post-mortem inspection, have been found fit for human consumption.

2. The raw materials must consist of adipose tissues or bones which are reasonably free from blood and impurities.

3. (a) For the preparation of rendered animal fat, only adipose tissues or bones collected at slaughterhouses, cutting premises or meat processing establishments may be used. Raw materials must be transported and stored until rendering in hygienic conditions and at an internal temperature of 7 °C or below;

   (b) by way of derogation from (a),

   — raw materials may be stored and transported unrefrigerated provided that they are rendered within 12 hours after they were obtained,

   — raw materials collected in retail shops or in premises adjacent to points of sale where the cutting and storage of meat is performed for the sole purpose of supplying the final consumer directly may be used for the preparation of rendered animal fat, provided they are in satisfactory hygiene condition and properly packaged. When the raw materials are not collected daily, they must be chilled immediately after collection.

4. Raw materials must be rendered by heat, pressure or other appropriate method, followed by separation of the fat by decantation, centrifuging, filtration or other appropriate method. The use of solvents is prohibited.

5. Rendered animal fat prepared in accordance with points 1, 2, 3 and 4 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality when the fat for refining meets the standards laid down in point 6.

6. Rendered animal fat, depending on type, must meet the following standards:

| | Ruminants | | | Pigs | | | Other animal fat | |
|---|---|---|---|---|---|---|---|---|
| | Edible tallow | | Tallow for refining | Edible pig fat | | Lard and other pig fat for refining | Edible | For refining |
| | Premier jus (1) | Other | | Lard (2) | Other | | | |
| FFA (m/m % oleic acid) maximum | 0,75 | 1,25 | 3,0 | 0,75 | 1,25 | 2,0 | 1,25 | 3,0 |
| Peroxide maximum | 4 meq/kg | 4 meq/kg | 6 meq/kg | 4 meq/kg | 4 meq/kg | 6 meq/kg | 4 meq/kg | 10 meq/kg |
| Total insoluble impurities | Maximum 0,15 % | | | Maximum 0,5 % | | | | |
| Odour, taste, colour | Normal | | | | | | | |

(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.

(2) Fresh fat obtained from rendering the adipose tissues of swine.

7. Greaves intended for human consumption must be stored:

(i) when rendered at a temperature of 70 °C or less: at a temperature of less than 7 °C for a period not exceeding 24 hours, or at - 18 °C or below;

(ii) when rendered at a temperature of more than 70 °C and having a moisture content of 10 % (m/m) or more:

— at a temperature of less than 7 °C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee,

— at - 18 °C or below;

(iii) when rendered at a temperature of more than 70 °C and having a moisture content of less than 10 % (m/m): no specific requirement.

## SECTION XIV

### Treated stomachs, bladders and intestines

1. In establishments treating stomachs, bladders and intestines it must be ensured that products which cannot be kept at ambient temperature are stored until their dispatch in rooms intended for that purpose. In particular, products which are not salted or dried must be kept at a temperature not exceeding 3 °C.

2. Animal intestines, bladders and stomachs may only be placed on the market if:

(a) the intestines, bladders or stomachs come from animals that have been slaughtered in a slaughterhouse under the supervision of the competent authority and have undergone ante- and post-mortem inspection;

(b) the intestines, bladders or stomachs come from establishments approved by the competent authority;

(c) the intestines, bladders or stomachs have been cleaned and scraped, then salted, heated or dried;

(d) after the treatment referred to in (c), effective measures have been taken to prevent re-contamination of the intestines, stomachs or bladders.

Animal intestines, bladders and stomachs may only be imported from third countries upon presentation of a certificate issued and signed by an official veterinarian attesting the above.

SECTION XV

## Gelatine

CHAPTER I

### REQUIREMENTS FOR RAW MATERIALS

1. For the production of gelatine intended for human consumption, the following raw materials may be used:

   — bones

   — hides and skins of farmed ruminant animals

   — pig skins

   — poultry skin

   — tendons and sinews

   — wild game hides and skins

   — fish skin and bones.

2. The use of bones obtained from ruminant animals born, reared or slaughtered in countries or regions classified as high BSE risk in accordance with Community legislation is prohibited.

3. The use of hides and skins submitted to tanning processes is prohibited.

4. Raw materials listed in the first five indents of paragraph 1 shall be derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection, or in the case of wild game hides and skins from wild game found fit for human consumption.

5. Raw materials must come from food premises approved or registered under the present Regulation.

   Collection centres and tanneries which intend to supply raw material for the production of gelatine intended for human consumption must be specifically authorised or registered for this purpose by the competent authorities and fulfil the following requirements:

   (a) they must have storage rooms with hard floors and smooth walls which are easy to clean and disinfect and where appropriate provided with refrigeration facilities;

   (b) the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;

   (c) if raw material not in conformity to this part is stored and/or processed in these premises, it must be segregated from raw material in conformity with this part throughout the period of receipt, storage, processing and dispatch.

6. Imports into the Community of raw materials for the production of gelatine for human consumption are subject to the following provisions:

   — Member States may authorise the importation of this raw material only from third countries which appear on a the list drawn-up for that purpose,

   — each consignment must be accompanied by a certificate that conforms to the model laid down in accordance with the procedure referred to in Article 6.

CHAPTER II

### TRANSPORT AND STORAGE OF RAW MATERIALS

1. During transportation, at the time of delivery to a collection centre, tannery and gelatine-processing establishment, raw materials must be accompanied by a document stating the origin of the raw materials.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure.

   However, degreased and dried bones or ossein, salted, dried and limed hides and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

CHAPTER III

**CONDITIONS TO BE COMPLIED WITH IN THE MANUFACTURE OF GELATINE**

1. Gelatine must be produced by a process which ensures that

   — all ruminant bone material which is derived from animals born, reared and slaughtered in countries or regions classified as low BSE risk in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days with a sterilisation step of 138-140 °C during four seconds or by an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee,

   — other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating once or several times in succession, followed by purification by means of filtration and sterilisation.

2. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

3. Provided the requirements for gelatine not intended for human consumption are exactly the same as for gelatine intended for human consumption, production and storage may be undertaken in the same establishment.

CHAPTER IV

**REQUIREMENTS FOR FINISHED PRODUCTS**

Limits for residues

| Elements | Limit |
|---|---|
| As | 1 ppm |
| Pb | 5 ppm |
| Cd | 0,5 ppm |
| Hg | 0,15 ppm |
| Cr | 10 ppm |
| Cu | 30 ppm |
| Zn | 50 ppm |
| Moisture (105 °C) | 15 % |
| Ash (550 °C) | 2 % |
| $SO_2$ (Reith Williams) | 50 ppm |
| $H_2O_2$ (European Pharmacopia 1986 ($V_2O_2$)) | 10 ppm |

*ANNEX III*

## IMPORTATION OF PRODUCTS OF ANIMAL ORIGIN FROM THIRD COUNTRIES

The provisions of this Annex shall apply without prejudice to the animal health requirements for the importation of products of animal origin laid down in Council Regulation . . ./. . . laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption.

I. **Provisions for drawing up lists of third countries from which imports of products of animal origin are permitted**

In order to ensure compliance with the general provisions referred to in Article 12 of Regulation . . . (on the hygiene of foodstuffs), the following shall apply.

In accordance with the procedure referred to in Article 6, the Commission must:

(a) Draw up lists of the third countries or parts of third countries from which imports of products of animal origin are permitted. These lists are to be drawn up after a Community inspection visit.

When drawing up these lists, particular account must be taken of:

(i) the legislation of the third country;

(ii) the organisation of the competent authority of the third country and of its inspection services, of the powers of these services and the supervision to which they are subject, as well as the authority that these services have to monitor effectively the application of their legislation;

(iii) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;

(iv) assurances which the third country can give regarding compliance or equivalence with the relevant health conditions;

(v) experience of marketing of the product from the third country and the results of import controls carried out;

(vi) the results of Community inspection and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities;

(vii) the state of health of the livestock, other domestic animals and wildlife in the third country and the general health situation in the country, which might endanger public health in the Community;

(viii) the regularity and rapidity of the information supplied by the third country relating to the presence of biological hazards, including the presence of marine biotoxins in fishing or aquaculture zones;

(ix) the existence, implementation and communication of a zoonoses control programme;

(x) the legislation of the third country on the use of substances and veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their marketing and the rules covering administration and inspection;

(xi) the existence, implementation and communication of a residue control programme;

(xii) the legislation of the third country on the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product.

(b) For each product or group of products, lay down special import conditions for each third country or group of third countries, having regard to the health situation of the third country or countries concerned.

The special import conditions shall include:

(i) identification of the competent authority responsible for official controls on the products concerned and for signing health certificates;

(ii) details of the health certification which must accompany consignments destined for the Community; these certificates must:

— be drawn up in at least one of the languages of the country of dispatch and of destination and one of those of the Member State in which the inspections at the border inspection post are carried out,

— accompany the products in their original version,

— consist of a single sheet of paper,

— be made out for a single consignee.

Certificates must be issued on the day on which the products are loaded with a view to dispatch to the country of destination;

(iii) affixing of a health mark identifying products of animal origin, in particular by identification of the third country of dispatch (the country's full name or its ISO abbreviation) and the approval number, name and address of the establishment of origin.

(c) Where considered appropriate, lay down general import conditions for a given product.

II. **Conditions for drawing up and up-dating lists of establishments, including factory vessels and freezer vessels**

An establishment, factory vessel or freezer vessel and with regard to live bivalve molluscs, production and harvesting areas, shall only dispatch products of animal origin to the Community when it figures on a list to be established and kept up-to-date in accordance with the following procedures:

1. Equivalence agreements

Drawing up and up-dating the lists of establishments must comply with the provisions of the relevant equivalence agreement.

2. By the Commission

In the case of a favourable outcome of the Commission controls referred to under I:

(a) Lists must be adopted by the Commission in accordance with the procedure referred to in Article 6 on the basis of a communication from the competent authorities of the third country to the Commission.

(i) An establishment may be placed on a list only if it is officially approved by the competent authority of the third country exporting to the Community. Such approval is subject to:

— compliance with Community requirements,

— supervision by an official inspection service in the third country.

(ii) A production or harvesting area for live bivalve molluscs must comply with the relevant legislation applicable within the Community.

(iii) The approval of factory vessels and freezer vessels must be carried out:

— by the competent authority of the third country of which the vessel is flying the flag,

— or by the competent authority of another third country, on condition that such third country figures on the Community list of third countries authorised to import fishery products into the Community and the fishery products are landed regularly on its territory and inspected by its competent authority, which must also apply health marks to the products and issue the health certificates,

— or by a Member State.

(b) Approved lists shall be amended as follows:

— the Commission shall inform the Member States of the modifications proposed by the third country concerned to the lists of establishments within five working days of the receipt of the proposed modifications,

— the Member States shall have seven working days, from receipt of the modifications to the lists of establishments referred to above to send any written comments to the Commission,

— where written comments are made by at least one Member State, the Commission shall inform the Member States within five working days and include the point at the next meeting of the Standing Veterinary Committee for decision in accordance with the procedure referred to in Article 6,

— where no comments are received from the Member States within the time limit referred to in the second indent, the modifications to the list shall be considered to have been accepted by the Member States. The Commission shall inform the Member States within five working days, and imports shall be authorised from such establishments five working days after receipt of this information by the Member States,

— the Commission shall shall publish the lists in the Official Journal of the European Communities.

3. EU authorisation to a third country to draw up and up-date lists of establishments.

Following a Commission on-the-spot inspection and/or audit for the criteria listed in point I, the competent authority of a third country may be granted the possibility to draw up and up-date lists, on the following conditions:

(a) An establishment may be placed on a list only if it is officially approved by the competent authority of the third country exporting to the Community. Such approval is subject to

— compliance with Community requirements,

— supervision by an official inspection service in the third country.

Each establishment must be given an approval number.

(b) The approval of factory vessels and freezer vessels is to be carried out by the competent authority of the third country of which the vessel is flying the flag.

(c) The approval of production and harvesting areas for live bivalve molluscs is subject to compliance with the rules applicable for that purpose within the Community.

(d) In the event of non-compliance with the Community requirements, the competent authority must have real powers

— to ensure correction of deficiencies within an appropriate time-limit and

— to ensure suspension of the activities for export to the Community or withdrawal of approved establishments, factory and freezer vessels, and production and harvesting areas of live bivalve molluscs under its responsibility, where it is not possible to correct deficiencies within an appropriate time-limit or where a risk to public health has been identified.

(e) An up-to-date list is to be transmitted by the competent authority in a third country to the Commission, which makes it available to any interested third party on a dedicated site on the Internet.

Only establishments appearing on this list may dispatch products of animal origin to the Community.

4. Case-by-case decisions

To deal with specific situations and in accordance with the procedure referred to in Article 6, imports may be authorised directly from an establishment of a third country where the latter is unable to provide the guarantees referred to under I. In this event, the establishment in question must receive special approval following a Commission inspection. The approval decision must fix the specific import conditions to be followed for products coming from that establishment.

III. **Other provisions**

1. Only products from a third country which

— are prepared in the third country of dispatch or, with regard to fishery products, on factory vessels or freezer vessels of the third country of dispatch,

— are obtained or prepared in another third country than the third country of dispatch, provided the product comes from an approved establishment in a third country appearing on a Community list,

— where appropriate, are prepared in the Community or manufactured therein,

may be imported into the Community.

2. If necessary, special conditions for the importation of products intended for specific purposes may be adopted by the Commission in accordance with the procedure referred to in Article 6.

# Proposal for a Regulation of the European Parliament and of the Council laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption

(2000/C 365 E/04)

**(Text with EEA relevance)**

*COM(2000) 438 final — 2000/0180(COD)*

*(Submitted by the Commission on 14 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Community legislation lays down the general rules for performing official controls of foodstuffs.

(2) In addition to the general rules, detailed rules must be laid down for official controls on products of animal origin in order to take account of specific animal and public health hazards that may be associated with such products.

(3) Such detailed rules for official controls on products of animal origin must include all aspects which may affect the safety of such products with regard to animal and public health, in particular requirements during the primary production and subsequent handling, manufacture, processing, storage and transport of animals and products, ante-mortem inspections of slaughter animals, animal welfare, post-mortem inspections of slaughtered animals, compliance with hygiene conditions in establishments, the treatment to be applied to products of animal origin in order to eliminate animal health risks and other measures to protect animal and public health.

(4) Official controls must cover those aspects which are most important for protecting animal and public health and be based on the most recent information available on problems which might constitute a hazard to human health.

(5) Official controls should be carried out with the aim of analysing and identifying potential risks to the health of those handling or consuming products of animal origin.

(6) The detailed rules for the organisation of official controls must be based on a proper risk analysis and on the opinion of the Scientific Committee. For that purpose, it is necessary to proceed to a risk assessment of the current ante- and post-mortem inspection procedures. Awaiting the results thereof, the present inspection procedures must remain in place.

(7) It must be ensured that the animal welfare rules are complied with, in particular with regard to humane slaughter of animals.

(8) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [1], as last amended by the Act of Accession of Austria, Finland and Sweden, provides that, in order to ensure the free movement of goods within the Community, official checks on products of animal origin must be carried out at the place of dispatch and that spot checks in the Member State of destination can be carried out at the place of destination. In the event of a serious presumption of irregularity, however, checks can be carried out while the goods are in transit.

(9) Community legislation on food safety must have a sound scientific basis. To that end, the scientific committees in the field of consumer protection and food safety set up by Commission Decision 97/579/EC [2] must be consulted wherever necessary.

(10) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

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[1] OJ L 395, 30.12.1989, p. 13.

[2] OJ L 237, 28.8.1997, p. 18.

[3] OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS REGULATION:

*Article 1*

This Regulation lays down the detailed rules for the organisation of official controls with regard to animal health and public health on products of animal origin intended for human consumption.

*Article 2*

For the purposes of this Regulation, the definitions laid down in

— Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market,

— Council Regulation . . ./. . . laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption,

— European Parliament and Council Regulation . . ./. . . on the hygiene of foodstuffs,

shall apply as appropriate.

*Article 3*

In addition to more general requirements on the official control of foodstuffs laid down in Community legislation, Member States shall ensure that products of animal origin are subject to official controls under this Regulation.

*Article 4*

In accordance with the procedure referred to in Article 5 and where necessary after having obtained the opinion of the appropriate Scientific Committee, the Commission shall:

(a) amend or supplement the Annexes to this Regulation in order to take account of scientific and technical progress, in particular with regard to the ante- and post-mortem inspection procedures for meat;

(b) adopt any implementing rules needed to ensure uniform implementation of this Regulation.

*Article 5*

1. The Commission shall be assisted by the Standing Veterinary Committee, instituted by Council Decision 68/361/EEC [1].

2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 3 months.

*Article 6*

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2004

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[1] OJ L 225, 18.10.1968, p. 23.

*ANNEX I*

**CONTROL REQUIREMENTS APPLICABLE TO ALL PRODUCTS**

1. Official controls shall be carried out on products of animal origin at all stages from primary production up to and including the marketing and in particular:

   (a) Controls on farms shall aim to verify compliance with hygiene rules and animal health rules. These controls shall be combined with controls concerning animal welfare, residues and feedstuffs required under Community legislation.

   Where hygiene, animal welfare or residue rules are not complied with, or diseases communicable to humans and animals are diagnosed, appropriate action shall be taken.

   In the case of slaughter animals, the official service responsible for carrying out ante- and post-mortem inspection at the slaughterhouse shall be informed about any problem occurring at the farm that may have an impact on food safety.

   (b) Controls on establishments, to verify or examine compliance with the specific hygiene rules laid down in Regulation . . . (laying down specific hygiene rules for food of animal origin) and in particular:

   — where appropriate, compliance with the approval conditions,

   — the correct use of the health marks or registration numbers,

   — the health status of the products,

   — compliance with temperature requirements and, where applicable, microbiological requirements.

   (c) Without prejudice to the requirements of Council Directive 89/662/EEC, controls during the marketing of products, to verify or examine in particular:

   — compliance with the rules on health marking,

   — compliance with maintaining of the cold chain,

   — where appropriate, the documents accompanying the consignment.

   (d) Any other control necessary to verify compliance with Community legislation.

2. During official controls,

   (a) the operators of establishments, the owner or his representative, as well as persons responsible for the products during marketing must facilitate the controls, ensure suitable conditions and make available any space and facilities needed to ensure a proper control;

   (b) the competent authority shall be given free access to establishments and any other infrastructures such as farms, vessels, means of transport, auction halls, etc.

*ANNEX II*

## MEAT INSPECTION

### CHAPTER I

### REQUIREMENTS APPLICABLE TO ALL MEAT

The official controls shall include ante-mortem and post-mortem inspections of food animals. Ante- and post-mortem inspections shall be carried out in accordance with the procedures described in this Annex pending an opinion of the appropriate Scientific Committee on their review.

#### I. **Responsibilities and frequency of controls**

1. Official controls shall be carried out under the supervision and responsibility of the official veterinarian. He may be assisted by auxiliaries placed under his authority and responsibility for carrying out the following activities:

   (a) where ante-mortem inspection on the holding is foreseen, collecting information needed by the official veterinarian to assess the health status of the herd or flock of origin and to make a diagnosis;

   (b) ante-mortem inspection in the slaughterhouse, provided that the official veterinarian is actually able to supervise the work of the auxiliaries directly on the spot. In this case the auxiliary's role is to make an initial check on the animals and to help with purely practical tasks;

   (c) post-mortem inspection, provided that the official veterinarian is actually able to supervise the work of the auxiliaries directly on the spot;

   (d) health control of cut and stored meat;

   (e) inspection and supervision of approved establishments, means of transport, etc.

2. In order to provide the assistance referred to above, the auxiliaries shall form part of an inspection team under the authority and responsibility of the official veterinarian and must be independent of the establishment being inspected. The competent authority of the Member State concerned shall determine the composition of the inspection team for each establishment in such a way that the official veterinarian is able to supervise the above operations.

3. The frequency of official controls shall be determined on the basis of an assessment of the health risks. Care shall be taken in particular to ensure that:

   (a) in slaughterhouses, at least one official veterinarian is present throughout both the ante-mortem and post-mortem inspection. Member States may request a derogation from this requirement to accommodate the needs of small and medium-sized slaughterhouses. For that purpose, they shall submit to the Commission a fully documented dossier to justify their request. This dossier shall contain information on the qualifications of the inspectors replacing the official veterinarian, the type of slaughterhouses where they will operate and the conditions under which they will perform inspections. The Commission shall examine the dossier and where appropriate approve the request in accordance with the procedure laid down in Article 5. This approval may include the conditions under which this derogation may be applied;

   (b) in cutting plants, a member of the inspection team is present at least once a day when meat is being worked on;

   (c) in approved cold stores and re-packaging centres, a member of the inspection team is regularly present.

4. Detailed rules governing the assistance referred to above shall be adopted if necessary, in accordance with the procedure referred to in Article 5.

#### II. **Ante-mortem health inspection**

1. Before slaughter, animals must undergo an ante-mortem inspection. Sufficient lighting must be available.

2. Where provided for in this Regulation, the ante-mortem inspection shall be carried out at the holding of provenance of the animals.

3. The inspection must determine, in particular, whether:

   (a) the animals are properly identified and do come from a holding or an area subject to a movement prohibition for reasons of animal health, unless permitted under Community law;

(b) the animals are suffering from a disease transmissible to humans or animals, show symptoms of such a disease or are in a general condition indicating that such a disease may occur;

(c) the animals show symptoms of a disease or a disorder affecting their general condition which may make their meat unfit for human consumption;

(d) animal welfare rules have been complied with;

(e) animals presented for slaughter are clean; if they are not clean, the official veterinarian shall give appropriate instructions to ensure that the animals are made clean or to prevent otherwise the meat being contaminated during the slaughter operations;

(f) the animals come from a holding or area subject to an animal or public health restriction;

(g) other conditions which might adversely affect human or animal health are present;

(h) rules on the use of veterinary medicinal products have been complied with.

4. Animals

— suffering from a notifiable animal disease or a disease transmissible to animals or humans,

— showing signs that they have had substances administered to them or have consumed substances which may make their meat harmful to human health,

may not be slaughtered for human consumption. Such animals must be killed separately and their meat hygienically disposed of.

5. The slaughter of animals suspected of suffering from a disease or showing signs of conditions which may adversely affect human or animal health, must be deferred. These animals must undergo, where necessary, detailed examination in order to make a diagnosis. Where post-mortem inspection is necessary in order to make a diagnosis the veterinarian may decide that the animals are to be slaughtered separately or after the normal slaughtering process. Those animals must undergo a post-mortem inspection supplemented, if necessary, by sampling and laboratory examinations.

6. The slaughter of animals under a specific scheme for the eradication or control of a specific disease such as brucellosis or tuberculosis or other zoonotic agents such as salmonellosis must be carried out under the conditions imposed by and the direct supervision of the official veterinarian.

III. **Post-mortem health inspection**

1. Slaughtered animals must be submitted without delay to a post-mortem health inspection in accordance with scientific rules. This inspection shall include, in particular:

(a) a visual inspection of the slaughtered animal and its organs with a view to detecting visible contamination or other defects;

(b) palpation and, where judged necessary by the official veterinarian, incision of those parts of the animal which have undergone any change or are suspect for any other reason;

(c) organoleptic examination;

(d) where necessary, laboratory tests, in particular to reveal the presence of agents of zoonotic diseases;

(e) any measure deemed necessary to check compliance with Community rules on the use of veterinary medicinal products and other chemical substances used during farming and on residues.

2. Where necessary in order to make a diagnosis or further investigations, the official veterinarian may request that the slaughter process be slowed down or halted.

3. Where the ante-mortem or post-mortem inspection reveals a condition likely to affect human or animal health the official veterinarian may ask for the requisite laboratory tests to be carried out if he considers them necessary to substantiate his diagnosis or to detect substances with pharmacological action likely to be present given the pathological condition observed.

Where any doubt remains, further cuts and inspections must be made until a definitive diagnosis can be reached.

4. Lymphnodes requiring incision must be systematically subjected to multiple incisions and a visual inspection.

5. During the inspection precautions must be taken to ensure that meat is not contaminated by actions such as palpation, cutting or incision.

IV. **Emergency slaughter**

The meat of animals that have undergone emergency slaughter must, in addition to the normal post-mortem inspection, undergo sampling for further examination or any other examination considered necessary.

V. **Decision following health inspections**

Following ante-mortem and post-mortem inspection, the following shall be declared unfit for human consumption:

(a) meat from

— animals affected by one of the diseases subject to animal-health restrictions, unless procedures have been introduced under the Community rules to eliminate any animal-health risk,

— cachectic animals,

— animals slaughtered too young;

(b) meat found to exhibit:

— cachexia,

— generalised infectious disease,

— septicaemia, pyaemia, toxaemia or viraemia,

— the presence of residues of prohibited substances or residues in excess of permitted Community levels,

— malignant or multiple tumours,

— multiple abscesses,

— serious injuries in different areas of the carcase or in different viscera,

— insufficient bleeding,

— extensive blood or serum infiltration,

— widespread subcutaneous or muscular parasitic infestation,

— ecchymosis,

— where appropriate, organoleptic anomalies,

— anomalies in consistency, particularly oedema or severe emaciation,

— widespread lesions, soiling or contamination;

(c) parts of a slaughtered animal which show localised lesions, contamination or inflammation not affecting the health of the rest of the meat;

(d) the blood of an animal whose meat has been declared unfit for human consumption in accordance with the preceding points, and blood contaminated by stomach contents or any other substance;

(e) carcases the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation;

(f) the carcases of animals suffering from any other condition which may constitute a public health danger according to the professional opinion of the official veterinarian.

The official veterinarian can give instruction that the meat can only be used for a particular purpose such as processing.

VI. **Communication of inspection results**

The official veterinarian shall record the results of the ante- and post-mortem inspections. If inspection reveals the presence of a disease or condition which might affect public or animal health, or of residues, this information shall be communicated to the competent authority responsible for supervising the holding of provenance of the animals, and to the person responsible for the animals concerned. Following such communication, immediate action must be taken to remedy the situation.

VII. **Professional qualifications of auxiliaries**

1. Only persons who have passed a test organised by the competent authority of the Member States may be appointed as auxiliaries.

2. Only candidates who prove that they have:

   (a) followed at least 400 hours of theoretical training, including laboratory demonstrations, and

   (b) received at least 200 hours of practical training

   shall be eligible for the above test. The practical training shall take place in slaughterhouses, cutting plants, cold stores and at inspection posts for meat or, in the case of ante-mortem inspection, on a holding.

3. The tests for auxiliaries shall consist of a theoretical part and a practical part and shall cover the following subjects:

   (a) for the inspection of holdings:

      (i) theoretical part:

         — familiarity with the farming industry – organisation, economic significance, production methods, international trade, etc.,

         — anatomy and pathology,

         — basic knowledge of diseases – viruses, bacteria, parasites, etc.,

         — monitoring for disease, use of medicines and vaccines, residue testing,

         — hygiene and health inspection,

         — animal welfare on the farm, during transport and at the slaughterhouse,

         — environmental requirements – in buildings, on farms and in general,

         — national and international rules,

         — consumer concerns and quality control;

      (ii) practical part:

         — visits to farms of different types and using different rearing methods,

         — visits to production establishments,

         — loading and unloading of means of transport,

         — visits to laboratories,

         — veterinary checks,

         — documentation,

         — practical experience;

   (b) for inspection at slaughterhouses:

      (i) theoretical part:

         — basic knowledge of the anatomy and physiology of slaughtered animals,

         — basic knowledge of the pathology of slaughtered animals,

         — basic knowledge of the pathological anatomy of slaughtered animals,

         — basic knowledge of hygiene, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work and the control of the HACCP system,

         — knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,

         — knowledge of the laws, regulations and administrative provisions relating to their work,

         — sampling procedures;

(ii) practical part:

— identification of animals,

— inspection and assessment of slaughtered animals,

— identification of animal species by examination of typical parts of the animal,

— identification of a number of parts of slaughtered animals in which changes have occurred, and comments thereon,

— post-mortem inspection in a slaughterhouse,

— hygiene control, including the control of the HACCP system,

— sampling,

— identification of meat.

VIII. **Other responsibilities during inspections**

Owners or persons responsible for the animals must cooperate with the officials carrying out ante- and post-mortem inspections. They must provide access to the animals, meat and relevant documentation, in a condition suitable for inspection. They must provide additional assistance at the request of the official veterinarian or auxiliary. Where they fail to cooperate as requested, the inspection shall be suspended until they consent to do so to the extent required for the inspection.

CHAPTER II

**MEAT OF DOMESTIC UNGULATES**

In addition to the common requirements, the following requirements shall apply:

I. **Ante-mortem health inspection**

Where the ante-mortem inspection is carried out at the slaughterhouse, the animals must undergo such inspection within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter. In addition, the official veterinarian may require inspection at any other time

II. **Post-mortem health inspection**

1. Post-mortem inspections shall include, where necessary:

— incision of certain organs and lymph nodes and, depending on the conclusions reached during the inspection, the uterus,

— a visual inspection or palpation. Where such inspection indicates that the animal has lesions which could contaminate the carcases, equipment, staff or premises, such organs may not be incised in the slaughter-room or any other part of the establishment where meat could be contaminated.

2. Inspections must proceed as follows:

A. *Bovine animals over six weeks old*

(a) visual inspection of the head and throat; incision and examination of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares and parotidei*); examination of the external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane. The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually inspected and palpated;

(b) inspection of the trachea; visual examination and palpation of the lungs and oesophagus; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) visual inspection of the diaphragm;

(e) visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;

(f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(g) visual inspection and, if necessary, palpation of the spleen;

(h) visual inspection of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and the peritoneum;

(j) visual inspection of the genital organs;

(k) visual inspection and, if necessary, palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*). In cows, each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

B. *Bovine animals under six weeks old*

(a) visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); inspection of the mouth and fauces; palpation of the tongue; removal of the tonsils;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) visual inspection of the diaphragm;

(e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*); palpation and, if necessary, incision of the liver and its lymph nodes;

(f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(g) visual inspection and, if necessary, palpation of the spleen;

(h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection and palpation of the umbilical region and the joints; in the event of doubt, the umbilical region must be incised and the joints opened. The synovial fluid must be examined.

C. *Swine*

(a) visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (*Lnn. mandibulares*); visual inspection of the mouth, fauces and tongue;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) visual inspection of the diaphragm;

(e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*); palpation of the liver and its lymph nodes;

(f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(g) visual inspection and, if necessary, palpation of the spleen;

(h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection of the genital organs;

(k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*); incision of the supramammary lymph nodes in sows;

(l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.

D. *Sheep and goats*

(a) visual inspection of the head after flaying and, in the event of doubt, examination of the throat, mouth, tongue and retropharyngeal and parotid lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*); in the event of doubt, these organs and lymph nodes must be incised and examined;

(c) visual inspection of the pericardium and heart; in the event of doubt, the heart must be incised and examined;

(d) visual inspection of the diaphragm;

(e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

(f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*);

(g) visual inspection and, if necessary, palpation of the spleen;

(h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection of the udder and its lymph nodes;

(k) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.

E. *Domestic solipeds*

(a) visual inspection of the head and, after freeing the tongue, the throat; palpation and, if necessary, incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares and parotidei*). The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined and palpated. The tonsils must be removed;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and, if necessary, incision of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

(c) visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) visual inspection of the diaphragm;

(e) visual inspection, palpation and, if necessary, incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);

(f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); incision, if necessary, of the gastric and mesenteric lymph nodes;

(g) visual inspection and, if necessary, palpation of the spleen;

(h) visual inspection and palpation of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection of the genital organs of stallions and mares;

(k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*) and, if necessary, incision of the supramammary lymph nodes;

(l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened;

(m) all grey or white horses must be inspected for melanosis and melanomata by examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder. The kidneys must be exposed and examined by incision through the entire kidney.

III. **Special controls**

A. *Trichinosis*

Meat from porcine animals (domestic, farmed game and wild game) and solipeds shall either be submitted to an examination to detect the possible presence of trichinae (*Trichinella spp*) or undergo a cold treatment.

B. *Cysticercosis in swine and cattle*

Examination for *Cysticercus bovis* and *Cysticercus cellulosae* shall include an examination of the parts of the animal likely to be infested.

After removal of parts unfit for human consumption, meat from animals with non-generalised infestation must undergo a cold treatment.

C. *Glanders in solipeds*

Examination for glanders in solipeds shall include a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

The following shall be established in accordance with the Standing Veterinary Committee procedure, and after the Scientific Committee has given its opinion:

(a) the methods to be applied when examining for the conditions referred to in this heading;

(b) the cold treatment to be applied to meat in the case of trichinosis and cysticercosis;

(c) the conditions under which derogations can be granted to the regions of the Community shown by epidemiological studies to be free of trichinosis or glanders.

IV. **Decision to declare meat unfit for human consumption following ante-mortem and post-mortem inspection**

1. In addition to the cases provided for in Chapter I(V), the following shall be declared unfit for human consumption:

(a) meat from animals:

(i) in which one of the following conditions has been diagnosed:

— generalised actinobacillosis or actinomycosis,

— blackleg and anthrax,

— generalised tuberculosis,

— generalised lymphadenitis,

— glanders,

— rabies,

— tetanus,

— acute salmonellosis,

— acute brucellosis,

— swine erysipelas,

— botulism;

(ii) showing acute lesions of broncho-pneumonia, pleurisy, peritonitis, metritis, mastitis, arthritis, pericarditis, enteritis or meningo-encephalomyelitis confirmed by a detailed inspection, possibly supplemented by a bacteriological examination and an investigation for residues of substances with a pharmacological effect. However, when the results of these special examinations are favourable, the carcases shall be declared fit for human consumption after the parts unfit for human consumption have been removed;

(iii) affected by the following parasitic diseases: generalised sarcocystosis, generalised cysticerosis, trichinosis;

(iv) which are dead, stillborn or unborn;

(v) which have been slaughtered too young, and the meat of which is oedematous;

(vi) showing clinical signs of emaciation or advanced anaemia;

(vii) which have produced a positive or inconclusive reaction to tuberculin and in which the post-mortem inspection has revealed localised tuberculous lesions located in a number of organs or areas of the carcase. However, when a tuberculous lesion has been found in the lymph nodes of the same organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes shall be declared unfit for human consumption;

(viii) which have reacted positively or inconclusively to brucellosis confirmed by lesions indicating acute infection. Even where no such lesion has been found, the udder, genital tract and blood must nevertheless be declared unfit for human consumption;

(b) parts of carcases showing signs of major serous or haemorrhagic infiltrations, localised abscesses or localised contamination;

(c) offal and viscera with pathological lesions of infectious, parasitic or traumatic origin;

(d) where a carcase or offal is affected with caseous lymphadenitis or any other suppurative condition but that condition is not generalised or associated with emaciation:

(i) any organ and its associated lymph node, if the condition concerned exists on the surface or in the substance of that organ or lymph node;

(ii) in any cases where (i) does not apply, the lesion and such of the surrounding parts as appropriate having regard to the age and degree of activity of the lesion, on the understanding that an old, firmly encapsulated lesion may be regarded as inactive;

(e) meat resulting from trimming of the sticking point;

(f) the liver and kidneys of animals more than two years old from regions where plans implemented under Article 5 of Directive 96/23/EC have revealed the generalised presence of heavy metals in the environment;

(g) meat which gives off a pronounced sexual odour.

2. The following must bear a special mark and be processed:

(i) meat from male pigs used for breeding;

(ii) meat from uncastrated male pigs, cryptorchid and hermaphrodite pigs with a carcase weight of more than 80 kg, except where the establishment is able to guarantee that carcases giving off a pronounced boar taint may be detected, using a method recognised in accordance with the Standing Veterinary Committee procedure or, in the absence of such a method, one recognised by the competent authority concerned.

V. **Special conditions for low capacity slaughterhouses**

(a) Slaughterhouse situated in regions suffering from special geographical constraits or affected by supply difficulties and slaughterhouses supplying meat locally must notify the veterinary service of the time of slaughter and the number and provenance of the animals, so that the ante-mortem inspection can be carried out either on the farm or immediately prior to slaughter at the slaughterhouse;

(b) The official veterinarian or an auxiliary must carry out the post-mortem inspection of the meat. Where the meat has lesions or appears to have deteriorated, the post-mortem inspection must be carried out by the official veterinarian. The official veterinarian or the auxiliary under his responsibility must regularly verify compliance with the hygiene rules laid down in this Regulation.

CHAPTER III

**POULTRYMEAT**

In addition to the common requirements, the following requirements shall apply:

I. **Ante-mortem inspection**

1. Slaughter of a flock of poultry from a holding may be authorised only when:

   (a) either the birds intended for slaughter have been submitted to an ante-mortem inspection at the holding and are accompanied by the health certificate provided for in point V,

   (b) or, 24 to 72 hours before the arrival of the birds at the slaughterhouse, the official veterinarian is in possession of a document to be established by the competent authority containing:

   — relevant up-to-date information regarding the flock of provenance, in particular details taken from the holding's records covering the type of poultry slaughtered,

   — proof that the holding of origin is under the supervision of a veterinarian responsible for the health at the farm.

   This information must be assessed before deciding what measures are to be taken with respect to birds coming from the holding concerned, particularly the type of ante-mortem inspection required.

   Where the conditions laid down in (a) or (b) above are not met, it may be decided:

   — either to postpone slaughter until the holding of origin has been inspected with a view to obtaining the required information,

   — or to authorise slaughter after carrying out the tests provided for in (2)(b) below.

   Any costs incurred as a result of the application of this paragraph shall be charged to the farmer in accordance with rules to be adopted by the competent authority.

   However, in the case of farmers with an annual production of not more than 20 000 domestic fowl, 15 000 ducks, 10 000 turkeys, 10 000 geese, or an equivalent number of another species of poultry, the ante-mortem inspection may be carried out at the slaughterhouse. In that case, the farmer must provide a statement to the effect that his annual production does not exceed the said numbers.

2. The ante-mortem inspection on the farm of provenance shall comprise:

   (a) checking the farmer's records or documentation;

   (b) additional examination to determine whether the birds:

   (i) are suffering from a disease transmissible to humans or animals or are behaving, individually or collectively, in a manner indicating that such a disease may occur,

   (ii) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption;

   (c) regular sampling of water and feed to check compliance with withdrawal periods;

   (d) tests for zoonotic agents.

3. Where there is doubt as to the identity of a consignment of poultry and the birds are to undergo ante-mortem health inspection at the slaughterhouse, the official veterinarian must examine each crate where the birds show symptoms as referred to in point 2(b) of this Chapter.

4. Where the birds are not slaughtered within three days of the issue of the health certificate provided for in point 1(a):

   — where the birds have not left the holding of origin, a new health certificate must be issued,

   — where the birds are already at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided a new health certificate is issued, or the birds are re-examined.

5. In the case of clinically healthy poultry from a flock which must be slaughtered under a programme for the control of infectious disease or a zoonotic disease, the birds must be slaughtered at the end of the day or under conditions such that other poultry are not contaminated.

If the animals of such a flock show clinical symptoms of the following diseases:

(a) ornithosis,

(b) salmonellosis,

their slaughter for human consumption shall be prohibited.

Slaughter is authorised at the end of the normal slaughter process provided precautions are taken to keep to a minimum the risk of spreading bacteria and to clean and disinfect the facilities after slaughter. The meat of such birds must be handled in the same way as meat declared unfit for human consumption.

6. In slaughterhouses situated in regions suffering from special geographical constraints or affected by supply difficulties, or in those serving the local market, the following rules must be complied with.

(a) Slaughterhouses must notify the veterinary service of the time of slaughter and the number and origin of the birds.

(b) The official veterinarian or an auxiliary must be present at the time of slaughter. Where this is not possible the meat may not leave the establishment until the post-mortem inspection has been carried out. The official veterinarian or the auxiliary under his responsibility must regularly monitor compliance with the hygiene rules.

(c) The competent authority must monitor the distribution chain of meat from the establishment and ensure that products declared unfit for consumption are appropriately marked, used and disposed of.

II. **Post-mortem inspection**

1. As part of the post-mortem inspection, the official veterinarian must:

(a) inspect the viscera and body cavities of a representative number of birds from each batch of birds from the same origin;

(b) subject to a detailed inspection a random sample of birds the meat of which was declared unfit for human consumption following the post-mortem health inspection;

(c) carry out any further investigations deemed necessary where there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

2. In the case of partly-eviscerated birds the intestines of which are removed immediately (effilé), the viscera and the body cavities of a representative number of birds from each batch shall be inspected after evisceration. Where such inspection reveals anomalies in a number of birds, all the birds in the consignment shall be inspected in accordance with point 1.

3. In the case of deferred evisceration:

(a) the post-mortem health inspection referred to in point 1 shall take place at the latest fifteen days after slaughter, during which period the poultry must be stored at a temperature below 4 °C;

(b) not later than the end of this period, evisceration must take place at an establishment approved for that purpose. In such cases, the carcases must be accompanied by the health certificate under point VI;

(c) the poultry meat must not bear the health mark before the evisceration referred to in point (b) has been performed.

III. **Decision to declare meat unfit for human consumption following the post-mortem inspection**

In addition to the cases provided for in Chapter I(V), poultrymeat must be declared unfit for human consumption where the post-mortem inspection reveals any of the following:

— systematic mycosis and local lesions in organs suspected of having been caused by pathogenic agents transmissible to humans or their toxins,

— cachexia,

— extensive mechanical lesions, including those due to extensive scalding,

— ascites,

— extensive subcutaneous or muscular parasitic infestation and systematic parasitism.

IV. **Technical assistance**

The competent authority may permit the members of staff of the undertaking to carry out technical operations related to inspection under the direct supervision of the official veterinarian provided they have received special training from the official veterinarian. The general criteria for such training shall be laid down in accordance with the procedure referred to in Article 5.

V. **Specimen health certificate**

**HEALTH CERTIFICATE** [1]

**for poultry transported from the holding to the slaughterhouse**

Competent service: ..... No [2] .....

I. **Identification of birds**

Species: .....

Number of birds: .....

II. **Provenance of birds**

Address of holding of origin: .....

Identification of poultry house: .....

III. **Destination of birds**

The birds will be transported to the following slaughterhouse: .....

.....

by the following means of transport: .....

IV. **Declaration**

I, the undersigned declare that the birds described above were examined before slaughter at the above-mentioned holding at (time) ..... on (date) ..... and were found to be healthy.

Done at ....., on .....
(Place) (Date)

Stamp

.....
(Signature of veterinarian)

[1] This certificate is valid for 72 hours.
[2] Optional.

VI. **Specimen health certificate**

**HEALTH CERTIFICATE**

**for poultry intended for the production of foie gras, stunned, bled and plucked at the fattening holding and transported to a cutting plant equipped with a separate room for evisceration**

Competent service: ..... No [1] .....

I. **Identification of uneviscerated carcases**

Species: .....

Number: .....

II. **Provenance of uneviscerated carcases**

Address of fattening holding: .....

III. **Destination of uneviscerated carcases**

The uneviscerated carcases will be transported to the following cutting plant: .....

.....

IV. **Declaration**

I, the undersigned declare that the uneviscerated carcases described above are of birds which were examined before slaughter on the above-mentioned fattening holding at (time) ..... on ..... (date) and found to be healthy.

Done at ....., on .....
(Place) (Date)

Stamp

.....
(Signature of veterinarian)

[1] Optional.

CHAPTER IV

**MEAT FROM FARMED LAGOMORPHS**

As a general rule, the requirements applicable to poultrymeat shall apply *mutatis mutandis*. However, where the ante-mortem inspection is not carried out at the holding of origin, the animals must undergo such inspection within 24 hours of arrival at the slaughterhouse. Where more than 24 hours elapse between the ante-mortem inspection and slaughter, the animals must be re-inspected immediately before slaughter.

CHAPTER V

**FARMED GAME MEAT**

In addition to the common requirements, the following requirements shall apply:

I. **Ante-mortem health inspections**

1. Ante-mortem inspection must be carried out either at the slaughterhouse or at the holding of provenance before slaughter at the holding or transportation to the slaughterhouse. In the latter case, the ante-mortem inspection at the slaughterhouse may be restricted to detecting injuries sustained during transport. In addition, the identification of the animals must be checked.

Live animals inspected at the holding must be accompanied by a certificate drawn up in accordance with the specimen in point III stating that the animals were inspected at the holding and found healthy.

2. Where the ante-mortem inspection is not carried out at the holding of provenance, the animals must undergo such inspection within 24 hours of arrival at the slaughterhouse. The animals must be re-inspected immediately before slaughter where more than 24 hours elapse between the ante-mortem inspection and slaughter.

   Each animal or batch of animals sent for slaughter must be identified to enable the competent authority to determine its provenance.

II. **Post-mortem health inspection**

Meat from species susceptible to trichinosis must be examined for the presence of trichinae.

III. **Specimen health certificate**

**HEALTH CERTIFICATE**

**for live farmed game transported from the holding to the slaughterhouse**

Competent service: ..... No [1]: .....

I. **Identification**

Species of animal: .....

Number of animals: .....

Identification marking: .....

II. **Provenance of animals**

Address of holding of origin: .....

III. **Destination of animals**

These animals are being transported to the following slaughterhouse: .....

.....

by the following means of transport: .....

IV. **Declaration**

I, the undersigned hereby declare that the animals described above underwent an ante-mortem inspection at the above holding on ..... (date) at ..... (time) and were found to be healthy.

Done at ....., on .....
(Place) (Date)

Stamp

.....
(Signature of veterinarian)

[1] Optional.

CHAPTER VI

**WILD GAME MEAT**

In addition to the common requirements, the following requirements shall apply:

I. **Post-mortem health inspection**

1. Wild game must be inspected as soon as possible after admission to the game processing house.

2. During post-mortem inspection, the official veterinarian must carry out:

   (a) a visual examination of the carcase, its cavities and where appropriate organs with a view to:

   — detecting any abnormalities. For this purpose, the diagnosis may be based on any information provided by the hunter concerning the behaviour of the animal before killing,

   — checking that death was not caused by reasons other than hunting.

   If an assessment cannot be made on the basis of visual examination alone, a more extensive inspection must be carried out in a laboratory;

   (b) an investigation of organoleptic abnormalities;

   (c) palpation of organs, where necessary;

   (d) an analysis of residues including environmental contaminants by sampling, where there are serious grounds for suspecting the presence of residues or contaminants. Where a more extensive inspection is made on the basis of such suspicions, the veterinarian must wait until that inspection has been concluded before assessing all the game killed during a specific hunt, or those parts which are suspected of showing the same abnormalities;

   (e) examination for characteristics indicating that the meat presents a health risk, including:

   (i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter;

   (ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles;

   (iii) arthritis, orchitis, changes in the liver or the spleen, inflammation of the intestines or the umbilical region;

   (iv) the presence of foreign bodies in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured;

   (v) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs;

   (vi) significant abnormalities of colour, consistency or odour of muscle tissue or organs;

   (vii) aged open fractures;

   (viii) emaciation and/or general or localised oedema;

   (ix) recent pleural or peritoneal adhesions;

   (x) other obvious extensive changes, such as putrefaction.

3. Where the official veterinarian so requires, the spinal column and the head must be split lengthwise.

4. In the case of small wild game not eviscerated immediately after killing, the official veterinarian must carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to man or defects as referred to in point 2, the veterinarian must carry out more checks on the entire batch to determine whether it must be declared unfit for human consumption or whether each carcase must be inspected individually.

5. In the event of doubt, the official veterinarian may perform any further cuts and inspections of the relevant parts of the animals necessary to reach a final diagnosis.

6. In the case of wild boar or other species susceptible to trichinosis, several samples of meat from each animal must be analysed. Samples must be taken at least from the jaw and diaphragmatic muscles, the muscles of the lower front leg, the intercostal muscles and the tongue muscles. The samples must be analysed using methods approved in accordance with the procedure referred to in Article 5 and on the basis of an opinion from the Scientific Veterinary Committee.

II. **Decision to declare meat unfit for human consumption following inspection**

In addition to the cases provided for in Chapter I(V), the following wild game meat shall be declared unfit for human consumption:

— meat presenting lesions, except for recent lesions due to killing, and localised malformations or abnormalities, in so far as these render the meat unfit for human consumption or dangerous to human health,

— meat presenting characteristics as listed in point I(2)(e) of this Chapter during post-mortem inspection,

— meat in which trichinosis is detected,

— meat showing anomalies which may render it unfit for human consumption.

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*ANNEX III*

**LIVE BIVALVE MOLLUSCS**

1. The competent authority must fix the location and the boundaries of production areas for bivalve molluscs. The areas from which harvesting of bivalve molluscs is authorised must be classified by the competent authority in three categories according to the level of the faecal contamination as follows:

   (a) *Class A areas:* areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the requirements of point IV of this Section.

   (b) *Class B areas:* areas from which live bivalve molluscs may be collected, but only placed on the market for human consumption after treatment in a purification centre or after relaying.

   (c) *Class C areas:* areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period (at least two months).

2. In order to determine the faecal contamination level of an area, the competent authority must:

   — make an inventory of the sources of pollution from human or animal origin likely to be a source of contamination for the production area,

   — examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste water treatment, etc.,

   — determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area,

   — establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

3. The public-health control arrangements must include the periodic monitoring of live bivalve molluscs relaying and production areas in order to:

   (a) prevent any malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

   (b) check the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;

   (c) check for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;

   (d) check for the presence of chemical contaminants, maximum permitted levels of which shall be fixed in accordance with the procedure referred to in Article 5.

   For the purposes of (b), (c) and (d) above, sampling plans must be drawn up for carrying out such checks at regular intervals or on a case-by-case basis where harvesting periods are irregular.

4. Sampling plans for production and relaying areas must take particular account of:

   (a) likely variations in faecal contamination;

   (b) possible variations in the presence of plankton containing marine biotoxins. Sampling must be carried out as follows:

      (i) monitoring plankton: periodic sampling to detect changes in the composition of the plankton containing toxins and the geographical distribution thereof. Results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling, by increasing the number of sampling points and number of samples taken in growing and fishing waters, and

      (ii) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.

      Molluscs from the area concerned may not be placed on the market until further sampling has yielded satisfactory toxicity test results;

   (c) possible contamination of the molluscs.

      If sampling shows that placing live bivalve molluscs on the market may constitute a hazard to human health, the competent authority must close the production area from which the contaminated molluscs originated until the situation has been remedied.

5. The competent authority shall monitor production areas where the harvesting of bivalve molluscs is forbidden or subject to special conditions, to ensure that products harmful to human health are not placed on the market.

6. A control system must be set up comprising laboratory tests to verify compliance with the requirements for the end product, in particular to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

7. The competent authority must:

   (a) establish and keep up-to-date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Section.

      This list must be communicated to interested parties affected by this Section, such as producers, gatherers and operators of purification centres and dispatch centres;

   (b) immediately inform the interested parties affected by the present Section, and in particular the producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of the production area, or its closure, be it temporary or final.

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*ANNEX IV*

**FISHERY PRODUCTS**

In addition to the common control requirements, the following shall apply:

1. Official controls on fishery products shall be carried out at the time of landing or before first sale at an auction or wholesale market.

2. Official controls shall include:

   (a) Organoleptic surveillance testing.

      Random checks must be carried out to check compliance with the freshness criteria laid down in Community legislation. Where there is doubt as to the freshness of the products, the organoleptic examination must be repeated.

   (b) Chemical analysis.

      Where the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of TVB-N (Total Volatile Basic Nitrogen).

      The TVB-N levels shall be specified for each category of species in accordance with the procedure referred to in Article 5.

      Where the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, samples may be taken for verification purposes.

   (c) Surveillance testing for histamine to verify compliance with the permitted levels laid down in Community legislation.

(d) Surveillance testing for contaminants.

Monitoring arrangements shall be set up to control the levels in fishery products of contaminants such as heavy metals and organochlorinated substances present in the aquatic environment.

(e) Microbiological checks, where necessary.

(f) Surveillance testing to verify compliance with Community legislation on endo-parasites.

Where necessary, the following shall be established in accordance with the procedure referred to in Article 5, after an opinion has been given by the Scientific Committee:

— freshness criteria for the organoleptic evaluation of fishery products, in particular where such criteria have not been established under existing Community legislation,

— the analytical limits, methods of analysis and sampling plans to be used for performing the official checks referred to above.

3. The following shall be declared unfit for human consumption:

(a) fishery products which the organoleptic, chemical, physical or microbiological checks show they are not fit for human consumption;

(b) fish or parts of fish which have not been properly examined to detect endo-parasites in accordance with Community legislation;

(c) fishery products which contain in their edible parts contaminants present in the aquatic environment, such as heavy metals and organochlorinated substances, at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

(d) poisonous fish and fishery products containing biotoxins;

(e) fishery products or parts thereof considered dangerous to human health.

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*ANNEX V*

**MILK AND MILK PRODUCTS**

In addition to the common control requirements, the following shall apply:

**Inspection of holdings**

Raw milk must come from holdings which are checked by the competent authorities of the Member State to verify compliance with the animal and public health conditions for milk production. The frequency of such checks must be proportionate to the risk. These inspections may be combined with checks carried out under other Community provisions.

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# Proposal for a Council Regulation laying down the animal-health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption

(2000/C 365 E/05)

**(Text with EEA relevance)**

*COM(2000) 438 final — 2000/0181(CNS)*

*(Submitted by the Commission on 14 July 2000)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

(1) In the context of the common agricultural policy, specific animal health rules have been laid down to govern intra-Community trade in and imports from third countries of products of animal origin included in Annex I to the Treaty.

(2) These rules have ensured the removal of obstacles to trade in the products concerned, thereby contributing to the creation of the internal market whilst ensuring a high level of animal health protection.

(3) These specific rules are contained in the following Directives:

— Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat ([1]), as last amended by the Act of Accession of Austria, Finland and Sweden,

— Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products ([2]), as last amended by the Act of Accession of Austria, Finland and Sweden,

— Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products ([3]), as last amended by Directive 98/45/EC ([4]),

— Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat ([5]), as last amended by Directive 93/121/EC ([6]),

— Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat ([7]), as last amended by the Act of Accession of Austria, Finland and Sweden,

— Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat ([8]), as last amended by Directive 97/79/EC ([9]),

— Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products ([10]), as last amended by Directive 96/23/EC ([11]),

— Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC ([12]), as last amended by Directive 97/79/EC.

(4) The aim of these Directives is to prevent the spread of animal diseases resulting from the placing on the market of products of animal origin.

(5) These Directives contain common provisions such as those restricting the placing on the market of products coming from a holding or area infected by epizootic diseases and those requiring products from restricted areas to undergo treatment to destroy the disease agent.

([1]) OJ L 302, 31.12.1972, p. 24.
([2]) OJ L 47, 21.2.1980, p. 4.
([3]) OJ L 46, 19.2.1991, p. 1.
([4]) OJ L 189, 3.7.1998, p. 12.
([5]) OJ L 268, 24.9.1991, p. 35.
([6]) OJ L 340, 31.12.1993, p. 39.
([7]) OJ L 268, 24.9.1991, p. 41.
([8]) OJ L 268, 14.9.1992, p. 35.
([9]) OJ L 24, 30.1.1998, p. 31.
([10]) OJ L 268, 14.9.1992, p. 1.
([11]) OJ L 125, 23.5.1996, p. 10.
([12]) OJ L 62, 15.3.1993, p. 49.

(6) These common provisions can be harmonised, thereby removing possible inconsistencies introduced when the specific animal health rules were adopted. Such harmonisation will also ensure uniform implementation of the animal health rules throughout the Community and greater transparency in the structure of Community legislation.

(7) The veterinary checks on products of animal origin intended for trade must be carried out in accordance with Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC. Directive 89/662/EEC contains safeguard measures that may be implemented in case of a serious hazard to animal health.

(8) Products imported from third countries must not present an animal health hazard for Community livestock.

(9) To that end, procedures must be introduced to prevent the introduction of epizootic diseases. Such procedures include an evaluation of the animal health situation in the third countries concerned.

(10) Procedures must be introduced for establishing general or specific rules or criteria to be applied to imports of products of animal origin.

(11) Rules concerning the importation of meat of domestic ungulates and meat products prepared from or with such meat are already contained in Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries [2], as last amended by Directive 97/79/EC.

(12) The procedures applicable to the importation of meat and meat products can be used as a model for the importation of other products of animal origin.

(13) Veterinary checks on products of animal origin imported into the Community from third countries must be carried out in accordance with Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries [3]; Directive 97/78/EEC contains safeguard measures that may be implemented in case of a serious hazard to animal health.

(14) Account must be taken of the rules laid down by the 'Office International des Epizooties' (OIE) when adopting rules for international trade.

(15) Provision must be made for the organisation of Community audits and inspections in order to ensure the uniform application of the animal health provisions.

(16) The products covered by this Regulation are listed in Annex I of the Treaty.

(17) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [4], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAS ADOPTED THIS REGULATION:

*Article 1*

This Regulation lays down the animal-health rules governing the placing on the market of and imports from third countries of products of animal origin.

*Article 2*

For the purposes of this Regulation, the definitions laid down in the Directives referred to in Annex I and, where applicable, in Council Regulation . . ./. . . on the hygiene of foodstuffs, shall apply.

CHAPTER I

**ANIMAL HEALTH REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF COMMUNITY PRODUCTS**

*Article 3*

The marketing of products of animal origin must not result in the spreading of diseases transferable to animals. To that effect, the following rules shall be complied with:

1. Products of animal origin shall be obtained from animals which fulfil the animal health conditions laid down by the relevant Community legislation.

2. Products of animal origin shall be obtained from animals:

   (a) which come from a holding, territory or part of a territory or, in the case of aquaculture products, from a farm, zone or part of a zone, not subject to animal health restrictions applicable to the animals and products concerned, and in particular restrictions under the rules referred to in Annex I or other disease-control measures imposed by Community legislation,

[1] OJ L 395, 30.12.1989, p. 13.

[2] OJ L 302, 31.12.1972, p. 28.

[3] OJ L 24, 30.1.1998, p. 9.

[4] OJ L 184, 17.7.1999, p. 23.

(b) which were not slaughtered in an establishment in which animals infected, or suspected of being infected with one of the diseases covered by the rules referred to at (a) above, or carcases of such animals, were present at the time of slaughter.

3. Notwithstanding part 2 and subject to compliance with the disease-control measures referred to in Annex I:

(a) the marketing of products of animal origin coming from a territory or part of a territory subject to animal health restrictions but which are not coming from a holding which is infected or suspected of being infected shall be permitted provided, as the case may be, that:

— the products, before being submitted to the treatment referred to hereunder, are obtained, handled, transported and stored separately from or at different times than products fulfilling all the animal-health conditions,

— the products have undergone a treatment sufficient to eliminate the animal-health problem concerned,

— the treatment is applied at an establishment approved for that purpose by the Member State where the animal-health problem occurred,

— the products which must be submitted to a treatment are properly identified.

This paragraph shall be applied in accordance with Annexes II and III(1) and (2) hereto, or with detailed rules to be adopted in accordance with the procedure referred to in Article 11;

(b) the marketing of aquaculture products not complying with the conditions laid down in paragraph 2 shall be permitted subject to the conditions laid down in Annex III(3) hereto and where necessary in accordance with further conditions to be laid down in accordance with the procedure referred to in Article 11.

4. Derogations from paragraph 2 may be granted in specific situations, in accordance with the procedure referred to in Article 11. In such cases, particular account shall be taken of:

(a) any measure or test to be carried out on the animals;

(b) the specific characteristics of the disease in the species concerned.

Where such derogations are granted, any measures needed to ensure the protection of animal health in the Community shall be adopted in accordance with the same procedure.

5. Where:

— provisions adopted for animal health reasons under Article 9 of Directive 89/662/EEC require products of animal origin from a Member State to be accompanied by a health certificate, or

— products must be accompanied by a certificate on account of the animal health situation in a Member State or part of a Member State,

the specimen for such certificates must conform to the model established in accordance with the procedure referred to in Article 11. Certificates must be drawn up at least in the language of the certifying official and the language of the place of destination. The products must be accompanied by the original certificate, which must consist of a single sheet of paper and be made out for a single consignee.

*Article 4*

**Official controls**

Official controls shall be carried out by the competent authorities of the Member States to ensure compliance with this Regulation, its implementing rules and any safeguard measures applied to products of animal origin, pursuant hereto.

Detailed rules on these controls, their results and the decisions to be taken on the basis of those results shall be adopted in accordance with the procedure referred to in Article 11.

*Article 5*

**Follow-up of official controls and right of appeal**

Where infringements of the animal-health rules are found, action shall be taken to remedy the situation.

Where the legal or natural person or persons involved in the infraction fail to remedy the situation within the time fixed by the competent authority, or if a serious animal-health risk is found, restrictions shall be placed on the production and marketing of the products concerned. Such restrictions may entail a ban on the production and marketing of products of animal origin and the withdrawal and, if necessary, destruction of products already placed on the market.

Infringements of this Regulation, its implementing rules or any safeguard health measures applied to products of animal origin, as well as any failure to cooperate with the competent authority shall result in the imposition of the appropriate criminal and/or administrative penalties by the competent national authorities.

In taking corrective action or imposing criminal and/or administrative penalties, Member States shall take account of the findings of Community checks.

Rights of appeal against decisions taken by the competent authorities as provided for by the national legislation in force in the Member States shall not be affected by this Regulation.

*Article 6*

**Community audits and inspections**

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make audits and/or inspections at all stages in the production and marketing of products of animal origin as well as on the organisation and functioning of the competent authorities in the Member States, in order to ensure the uniform application of this Regulation, its implementing rules and any safeguard measures pursuant hereto. Commission experts may be accompanied by the competent authority of the Member State and any expert appointed by the Commission for the purpose of an audit and/or inspection.

2. The Commission shall communicate its general programme of audits and/or inspections to the Member States on a regular basis and shall inform them of the results.

3. The procedure for inspections and/or audits referred to in paragraph 1 may be determined or amended in accordance with the procedure referred to in Article 11.

4. To enable audits and/or inspections to be carried out efficiently, the Member State in whose territory an audit and/or inspection is undertaken shall give all necessary assistance and provide all documentation requested by the Commission experts for the purpose of the audit.

5. The Commission shall ensure that the experts referred to in paragraph 1 received adequate training in food hygiene and safety, auditing techniques and where relevant to their duties the principles of the hazard analysis and critical control points system, in order for them to undertake their duties competently,

6. Member States shall ensure that the experts referred to in paragraph 1 have access to all premises or parts of premises and information relevant to the execution of their duties under this Regulation.

If during a Commission audit or inspection a serious risk to animal health is identified, the Member State concerned shall immediately take all measures necessary to safeguard animal health. If such measures are not taken, or if they are considered to be insufficient, the Commission shall take the measures necessary to safeguard animal health and inform the Member States thereof.

CHAPTER II

**IMPORTS FROM THIRD COUNTRIES**

*Article 7*

**General provisions**

The provisions applicable to the importation of products of animal origin from third countries shall comply with or be equivalent to those applicable to the production and marketing of Community products.

*Article 8*

**Compliance with Community rules**

In order to ensure the respect of the general obligation laid down in Article 7, the following shall be established in accordance with the procedure referred to in Article 11:

1. Lists of the third countries or parts of third countries from which imports of specified products of animal origin are permitted.

   When establishing these lists, particular account shall be taken of:

   — the legislation of the third country,

   — the organisation of the competent authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation,

   — the actual animal health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community,

   — the assurances the third country can give regarding compliance with the relevant animal health conditions,

   — experience of marketing the product from the third country and the results of import checks carried out,

   — the results of Community inspections in the third country,

   — the health status of the livestock, other domestic animals and wildlife in the third country, having particular regard to exotic animal diseases and any aspects of the general health situation in the country, which might pose a risk to public or animal health in the Community,

   — the regularity and speed with which the third country supplies information about the existence of infectious or contagious animal diseases in its territory, in particular the diseases mentioned in Lists A and B of the International Office of Epizootic Diseases (OIE) or, in the case of diseases of aquaculture animals, the notifiable diseases as listed in the Aquatic Animal Health Code of the OIE,

— the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries.

The list drawn up under this paragraph may be combined with other lists drawn up for public health purposes.

2. Special import conditions for each third country or group of third countries, having regard to the health situation of the third country or countries concerned. Such conditions shall include details of the health certificate to accompany consignments bound for the Community. Such certificates must:

— be drawn up in the language or languages of the Member State of destination and those of the Member State in which the border inspection takes place; the Member State of inspection or destination may consent to the use of a Community language other than its own,

— accompany the products in the original,

— consist of a single sheet of paper,

— be made out for a single consignee.

The certificate must be issued on the day the products are loaded for dispatch to the country of destination and be signed by a representative of the competent authority. It may be combined with the certificate to be provided for under the public health rules.

3. Where necessary,

— the detailed rules for the application of this Article, and

— criteria for classifying third countries and parts thereof with regard to animal diseases.

*Article 9*

**Community inspections and audits**

1. Audits and/or inspections at all stages covered by this Regulation may be carried out by experts from the Commission in third countries in order to verify compliance or equivalence with Community animal health rules. Commission experts may be accompanied by any other expert appointed by the Commission for the purposes of the audit and/or inspection.

2. The audits and/or inspections in third countries referred to in paragraph 1 shall be carried out on behalf of the Commission and the latter shall meet the costs incurred.

3. The procedure for the audits and/or inspections in third countries referred to in paragraph 1 may be determined or amended in accordance with the procedure referred to in Article 11.

4. If during a Community audit and/or inspection a serious risk to animal health is identified, the Commission shall immediately take the measures necessary to safeguard animal health and shall immediately inform the Member States thereof.

5. The Commission shall ensure that its experts and other experts referred to in paragraph 1 have received adequate training in animal health and auditing techniques in order for them to undertake their duties competently.

CHAPTER III

**FINAL PROVISIONS**

*Article 10*

The Annexes hereto may be amended or supplemented in accordance with the procedure referred to in Article 11. This procedure shall in particular be followed to lay down the criteria for classifying third countries and parts thereof with regard to particular diseases.

*Article 11*

**Standing Veterinary Committee procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee, instituted by Council Decision 68/361/EEC [1].

2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 3 months.

*Article 12*

Member States shall notify the Commission of any provisions they adopt specifically to implement this Regulation and all the legal instruments used and measures taken for its implementation and enforcement.

*Article 13*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2004.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[1] OJ L 225, 18.10.1968, p. 23.

*ANNEX I*

## DISEASES OF CONCERN IN TRADE WITH PRODUCTS OF ANIMAL ORIGIN

### I. **Diseases for which control measures have been introduced under Community legislation**

| Disease | Directive |
|---|---|
| Classical swine fever | Council Directive 80/217/EEC introducing Community measures for the control of classical swine fever |
| Foot-and-mouth disease | Council Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease |
| Avian influenza | Council Directive 92/40/EEC introducing Community measures for the control of avian influenza |
| Newcastle disease | Council Directive 92/66/EEC introducing Community measures for the control of Newcastle disease |
| Rinderpest<br>Peste des petits ruminants<br>Swine vesicular disease | Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease |
| Infectious Salmon Anaemia (ISA)<br>Infectious haematopoietic necrosis (IHN)<br>Viral haemorrhagic septicaemia (VHS) | Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases |
| Molluscs diseases | Council Directive 95/70/EC introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs |

### II. **Measures relating to African swine fever**

Pending the adoption of specific control measures for African swine fever, Directive 80/217/EEC shall apply, *mutatis mutandis*, in the event of outbreaks of African swine fever. Notwithstanding that Directive, decisions to lift the restrictions applied under this point shall be taken in accordance with the procedure referred to in Article 11.

1. *Meat*

A Member State in whose territory African swine fever has been recorded shall impose an immediate ban on movements of fresh pigmeat from the part of its territory in which the outbreak occurred to the rest of the Community.

For the purpose of defining parts of the territory as referred to above, particular account shall be taken of:

— the methods used to combat the disease, in particular the elimination of pigs from holdings which are infected, contaminated or suspected of infection or contamination,

— the surface area of the parts of the territory concerned and their administrative and geographical boundaries,

— the incidence of the disease and its tendency to spread,

— the measures taken to prevent the disease from spreading,

— the measures taken to restrict and control the movement of pigs both inside and outside the part of the territory concerned.

2. *Meat products*

A Member State in whose territory African swine fever has been recorded shall impose an immediate ban on movements of meat products from the part of its territory in which the outbreak occurred to the rest of the Community. However, the derogation provided for in Article 3(3) shall apply to meat products that have undergone one of the treatments referred to in Annex III points 1(a) and (e).

*ANNEX II*

**Special identification mark for fresh meat coming from a territory or a part of a territory not fulfilling all relevant animal health requirements**

Fresh meat obtained from animals coming from a holding situated in an area under animal health restrictions for one of the diseases referred to in Annex I and to be submitted to a treatment to eliminate the animal health problem concerned must be identified as follows:

1. The health mark for fresh meat must be covered by a cross consisting of two straight lines crossing at right angles with the point of intersection in the centre of the stamp and the information thereon remaining legible.

2. The mark may also be made with a single stamp; the following information must appear on the mark in perfectly legible characters:

   — on the upper part, the name of the exporting country in capitals,

   — in the centre, the veterinary approval number of the slaughterhouse,

   — on the lower part, one of the following abbreviations: CE — EF — EK — EC — EY — EG,

   — two straight lines crossing the stamp, intersecting at right angles at the centre of the stamp in such a way that the information is not obscured,

   — information whereby the veterinarian who inspected the meat may be identified.

   The mark must be applied by or under the responsibility of the official veterinarian responsible for controlling the implementation of the animal health requirements.

*ANNEX III*

1. **Treatments in order to eliminate animal health risks from meat**

| Treatment (*) | Disease | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Foot-and-mouth disease | Classical swine fever | Swine vesicular disease | African swine fever | Rinderpest | Newcastle disease | Avian influenza | Peste des petits ruminants |
| (a) Heat treatment in a hermetically sealed container with a $F_0$ value of 3,00 or more | + | + | + | + | + | + | + | + |
| (b) Heat treatment at a minimum temperature of 70 °C, which must be reached throughout the meat | + | + | + | — | + | + | + | + |
| (c) Heat treatment at a minimum temperature of 80 °C which must be reached throughout the meat | + | + | + | + | + | + | + | + |
| (d) Heat treatment in a hermetically sealed container to at least 60 °C for a minimum of 4 hours, during which time the core temperature must be at least 70 °C for 30 minutes | + | + | + | + | + | + | + | + |
| (e) Natural fermentation and maturation of not less than 9 months for boneless meat, resulting in the following characteristics: aw value of not more than 0,93 or a pH value of not more than 6,0 | + | + | — | + | + | + | — | — |
| (f) As (e) above but meat may contain bone. All the necessary measures must be taken to avoid cross contamination | + | — | — | — | — | — | — | — |
| (g) Salami processing in accordance with criteria to be laid down in accordance with the Standing Veterinary Committee procedure, following opinion of the relevant Scientific Committee | + | + | — | + | + | — | — | — |
| (h) Ham and loins which have undergone natural fermentation and maturation, of at least 190 days for hams and 140 days for loins | — | — | — | + | — | — | — | — |
| (i) Heat treatment ensuring a core temperature of at least 65 °C is reached for the time necessary to achieve a pasteurisation value (pv) equal to or more than 40 | + | — | — | — | — | — | — | + |

'+': Effectiveness recognised.

(*) All the necessary measures must be taken to avoid cross contamination.

2. **Treatment to eliminate animal health risks from milk**

Milk of species susceptible to foot-and-mouth disease and milk products manufactured entirely or partly with such milk, may not come from a surveillance area as provided for by Directive 85/811/EEC unless the milk or milk product has undergone one of the following treatments, under the supervision of the competent authority:

(a) sterilisation to an $F_o$ value of 3 or above; or

(b) a single UHT treatment at 130 °C for 2-3 sec.;

(c) an initial heat treatment having a heating effect at least equivalent to that obtained by pasteurisation at a temperature of at least 72 °C for at least 15 seconds and sufficient to result in a negative reaction to the phosphatase test, followed by:

(i) a second heat treatment, resulting in a negative reaction to the peroxidase test, or

(ii) in the case of milk powder or a product containing milk powder, a second heat treatment having an effect at least equivalent to that obtained by the first heat treatment and sufficient to result in a negative reaction to the phosphatase test, followed by a drying procedure, or

(iii) an acidification procedure whereby the pH is reduced to below 6 and maintained at that level for at least one hour,

(iv) a second heat treatment having an effect at least equivalent to that obtained by the first heat treatment; both heat treatments shall be applied to milk with a pH above 7,0 (this treatment is not allowed for milk from a protection and surveillance zone);

(d) the initial heat treatment referred to under (c), applied to milk with a pH of less than 7,0 (this treatment is not allowed for milk from a protection and surveillance zone).

3. **Treatment to reduce animal health risks in aquaculture products**

(a) Aquaculture fish susceptible to infectious haematopoietic necrosis and viral haemorrhagic septicaemia originating in a zone not approved for those diseases may be introduced into an approved zone only if such fish are killed, headed and eviscerated prior to dispatch. This requirement shall be waived for fish from an approved farm in a non-approved zone.

(b) Live molluscs susceptible to bonamiosis and marteiliosis originating in a zone not approved for those diseases may be introduced into an approved zone only where they are either intended for direct human consumption or delivered to the canning industry. They shall not be relayed unless:

— they originate in an approved farm in a non-approved zone, or

— they are temporarily immersed in storage ponds or purification centres specially equipped and approved for that purpose by the competent authority, and having, in particular, a system for the treatment and disinfection of waste water.

Any detailed rules needed for the implementation of these requirements shall be adopted in accordance with the procedure referred to in Article 11.

# Proposal for a Directive of the European Parliament and of the Council repealing certain Directives on the hygiene of foodstuffs and the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC

(2000/C 365 E/06)

**(Text with EEA relevance)**

*COM(2000) 438 final — 2000/0182(COD)*

*(Submitted by the Commission on 14 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs [1] lays down the general requirements for ensuring the production of safe food.

(2) The animal and public health conditions for the production and the placing on the market of products of animal origin are laid down in a number of different Council Directives.

(3) These conditions concern, in particular, products such as fresh meat, poultrymeat, meat products, egg products, live bivalve molluscs, fishery products, rabbit and game meat, milk and milk products, minced meat as well as certain other products intended for human consumption.

(4) The rules contained in these Directives have been recast and adopted as:

— European Parliament and Council Regulation .../... on the hygiene of foodstuffs,

— European Parliament and Council Regulation .../... laying down specific hygiene rules for food of animal origin,

— European Parliament and Council Regulation .../... laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption,

— Council Regulation .../... laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption.

(5) The Directives concerned must therefore be repealed.

(6) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [2], as last amended by Directive 92/118/EEC [3], and Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products [4], as last amended by Directive 98/45/EC [5], must also be amended to take account of the recasting exercise,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

The following Directives are hereby repealed:

1. Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.

2. Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat [6], as last amended by Directive 95/23/EC [7].

3. Council Directive 71/118/EEC of 15 February 1971 on health problems affecting the production and placing on the market of fresh poultrymeat [8], as last amended by Directive 97/79/EC [9].

[1] OJ L 157, 19.7.1993, p. 1.

[2] OJ L 395, 30.12.1989, p. 13.

[3] OJ L 62, 15.3.1993, p. 49.

[4] OJ L 46, 19.2.1991, p. 1.

[5] OJ L 189, 3.7.1998, p. 12.

[6] OJ 121, 29.7.1964, p. 2012/64.

[7] OJ L 243, 11.10.1995, p. 7.

[8] OJ L 55, 8.3.1971, p. 23.

[9] OJ L 24, 30.1.1998, p. 31.

4. Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat ([1]), as last amended by the Act of Accession of Austria, Finland and Sweden.

5. Council Directive 77/96/EEC of 21 December 1976 on the examination for trichinae (*Trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine ([2]), as last amended by the Act of Accession of Austria, Finland and Sweden.

6. Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin ([3]), as last amended by Directive 97/76/EC ([4]).

7. Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products ([5]), as last amended by the Act of Accession of Austria, Finland and Norway.

8. Council Directive 89/362/EEC of 26 May 1989 on general conditions of hygiene in milk production holdings ([6]).

9. Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products ([7]), as last amended by Directive 96/23/EC ([8]).

10. Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs ([9]), as last amended by Directive 97/79/EC.

11. Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products ([10]), as last amended by Directive 97/79/EC.

12. Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat ([11]), as last amended by Directive 93/121/EC ([12]).

13. Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat ([13]), as last amended by the Act of Accession of Austria, Finland and Sweden.

14. Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat ([14]), as last amended by Directive 97/79/EC.

15. Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products ([15]), as last amended by Directive 96/23/EC.

16. Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC ([16]).

17. Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations ([17]).

*Article 2*

Annex II of Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A, Chapter I to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC ([18]), as last amended by Directive 97/79/EC ([19]), is hereby repealed.

*Article 3*

Notwithstanding Article 1:

1. Until temperature requirements for the storage and transport of products of animal origin and microbiological standards for these products have been established in accordance with the procedure laid down in Article 6 of European Parliament and Council Regulation . . ./. . . on the hygiene of foodstuffs, the requirements and standards laid down in the Directives referred to in Articles 1 and 2 or their implementing rules shall continue to apply.

([1]) OJ L 302, 31.12.1972, p. 24.
([2]) OJ L 26, 31.1.1977, p. 67.
([3]) OJ L 26, 31.1.1977, p. 85.
([4]) OJ L 10, 16.1.1998, p. 25.
([5]) OJ L 47, 21.2.1980, p. 4.
([6]) OJ L 156, 8.6.1989, p. 30.
([7]) OJ L 212, 22.7.1989, p. 87.
([8]) OJ L 125, 23.5.1996, p. 10.
([9]) OJ L 168, 24.9.1991, p. 1.
([10]) OJ L 268, 24.9.1991, p. 15.
([11]) OJ L 268, 24.9.1991, p. 35.
([12]) OJ L 340, 31.12.1993, p. 39.
([13]) OJ L 268, 24.9.1991, p. 41.
([14]) OJ L 268, 14.9.1992, p. 35.
([15]) OJ L 268, 14.9.1992, p. 1.
([16]) OJ L 187, 7.7.1992, p. 41.
([17]) OJ L 368, 31.12.1994, p. 10.
([18]) OJ L 62, 15.3.1993, p. 49.
([19]) OJ L 24, 30.1.1998, p. 31.

2. Implementing rules adopted on the basis of the Directives referred to in Articles 1 and 2 shall remain in force until they are replaced by rules having the same effect adopted on the basis of

   — European Parliament and Council Regulation . . ./. . . on the hygiene of foodstuffs,

   — European Parliament and Council Regulation . . ./. . . laying down specific hygiene rules for food of animal origin,

   — European Parliament and Council Regulation . . ./. . . laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption,

   — Council Regulation . . ./. . . laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption.

3. When the health mark prescribed in the Directives referred to in Article 1 is different from the one prescribed in European Parliament and Council Regulation . . ./. . . laying down specific hygiene rules for food of animal origin, Member States shall ensure that the former health mark is replaced by the latter at the latest five years after entry into force of the said Regulation.

*Article 4*

Annex A of Council Directive 89/662/EEC is replaced by the following:

'*ANNEX A*

CHAPTER I

— Council Regulation . . ./. . ., of. . . laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption,

— The products of animal origin as referred to in European Parliament and Council Regulation . . ./. . ., of . . ., on the hygiene of foodstuffs.

CHAPTER II

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(1) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (with the exception of pathogens).'

*Article 5*

In Directive 91/67/EEC, Article 9 is replaced by the following:

'*Article 9*

The placing on the market for human consumption in an approved zone of aquaculture products and molluscs originating in a non-approved zone shall be subject to the relevant requirements laid down in Council Regulation . . ./. . . (laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption).'

*Article 6*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2004 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 7*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 8*

This Directive is addressed to the Member States.

# Proposal for a Decision of the European Parliament and of the Council extending certain programmes of Community action in the field of public health adopted by Decisions No 645/96/EC, No 646/96/EC, No 647/96/EC, No 102/97/EC, No 1400/97/EC and No 1296/1999/EC and amending those Decisions

(2000/C 365 E/07)

**(Text with EEA relevance)**

*COM(2000) 448 final — 2000/0192(COD)*

*(Submitted by the Commission on 25 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) A number of programmes of Community action within the framework for action in the field of public health are to expire shortly.

(2) The following expire at the end of 2000:

— the programme of Community action on health promotion, information, education and training, adopted by Decision No 645/96/EC of the European Parliament and of the Council [1],

— the action plan to combat cancer, adopted by Decision No 646/96/EC of the European Parliament and of the Council [2].

— the programme of Community action on the prevention of AIDS and certain other communicable diseases, adopted by Decision No 647/96/EC of the European Parliament and of the Council [3],

— the programme of Community action on the prevention of drug dependence, adopted by Decision No 102/97/EC of the European Parliament and of the Council [4].

(3) The following expire at the end of 2001:

— the programme of Community action on health monitoring, adopted by Decision No 1400/97/EC of the European Parliament and of the Council [5],

— the programme of Community action on pollution-related diseases, adopted by Decision No 1296/1999/EC of the European Parliament and of the Council [6].

(4) The Council, in its Resolution of 8 June 1999 on the future Community action in the field of public health [7], stressed the need for continuity of Community action in the field of public health in the light of the perspective of expiry of existing programmes.

(5) The Commission, in its Communication of 15 April 1998 to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the development of public health policy in the European Community [8], indicated that existing public health programmes will be coming to an end from the end of year 2000 onwards and stressed that there is a need to ensure that there is no vacuum in Community policy in this important field. The subsequent debate on that communication resulted in a consensus among the Community Institutions in favour of developing a new health strategy with an overall public health programme of action in the field of public health.

(6) While a new strategy and proposals for a new, overall, public health programme are being considered, the present programmes in the public health area should be extended until the end of 2002 in order to avoid any interruption in the Community action concerned.

(7) The Agreement on the European Economic Area (EEA) provides for greater cooperation in the field of public health between the Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the EEA (EFTA/EEA countries), on the other. Provision should also be made to open the programmes in the field of

[1] OJ L 95, 16.4.1996, p. 1.
[2] OJ L 95, 16.4.1996, p. 9.
[3] OJ L 95, 16.4.1996, p. 16.
[4] OJ L 19, 22.1.1997, p. 25.
[5] OJ L 193, 22.7.1997, p. 1.
[6] OJ L 155, 22.6.1999, p. 7.
[7] OJ C 200, 15.7.1999, p. 1.
[8] COM(1998) 230 final.

public health to participation of the associated Central and Eastern European countries in accordance with the conditions established in the Europe Agreements, in their additional protocols and in the decisions of the respective Association Councils, of Cyprus, funded by additional appropriations in accordance with the procedures to be agreed with that country, as well as of Malta and Turkey, funded by additional appropriations, in accordance with the provisions of the Treaty.

(8) In extending the programmes, account should be taken of the Communication of 15 June 2000 from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, on the health strategy of the European Community ([1]), the Council Conclusions of 26 November 1998 on the future framework for Community action in the field of public health ([2]), the Council Resolution of 8 June 1999 on the future Community action in the field of public health, the European Parliament Resolution of 12 March 1999 ([3]), the opinion of the Economic and Social Committee of 9 September 1998 ([4]) and the opinion of the Committee of the Regions of 19 November 1998 ([5]). Account should also be taken of the interim report from the Commission of 14 October 1999 to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the implementation of the programmes of Community action on the prevention of cancer, AIDS and certain other communicable diseases, and drug dependence within the framework for action in the field of public health ([6]), and the interim report from the Commission of 22 March 2000 to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the implementation of the programme of Community action on health promotion, information, education and training ([7]).

(9) The present Decision lays down, for the period of extension of the action programmes, the financial framework constituting the prime reference, within the meaning of point 33 of the Interinstitutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure ([8]), for the budgetary authority during the annual budgetary procedure.

(10) Decisions No 645/96/EC, No 646/96/EC, No 647/96/EC, No 102/97/EC, No 1400/97/EC and No 1296/1999/EC should be amended to take account of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers of the Commission ([9]).

(11) The action programmes should be monitored and continuously evaluated in cooperation between the Commission and the Member States,

HAVE DECIDED AS FOLLOWS:

*Article 1*

**Extension**

1. The following shall be extended from 1 January 2001 until 31 December 2002:

(a) the programme of Community action on health promotion, information, education and training adopted by Decision No 645/96/EC,

(b) the plan of action to combat cancer adopted by Decision No 646/96/EC,

(c) the programme of action for the prevention of AIDS and certain other communicable diseases adopted by Decision No 647/96/EC,

(d) the programme of action for the prevention of drug dependence adopted by Decision No 102/97/EC.

2. The following shall be extended from 1 January 2002 until 31 December 2002:

(a) the programme of action on health monitoring adopted by Decision No 1400/97/EC,

(b) the programme of action on pollution-related diseases adopted by Decision No 1296/1999/EC.

*Article 2*

**Budget**

1. The total financial framework for the implementation of the programmes and plan referred to in Article 1 for the period 1 January 2001 to 31 December 2002 shall be EUR 79,1 million.

2. The financial framework for the implementation for the period 1 January 2001 to 31 December 2002 of the programme of action on health promotion, information, education and training shall be EUR 8,5 million, that of the plan of action on cancer shall be EUR 31,142 million, that of the programme of action on the prevention of drug dependence shall be EUR 11,434 million and that of the programme of action on the prevention of AIDS and certain other communicable diseases shall be EUR 22,324 million.

([1]) COM(2000) 285 final.
([2]) OJ C 390, 15.12.1998, p. 1.
([3]) OJ C 175, 21.6.1999, p. 135.
([4]) OJ C 407, 28.12.1998, p. 21.
([5]) OJ C 51, 22.2.1999, p. 53.
([6]) COM(1999) 463 final.
([7]) COM(2000) 165 final.
([8]) OJ C 172, 18.6.1999, p. 1.
([9]) OJ L 184, 17.7.1999, p. 23.

3. The financial framework for the implementation for the period 1 January 2002 to 31 December 2002 of the programme of action on health monitoring shall be EUR 4,4 million and that of the programme of action on pollution-related diseases shall be EUR 1,3 million.

4. Annual appropriations shall be authorised by the budgetary authority within the limits of the financial perspective.

*Article 3*

**Adaptation of the committee procedure**

1. Article 5 of Decisions No 645/96/EC, No 646/96/EC, No 647/96/EC, No 102/97/EC and No 1400/97/EC is amended as follows:

(a) Paragraph 1 is replaced by the following:

'1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.'

(b) In paragraph 2, the second and third subparagraphs are replaced by the following:

'The management procedure laid down in Article 4 of Decision 1999/468/EC shall apply for the adoption of the measures referred to in the first subparagraph of this paragraph, in compliance with Article 7 and Article 8 of Decision 1999/468/EC. The period provided for in Article 4(3) of Decision 1999/468/EC shall be two months.'

(c) Paragraph 3 is replaced by the following:

'3. In addition, the Commission may consult the Committee on any other matter concerning the implementation of this decision. In this case, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.'

2. Article 5 of Decision No 1296/1999/EC is amended as follows:

(a) Paragraph 1 is replaced by the following:

'1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.'

(b) In paragraph 2, the second, third and fourth subparagraphs are replaced by the following:

'The advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply for the adoption of the measures referred to in the first subparagraph of this paragraph, in compliance with Article 7 and Article 8 of Decision 1999/468/EC.'

*Article 4*

**Participation of the EFTA/EEA countries, the associated Central and Eastern European countries, Cyprus, Malta and Turkey**

The programmes referred to in Article 1 shall be open to the participation of:

(a) The EFTA/EEA countries in accordance with the conditions established in the EEA Agreement;

(b) The associated countries of Central and Eastern Europe, in accordance with the conditions laid down in the Europe Agreements, in their Additional Protocols and in the Decisions of the respective Association Councils;

(c) Cyprus, funded by additional appropriations in accordance with the procedures to be agreed with that country;

(d) Malta and Turkey, funded by additional appropriations in accordance with the provisions of the Treaty.

*Article 5*

**Monitoring and evaluation**

1. In the implementation of this Decision, the Commission in cooperation with the Member States shall take the necessary measures to ensure the monitoring and evaluation of the activities provided under the programmes and plan referred to in Article 1.

2. The Commission shall submit a report to the European Parliament and to the Council upon completion of the programmes and plan referred to in Article 1. It shall include in this report the results of the evaluation mentioned in the first paragraph of this Article. The report shall also be submitted to the Economic and Social Committee and to the Committee of the Regions.

*Article 6*

**Entry into force**

This Decision shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2001.

# Amended proposal for a Directive of the European Parliament and of the Council amending Directive 82/714/EEC of 4 October 1982 laying down technical requirements for inland waterway vessels [1]

(2000/C 365 E/08)

**(Text with EEA relevance)**

*COM(2000) 419 final — 97/0335(COD)*

*(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 19 July 2000)*

[1] OJ C 105, 6.4.1998, p. 1.

| INITIAL PROPOSAL | AMENDED PROPOSAL |
|---|---|
| THE COUNCIL OF THE EUROPEAN UNION, | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, |
| Having regard to the Treaty establishing the European Community, and in particular Article 75.1 thereof, | Having regard to the Treaty establishing the European Community, and in particular Article 71.1 thereof, |
| Having regard to the proposal from the Commission, | Unchanged |
| Having regard to the opinion of the Economic and Social Committee, | Having regard to the opinion of the Economic and Social Committee [1], |
| Acting in accordance with the procedure laid down in Article 189c of the Treaty, in cooperation with the European Parliament, | Acting in accordance with the procedure laid down in Article 251 of the Treaty, |
| | Whereas: |
| Whereas Council Directive 82/714/EEC of 4 October 1982 laying down technical requirements for inland waterway vessels [1] introduced harmonised conditions for issuing technical certificates for inland waterway vessels in all Member States, whereas in the interest of safety these conditions have to be adapted to technical progress also taking into account changes in the Community's waterway network. | (1) Council Directive 82/714/EEC of 4 October 1982 laying down technical requirements for inland waterway vessels [2] introduced harmonised conditions for issuing technical certificates for inland waterway vessels in all Member States, albeit excluding operations on the Rhine. Nevertheless, at the European level, various technical requirements for inland waterway vessels will remain in force. Up to now, the coexistence of various international and national regulations has obstructed efforts to ensure mutual recognition of national navigation certificates without the need for an additional inspection of foreign vessels. Furthermore, the standards contained in Directive 82/714/EEC no longer reflect, in part, current technological developments; whereas in the interest of safety these conditions have to be adapted to technical progress also taking into account changes in the Community's waterway network. |

[1] OJ L 301, 28.10.1982, p. 1.

[1] OJ C 157, 25.5.1998, p. 17.

[2] OJ L 301, 28.10.1982, p. 1.

| INITIAL PROPOSAL | AMENDED PROPOSAL |
| --- | --- |
| Whereas the conditions and technical requirements for issuing inland navigation certificates under Article 22 of the Revised Convention for Navigation on the Rhine have been revised as from 1 January 1995. For competition and safety reasons it is desirable to adopt the scope and content of such technical requirements for the whole of the Community's network. | (2) Essentially, the technical requirements set out in the annexes to Directive 82/714/EEC incorporate the provisions laid down in the Revised Convention for the Navigation of the Rhine, in the version approved in 1982 by the Central Commission for Navigation on the Rhine (CCNR). The conditions and technical requirements for issuing inland navigation certificates under Article 22 of the Revised Convention for Navigation on the Rhine have been revised as from 1 January 1995. They are recognised as reflecting current technological developments and have been in force since 1 January 1995. For competition and safety reasons it is desirable, specifically in the interests of promoting harmonisation on a European scale, to adopt the scope and content of such technical requirements for the whole of the Community's waterway network. Account should be taken in this regard of the changes that have occurred in the Community's inland waterway network. |
| Whereas it is appropriate that Community inland navigation certificates attesting the full compliance of vessels with the aforementioned revised technical requirements shall be valid on all Community waterways. | (3) It is appropriate that Community inland navigation certificates attesting the full compliance of vessels with the aforementioned revised technical requirements shall be valid on all Community waterways. |
| Whereas it is desirable to ensure a greater degree of harmonisation between the conditions for issuing supplementary Community certificates by Member States for operations in Zone 1 and 2 waterways (estuaries), as well as for operations on Zone 4 waterways. | (4) It is desirable to ensure a greater degree of harmonisation between the conditions for issuing supplementary Community certificates by Member States for operations in Zone 1 and 2 waterways (estuaries), as well as for operations on Zone 4 waterways. |
| | (5) In the interests of passenger transport safety, it is desirable that the scope of the Directive be extended to include passenger vessels designed to carry more than 12 passengers, along the lines of the Regulation on Inspection of Shipping on the Rhine. |
| Whereas it is appropriate to provide for a transitional regime for vessels in service not yet carrying a Community inland navigation certificate when subjected to a first technical inspection under the revised technical requirements established by this Directive. | (6) It is appropriate to provide for a transitional regime for vessels in service not yet carrying a Community inland navigation certificate when subjected to a first technical inspection under the revised technical requirements established by this Directive. |
| Whereas it is appropriate, within certain limits and according to the category of vessel concerned, to determine the period of validity of Community certificates in each specific case. | (7) It is appropriate, within certain limits and according to the category of vessel concerned, to determine the period of validity of Community certificates in each specific case. |
| Whereas it is necessary, in order to allow for a more rapid adaptation of the annexes to the Directive to technical progress, to introduce procedures foreseen for this purpose based on Council Decision 87/373/EEC. | (8) In accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1], measures for the implementation of this Directive should be adopted by use of the advisory procedure provided for in Article 3 of that Decision. |

[1] OJ L 184, 17.7.1999, p. 23.

| INITIAL PROPOSAL | AMENDED PROPOSAL |
|---|---|
| Whereas it is necessary that the measures provided for in Directive 76/135/EEC of 20 January 1976 on reciprocal recognition of navigability licenses for inland waterway vessels [1] remain in force for those vessels covered by it which are not covered by this Directive, | (9) It is necessary that the measures provided for in Directive 76/135/EEC of 20 January 1976 on reciprocal recognition of navigability licenses for inland waterway vessels [1] remain in force for those vessels covered by it which are not covered by this Directive, |
| HAS ADOPTED THIS DIRECTIVE: | HAVE ADOPTED THIS DIRECTIVE: |
| *Article 1* | Unchanged |
| Directive 82/714/EEC is hereby amended as follows: | |
| 1. The third indent of Article 1 is replaced by the following: | |
| '— Zone 4: the other Community waterways listed in Chapter III of Annex I.' | |
| 2. Article 2 is replaced by the following: | |
| '1. This Directive shall apply to: | |
| — vessels having a length of 20 metres or more; | |
| — vessels for which the product of L × B × T as defined in Annex II Article 1.01 is 100 $m^3$ or more; | |
| — tugs and pusher craft, including those with a length of less than 20 metres or those for which the product of L × B × T as defined in Annex II Article 1.01 is less than 100 $m^3$, provided that they have been built to tow or to push or to move alongside vessels as referred to in the first indent. | |
| 2. The following are excluded from this Directive: | |
| — vessels intended for passenger transport which carry no more than 12 people in addition to the crew, | |
| — ferries, | |
| — pleasure craft with a length of less than 24 metres, | |
| — service craft belonging to supervisory authorities and fire-service vessels, | |
| — naval vessels, | |

[1] OJ L 184, 17.7.1999, p. 23.

[1] OJ L 21, 29.1.1976, p. 10.

| INITIAL PROPOSAL | AMENDED PROPOSAL |
| --- | --- |
| — sea going vessels, including sea going tugs and pusher craft operating or based on tidal waters or temporarily on inland waterways, provided that they carry the following valid navigation or safety certificates: | |
| — a certificate proving conformity with the 1974 International Convention for the Safety of Life at Sea (SOLAS), as amended, or equivalent, | |
| — a certificate proving conformity with the 1966 International Convention on Load Lines, as amended, or equivalent, and an IOPP certificate proving conformity with the 1973 International Convention for the Prevention of Pollution from Ships (MARPOL), as amended, | |
| where | |
| — for passenger vessels not covered by all of these Conventions, a certificate issued in conformity with Council Directive 97/. . ./EC on safety rules and standards for passenger ships.' | — for passenger vessels not covered by all of these Conventions, a certificate issued in conformity with Council Directive 98/18/EC on safety rules and standards for passenger ships.' |
| 3. The first and second indents of Article 3 are replaced by the following: | Unchanged |
| '— a certificate issued pursuant to Article 22 of the Revised Convention for the Navigation of the Rhine or a Community inland-navigation certificate issued after 1 July 1998 pursuant to Article 8 attesting the full compliance of the vessel with the technical requirements of Annex II, when operating on a Zone R waterway, | |
| — a Community inland navigation certificate issued to vessels in accordance with the provisions of this Directive and the technical requirements of Annex II when operating on waterways of other zones.' | |
| 4. Article 5 is replaced by the following: | |
| '1. Each Member State may, subject to the requirements of the Revised Convention for the Navigation of the Rhine and subject to approval by the Commission acting in accordance with the procedure laid down in Article 19.3, adopt technical requirements additional to those in Annex II for vessels operating on Zone 1 and 2 waterways within its territory. | |

| INITIAL PROPOSAL | AMENDED PROPOSAL |
| --- | --- |
| Such additional requirements shall be restricted to the subjects listed in Annex Va and shall be drawn up in conformity with the provisions thereof. | |
| 2. Compliance with these additional requirements shall be specified in the Community certificate referred to in Article 3 or, where Article 4(2) applies, in the supplementary Community certificate. Such proof of compliance shall be recognised on Community waterways of the corresponding zone. | |
| 3. Each Member State may, subject to approval by the Commission acting in accordance with the procedure laid down in Article 19.3, allow a reduction of the technical requirements of Annex II for vessels operating exclusively on Zone 4 waterways within its territory. Such a reduction shall be restricted to the subjects listed in Annex Vb. Where the technical characteristics of a vessel correspond to these reduced technical requirements it shall be specified in the Community certificate or, where Article 4(2) applies, in the supplementary Community certificate, that its validity is restricted to the Zone 4 waterways concerned.' | |
| 5. The following is added to Article 8(2): | |
| 'In cases where the first such technical inspection is carried out after 1 July 1998, any failure to meet the requirements laid down in Annex II shall be specified in the Community certificate. Provided that the competent authorities consider that these shortcomings do not constitute a manifest danger, the vessels concerned may continue to operate until such time as those components or areas of the vessel which have been certified as not meeting the requirements are replaced or altered, whereafter these components or areas shall meet the requirements of Annex II. | |
| The replacement of existing parts with identical parts or parts of an equivalent technology and design during routine repairs and maintenance shall not be considered as a replacement within the meaning of this paragraph.' | |

| INITIAL PROPOSAL | AMENDED PROPOSAL |
|---|---|

6. The following is added to Article 8:

'4. The Community certificate shall be issued to vessels initially excluded from the scope of this Directive which become subject to it as a result of the modifications of Article 2, paragraphs 1 and 2 introduced by Directive 98/. . ./EC following a technical inspection which shall be carried out upon expiry of the vessel's current certificate, but in any case no later than 30 June 2008, to check that the vessel complies with the technical requirements laid down in Annex II. Any failure to meet these requirements shall be specified in the Community certificate. Provided that the competent authorities consider that these shortcomings do not constitute a manifest danger, these vessels may continue to operate until such time as those components or areas of the vessel which have been certified as not meeting the requirements are replaced or altered, whereafter these components or areas shall meet the requirements of Annex II.

The replacement of existing parts with identical parts or parts of an equivalent technology and design during routine repairs and maintenance shall not be considered as a replacement within the meaning of this paragraph.'

7. Article 11 is replaced by the following:

'1. In each individual instance, the period of validity of the Community certificate shall be determined by the authority responsible for issuing this certificate. However, this period shall not exceed five years for passenger vessels or 10 years for other vessels.

2. Each Member State may, in the cases specified in Articles 12 and 16 of this Directive and in Chapter 2.05 of Annex II, issue temporary Community certificates, the period of validity of which shall not exceed six months.'

8. The following is added to Article 13:

'However, for the renewal of Community certificates issued before 1 July 1998 the transitional provisions of Chapter 24 of Annex II shall apply.'

9. The first sentence of the second paragraph of Article 15 shall read as follows:

'Following this inspection, a new certificate stating the technical characteristics of the vessel shall be issued or the existing certificate amended accordingly.'

| INITIAL PROPOSAL | AMENDED PROPOSAL |
|---|---|
| 10. Article 19 is replaced by the following: | |
| '1. Any amendments which are necessary to adapt the annexes of the Directive to technical progress, to developments in this area arising out of the work of other international organisations, in particular that of the Central Commission for Navigation on the Rhine, to ensure that the two certificates referred to in Article 3, first indent are issued on the basis of technical requirements which guarantee an equivalent level of safety, or to take account of the cases referred to in Article 5, shall be adopted by the Commission in accordance with the procedure laid down in the present Article, paragraphs 2 and 3. | |
| 2. The Commission shall be assisted by the Committee established under Article 7 of Council Directive 91/672/EEC, hereinafter referred to as "the Committee". | 2. The Commission shall be assisted by the Committee established under Article 7 of Council Directive 91/672/EEC [1] composed of representatives of the Member States and chaired by the representative of the Commission. |
| 3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes. The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the action taken in connection with its opinion.' | 3. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.' |
| 11. Article 20 is replaced by the following: | Unchanged |
| 'For those vessels outside the scope of Article 2, paragraph 1, but falling within the scope of Article 1a. of Directive 76/135/EEC, the provisions of the latter shall apply.' | |
| 12. Annexes I, II and III shall be replaced by the new versions set out in the Annex attached to this Directive. Annexes Va, Vb and VI as set out in the Annex hereto are added to the Directive. | |

[1] OJ L 373, 31.12.1991.

| INITIAL PROPOSAL | AMENDED PROPOSAL |
| --- | --- |
| *Article 2* | |
| 1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive at the same time not later than 1 July 1998 and shall inform the Commission thereof. They shall apply such laws, regulations and administrative provisions from 1 July 1998. | 1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive at the same time not later than a year after the entry into force of the Directive and shall inform the Commission thereof. |
| 2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States. | Unchanged |
| 3. Member States shall lay down the system of penalties for breaching the national provisions adopted pursuant to this Directive and shall take all the measures necessary to ensure that these penalties are applied. The penalties thus provided for shall be effective, proportionate and dissuasive. | |
| 4. The Member States shall immediately notify to the Commission all provisions of domestic law which they adopt in the field governed by this Directive. The Commission shall inform the Member States thereof. | |
| *Article 3* | |
| This Directive is addressed to the Member States. | |

*ANNEX I*

**LIST OF COMMUNITY INLAND WATERWAYS DIVIDED GEOGRAPHICALLY INTO ZONES 1, 2, 3 AND 4**

CHAPTER I

**Zone 1**

*Federal Republic of Germany*

Ems: from a line linking the Delfzijl church tower and the Knock lighthouse towards the open sea as far as latitude 53° 30' N and longitude 6° 45' E (i.e. somewhat outside the trans-shipment zone for dry-cargo carriers in the Alte Ems, taking account of the Ems-Dollard cooperation treaty).

**Zone 2**

*Federal Republic of Germany*

Ems: from a line going from the entrance of the port towards Papenburg crossing the Ems, which links the Diemen pumping station (Diemer Schöpfwerk) and the opening of the dyke at Halte as far as a line linking the Delfzijl and Knock lighthouses, taking account of the Ems-Dollard cooperation treaty.

Jade: inside a line linking the Schillighörn upper light and Langwarden church tower.

Weser: from the Bremen railway bridge to a line linking the Langwarden and Kappel church towers with the Schwerburg secondary arm including the Kleine Weser, Rekumder-Loch, and Rechter Nebenarm secondary arms.

Elbe: from the lower limit of the port of Hamburg to a line linking the Döse beacon and the north-west point of the Hohe Ufer (Dieksand) with the Este, Lühe, Schwinge, Oste, Pinnau, Krückau and Stör tributaries (in each case from the barrage to the mouth) including the Nebenelbe.

Meldorfer Bucht: inside a line linking the north-west point of the Hohe Ufer (Dieksand) and the Büsum west pier head.

Flensburger Förde: inside a line linking the Kekenis lighthouse and Birknack.

Eckernförder Bucht: inside a line linking Bocknis-Eck to the north-west tip of the mainland at Dänisch Nienhof.

Kieler Förde: inside a line linking the Bülk lighthouse and the Laboe naval memorial.

Leda: from the entrance to the outer harbour of Leer sea lock to the mouth.

Hunte: from the port of Oldenburg and from 140 m downstream of the Amalienbrücke in Oldenburg to the mouth.

Lesum: from the Bremen-Burg railway bridge to the mouth.

Este: from the Buxtehude barrage gate to the Este barrage.

Lühe: from the mill 250 m upstream of the Marschdamm-Horneburg road bridge to the Lühe barrage.

Schwinge: from the footbridge downstream of the Güldenstern bastion at Stade to the Schwinge barrage.

Freiburger-Hafenpriel: from the Freiburg/Elbe sluices to the mouth.

Oste: from the Bremervorde mill dam to the Oste barrage.

Pinnau: from the Pinneburg railway bridge to the Pinnau barrage.

Krückau: from the Elmshorn watermill to the Kruckau barrage.

Stör: from Pegel Rensing to the Stör barrage.

Eider: from the Gieselau Canal to the Eider barrage.

Nord-Ostsee-Kanal (Kiel Canal): from a line linking the Brunsbüttel pierheads to a line linking the Kiel-Holtenau entry lights and the Schirnauer See, Bergstedter See, Audorfer See, Obereidersee with Enge, the Achterwehrer canal and the Flemhuder See.

Trave: from the railway bridge and the Holsten bridge (Stadttrave) in Lübeck to a line linking the two outer pierheads of Travemünde and the Pötenitzer Wick and the Dassower See.

Schlei: inside a line linking the Schleimünde pier heads.

Wismarbucht, Kirchsee.

Breitling, Salzhaff and Wismar harbour: seawards from the lines linking Hohen Wieschendorf Huk and the Timmendorf lights and the lights of Gollwitz on the isle of Poel and the southern tip of the Wustrow peninsula.

Unterwarnow and Breitling: seawards from the line linking the most northern points of the western, middle and eastern mole of Warnemünde.

Waters, encircled by the mainland and the Darß and Zingst peninsulas and the islands of Hiddensee and Rügen (including the Stralsund harbour):

towards the open sea as far as:

— latitude 54° 27' N between the Zingst peninsula and the island of Bock

— the line linking the northern tip of the island of Bock with the southern tip of the island of Hiddensee

— on the islands of Hiddensee and Rügen (Bug), the line linking the southeastern tip of Neubessin with the Buger Haken.

Greifswald Bodden and Greifswald harbour (with Ryck): towards the open sea as far as the line linking the eastern tip of Thiessower Haken (Süd perd) with the eastern tip of the island or Ruden and ending at the northern tip of the island of Usedom (latutitude 54° 10' 37 N and 13° 47' 51 E).

Waters encircled by the mainland and the island of Usedom (River Peene including the Wolgast harbour, backwaters, Stettin lagoon): towards the east as far as the German-Polish border line crossing the Stettin lagoon.

*French Republic*

Seine: downstream of the Jeanne-d'Arc bridge in Rouen.

Garonne and Gironde: downstream from the stone bridge at Bordeaux.

Rhône: downstream of the Trinquetaille bridge in Arles and beyond towards Marseille.

Dordogne: downstream from the stone bridge at Libourne.

Loire: downstream from the Haudaudine bridge of the Madeleine arm and downstream from the Pirmil bridge on the Pirmil arm.

*Kingdom of the Netherlands*

Dollard.

Eems.

Waddenzee: including the links with the North Sea.

IJsselmeer: including the Markermeer and IJmeer but excluding the Gouwzee.

Nieuwe Waterweg and the Scheur.

Caland Kanaal west from the Benelux harbour.

Hollands Diep.

Breeddiep, Beerkanaal and its connected harbours.

Haringvliet and Vuile Gat: including the waterways between Goeree-Overflakkee on the one hand and Voorne-Putten and Hoeksche Waard on the other.

Hellegat.

Volkerak.

Krammer.

Grevelingenmeer and Brouwerschavensche Gat: including all the waterways between Schouwen-Duiveland and Goeree-Overflakkee.

Keten, Mastgat, Zijpe, Krabbenkreek, Eastern Scheldt and Roompot: including the waterways between Walcheren, Noord-Beveland and Zuid-Beveland on the one hand and Schouwen-Duiveland and Tholen on the other hand, excluding the Scheldt-Rhine Canal.

Scheldt and Western Scheldt and its mouth on the sea: including the waterways between Zeeland Flanders, on the one hand, and Walcheren and Zuid-Beveland, on the other, excluding the Scheldt-Rhine Canal.

CHAPTER II

**Zone 3**

*Republic of Austria*

Danube: from the border with Germany to the border with Slovakia.

Inn: from the mouth to the Passau-Ingling Power Station.

Traun: from the mouth to km 1,80.

Enns: from the mouth to km 2,70.

March: to km 6,00.

*Kingdom of Belgium*

Maritime Scheldt (downstream of Antwerp open anchorage).

*Federal Republic of Germany*

Danube: from Kelheim (km 2414,72) to the German-Austrian border.

Rhine: from the German-Swiss border to the German-Netherlands border.

Elbe: from the mouth of the Elbe-Seiten-Canal to the lower limit of the port of Hamburg.

Müritz.

*French Republic*

Rhine.

*Kingdom of the Netherlands*

Rhine.

Sneekermeer, Koevordermeer, Heegermeer, Fluessen, Slotermeer, Tjeukemeer, Beulakkerwijde, Belterwijde, Ramsdiep, Ketelmeer, Zwartemeer, Veluwemeer, Eemmeer, Alkmaardermeer, Gouwzee, Buiten IJ, afgesloten IJ, Noordzeekanaal, port of IJmuiden, Rotterdam port area, Nieuwe Maas, Noord, Oude Maas, Beneden Merwede, Nieuwe Merwede, Dordische Kil, Boven Merwede, Waal, Bijlandsch Canal, Boven Rijn, Pannersdensch Canal, Geldersche IJssel, Neder Rijn, Lek, Amsterdam-Rhine-Canal, Veerse Meer, Schelde-Rhine-Canal as far as the mouth in the Volkerak, Amer, Bergsche Maas, the Meuse below Venlo, Gooimeer, Europort, Calandkanaal (east from the Benelux harbour), Hartelkanaal.

CHAPTER III

**Zone 4**

*Republic of Austria*

Thaya: up to Bernhardsthal.

March: above km 6,00.

*Kingdom of Belgium*

The entire Belgian network except the waterways in Zone 3.

*Federal Republic of Germany*

All Federal waterways except those in Zones 1, 2 and 3.

*French Republic*

The entire French network except the waterways in Zones 1, 2 and 3.

*Kingdom of the Netherlands*

All other rivers, canals and inland seas not listed in Zones 1, 2 and 3.

*Italian Republic*

River Po: from Piacenza to the mouth.

Milan-Cremona Canal, River Po: final stretch of 15 km to the Po.

River Mincio: from Mantua, Governolo to the Po.

Ferrara Waterway: from the Po (Pontelagoscuro), Ferrara to Porto Garibaldi.

Brondolo and Valle Canals: from the eastern Po to the Venice lagoon.

Fissero Canal-Tartaro-Canalbianco: from Adria to the eastern Po.

Venetian coastline: from the Venice lagoon to Grado.

*Grand Duchy of Luxembourg*

Moselle.

*ANNEX II*

**Minimum technical requirements applicable to vessels navigating on waterways in Zones 1, 2, 3 and 4**

**PART I**

CHAPTER 1

**GENERAL**

*Article 1.01*

**Definitions**

The following definitions are contained in this Directive:

**Types of craft**

1. 'craft': a vessel or item of floating equipment;

2. 'vessel': an inland waterway vessel or sea-going ship;

3. 'inland waterway vessel': a vessel intended solely or mainly for navigation on inland waterways;

4. 'sea-going ship': a vessel admitted and intended mainly for maritime or coastal navigation;

5. 'self-propelled craft': an ordinary self-propelled craft or a self-propelled tanker;

6. 'self-propelled tanker': a vessel intended for the carriage of goods in fixed tanks and built to navigate independently under its own motive power;

7. 'ordinary self-propelled vessel': a vessel, other than a powered tanker, intended for the carriage of goods and built to navigate independently under its own motive power;

8. 'canal barge': an inland waterway vessel not exceeding 38,5 m in length and 5,05 m in breadth;

9. 'tug': a vessel specially built to perform towing;

10. 'pusher': a vessel specially built to propel a pushed train of craft;

11. 'self-propelled craft': an ordinary self-propelled craft or a self-propelled tanker;

12. 'tank barge': a vessel intended for the carriage of goods in fixed tanks and built to be towed, either having no motive power of its own or having only sufficient motive power to perform restricted manoeuvres;

13. 'dumb barge': a vessel, other than a tank barge, intended for the carriage of goods and built to be towed, either having no motive power of its own or having only sufficient motive power to perform restricted manoeuvres;

14. 'lighter': a tank lighter, ordinary lighter or ship-borne lighter;

15. 'tank lighter': a vessel intended for the carriage of goods in fixed tanks, built or specially modified to be pushed, either having no motive power of its own or having only sufficient motive power to perform restricted manoeuvres when not part of a pushed train of craft;

16. 'ordinary lighter': a vessel, other than a tank lighter, intended for the carriage of goods and built or specially modified to be pushed, either having no motive power of its own or having only sufficient motive power to perform restricted manoeuvres when not part of a pushed train of craft;

17. 'ship-borne lighter': a pushed lighter built to be carried aboard sea-going ships and to navigate on inland waterways;

18. 'passenger vessel': a vessel built and fitted out to carry more than 12 passengers;

19. 'day-excursion vessel': a passenger vessel without overnight passenger cabins;

19a. 'passenger sailing vessel': a passenger vessel built and fitted out mainly with a view to propulsion under sail;

20. 'passenger-cabin vessel': a passenger vessel with overnight passenger cabins;

21. 'floating equipment': a floating installation carrying working gear such as cranes, dredgers, pile drivers or elevators;

22. 'worksite craft': an appropriate vessel, built and equipped for use at worksites, such as a reclamation dredger, hopper or pontoon barge, pontoon or block-layer;

23. 'recreational craft': a vessel other than a passenger vessel, intended for sport or pleasure;

24. 'floating establishment': any floating installation not normally intended to be moved, such as a swimming bath, dock, jetty or boathouse;

25. 'floating installation': a raft or other structure, object or assembly capable of navigation, not being a vessel or floating equipment or establishment;

**Assemblies of craft**

26. 'train of craft': a rigid or towed train of craft;

27. 'formation': the manner in which a train of craft is assembled;

28. 'rigid train': a pushed train or breasted-up formation;

29. 'pushed train': a rigid assembly of craft of which at least one is positioned in front of the craft providing the power for propelling the train, known as the 'pusher(s)'; a train composed of a pusher craft and a pushed craft coupled so as to permit guided articulation is also considered as rigid;

30. 'breasted-up formation': an assembly of craft coupled rigidly side by side, none of which is positioned in front of the craft propelling the assembly;

31. 'towed train': an assembly of one or more craft, floating establishments or floating installations towed by one or more self-propelled craft forming part of the train;

**Particular areas on board**

32. 'main engine room': space where the propulsion engines are installed;

33. 'engine room': space where combustion engines are installed;

34. 'boiler room': a space housing a fuel-operated installation designed to produce steam or a thermal fluid;

35. 'enclosed superstructure': a watertight, rigid, continuous structure with rigid walls joined to the deck in a permanent and watertight manner;

36. 'wheelhouse': the area which houses all the control and monitoring instruments necessary for manoeuvring the vessel;

37. 'accommodation': a space intended for the use of persons normally living on board, including galleys, storage space for provisions, toilets and washing facilities, laundry facilities, landings and gangways, but not the wheelhouse;

38. 'hold': part of the vessel, delimited fore and aft by bulkheads, opened or closed by means of hatch covers, intended for the carriage of goods, whether packaged or in bulk, or for housing tanks not forming part of the hull;

39. 'fixed tank': a tank joined to the vessel, the walls of the tank consisting either of the hull itself or of a casing separate from the hull;

40. 'working station': an area where members of the crew carry out their duties, including gangway, derrick and ship's boat;

41. 'passageway': an area intended for the normal movement of persons and goods;

**Marine engineering terms**

42. 'plane of maximum draught': the water plane corresponding to the maximum draught at which the craft is authorised to navigate;

43. 'safety clearance': the distance between the plane of maximum draught and the parallel plane passing through the lowest point above which the craft is no longer deemed to be watertight;

44. 'freeboard (F)': the distance between the plane of maximum draught and a parallel plane passing through the lowest point of the gunwale or, in the absence of a gunwale, the lowest point of the upper edge of the hull planking or plating;

45. 'margin line': an imaginary line drawn on the side plating not less than 10 cm below the bulkhead deck and not less than 10 cm below the lowest non-watertight point of the side plating. If there is no bulkhead deck, a line drawn not less than 10 cm below the lowest line up to which the outer plating is watertight shall be used;

46. 'water displacement' ($\nabla$): the immersed volume of the vessel in $m^3$;

47. 'displacement' (D): the total weight of the vessel, inclusive of cargo, in tonnes;

48. 'block coefficient (d)': the ratio between the water displacement and the product of length, breadth and draught T;

49. 'sheer plan above water (S)': sheer plan of the vessel above the waterline in $m^2$;

50. 'bulkhead deck': the deck to which the required watertight bulkheads are taken and from which the freeboard is measured;

51. 'bulkhead': a wall of a given height, usually vertical, partitioning the vessel and delimited by the bottom of the vessel, the plating or other bulkheads;

52. 'transverse bulkhead': a bulkhead extending from one side of the vessel to the other;

53. 'wall': a dividing surface, usually vertical;

54. 'partition wall': a non-watertight wall;

55. 'length' (L): the maximum length of the hull, excluding rudder and bowsprit;

56. 'length overall': the greatest length of the craft in metres, including all fixed installations such as parts of the steering system or power plant, mechanical or similar devices;

57. 'length' (LF): the length of the hull in metres, measured at maximum draught;

58. 'breadth' (B): the maximum breadth of the hull in metres, measured to the outer edge of the shell plating (excluding paddle wheels, rubbing strakes, etc.);

59. 'overall breadth': the maximum breadth of the craft in metres, including all fixed equipment such as paddle wheels, plinths, mechanical devices and the like;

60. 'breadth' (BF): breadth of the hull in metres, measured from the outside of the side plating at the maximum draught line;

61. 'side height (H)': the shortest vertical distance between the top of the keel and the lowest point of the deck on the side of the vessel;

62. 'draught (T)': the vertical distance between the lowest moulded point of the hull or the keel and the maximum draught line;

63. 'forward perpendicular': the vertical line at the forward point of the intersection of the hull with the maximum draught line;

64. 'clear width of gunwale': the distance between the vertical line passing through the most prominent part of the gunwale on the coaming side and the vertical line passing through the inside edge of the slip guard (guard rail, foot rail) on the outer side of the gunwale;

**Steering system**

65. 'steering system': all the equipment required for steering the vessel, such as to ensure the manoeuvrability laid down in Chapter 5 of this Regulation;

66. 'rudder': the rudder or rudders, with shaft, including the rudder quadrant and the components connecting with the steering apparatus;

67. 'steering apparatus': the part of the steering system which produces the movement of the rudder;

68. 'steering control': the steering-apparatus control, between the power source and the steering apparatus;

69. 'power source': the power supply to the steering control and the steering apparatus produced by an on-board network, batteries or an internal combustion engine;

70. 'drive unit': the component parts of and circuitry for the operation of a power-driven steering control;

71. 'steering apparatus control unit': the control for the steering apparatus, its drive unit and its power source;

72. 'manual drive': a system whereby manual operation of the hand wheel, moves the rudder by means of a mechanical or hydraulic transmission, without any additional power source;

73. 'manually-operated hydraulic drive': a manual control actuating a hydraulic transmission;

74. 'rate-of-turn regulator': equipment which automatically produces and maintains a given rate of turn of the vessel in accordance with preselected values;

75. 'wheelhouse arranged for steering on radar by one person': a wheelhouse arranged in such a way that, during navigation on radar, the vessel can be manoeuvred by one person;

**Properties of structural components and materials**

76. 'watertight': a structural component or device fitted out in such a manner as to prevent any ingress of water;

77. 'spray-proof and weathertight': a structural component or device so fitted that in normal conditions it allows only a negligible quantity of water to penetrate;

78. 'gastight': a structural component or device so fitted as to prevent the ingress of gas and vapours;

79. 'non-combustible': material which does not burn or give off inflammable vapours in a sufficient quantity to ignite when it reaches a temperature of approximately 750° C;

80. 'fire-resistant': material which does not readily catch fire, or the surface of which does not readily catch fire, and which impedes the spread of fire in an appropriate manner;

81. 'fire-retardant': a structural component or device which meets certain fire-resistance requirements;

**Other concepts**

82. The following are considered to be 'approved classification societies': Germanischer Lloyd, Bureau Veritas and Lloyd's Register of Shipping;

83a. 'Community certificate': a certificate which, in accordance with Article 3 of the Directive, is issued by the competent authorities of a Member State for vessels complying with the technical requirements laid down in this Annex;

83b. 'supplementary Community certificate': according to Article 4(2) of the Directive, all vessels require a supplementary Community certificate, in addition to the Rhine certificate, for Zones 1 and 2 and for Zones 3 and 4, if they wish to take advantage of the reduction in technical requirements on these waterways;

84. 'inspection bodies': competent authorities appointed by the Member States, which inspect vessels on the basis of the provisions in this Annex and issue the certificate(s).

*Article 1.02*

(left void)

*Article 1.03*

(left void)

*Article 1.04*

(left void)

*Article 1.05*

(left void)

*Article 1.06*

**Temporary requirements**

After invoking the procedure provided for in Article 19 of the Directive the competent authority may issue temporary requirements where this would seem essential, in order to enable tests to be carried out without disrupting the safety or orderly functioning of navigation. Those requirements shall be valid for a maximum period of three years.

*Article 1.07*

**Administrative instructions to the inspection bodies**

In order to make the implementation of this Directive easier and uniform administrative instructions to the inspection bodies may be adopted if the procedure provided for in Article 19 of the Directive is applied.

Those administrative instructions shall be brought to the attention of the inspection bodies by the competent authorities.

The inspection bodies shall follow those administrative instructions.

## PART II

CHAPTER 15

## SPECIAL PROVISIONS FOR PASSENGER VESSELS

*Article 15.01*

### General provisions

1. Articles 4.01 to 4.04 and 8.06, Section 7 are not applicable.

2. Vessels with no motive power of their own are not authorised to carry passengers.

3. In the case of vessels with a length $L_F$ of 25 m or more, buoyancy in the event of a leak shall be demonstrated in accordance with Article 15.02 for all possible loading situations.

4. On all decks, passenger spaces shall be situated aft of the collision bulkhead.

5. Spaces intended for the accommodation of on-board staff shall by analogy satisfy the requirements of Articles 15.07 and 15.09.

6. (a) Notwithstanding Article 3.02, Section 1(b), the minimum thickness $t_{mind}$ of bottom, bilge and side plating of passenger vessels shall be the greater of the values obtained as follows:

$$t_{1mind} = 0{,}006 \cdot a \cdot \sqrt{T}\ [mm]$$

$$t_{2mind} = f \cdot 0{,}55 \cdot \sqrt{L_F}\ [mm]$$

where

f = 1 + 0,0013 · (a − 500), where 'a' is 400 mm or more,

a = spacing between the longitudinal or transverse pairs in [mm] (when the spacing of the pairs is less than 400 mm, it will be assumed that a = 400 mm.

The greater value produced by the formulae shall be taken as the minimum thickness. Plates shall be replaced when the thickness of bottom or side plating no longer attains the minimum value determined according to the above requirement.

(b) Plate thickness may be less than the minimum value produced by the formulae where the permissible value has been determined and certified on the basis of calculated evidence of sufficient hull strength.

(c) However the minimum thickness shall not be less than 3 mm at any point on the hull.

*Article 15.01a*

### Passenger sailing vessels

The special provisions applicable to passenger vessels shall not apply in the case of passenger sailing vessels. For such vessels, other special provisions will be adopted, in accordance with the procedures of the committee provided for in Article 19 of the Directive, and will be incorporated in this Annex.

*Article 15.02*

### Basic requirements for subdivision of vessels

1. The distribution of bulkheads shall be such that, if any watertight compartment becomes flooded, the hull does not sink below the margin line and the requirements of Article 15.04, Section 7, are met.

2. Watertight glazing may be installed below the margin line on condition that it cannot be opened, is sufficiently strong and meets the requirements of Article 15.07, Section 7.

3. Structural specifications shall be taken into account in calculating stability in the event of a leak.

In general, calculations should be based on a permeability factor of 95 %.

If it is established by calculation that the average permeability of any compartment is less than 95 %, the calculated permeability may be used instead. In such calculations, the following minimum values shall, however, be observed:

| | |
|---|---|
| Passenger areas and areas set aside for the crew | 95 % |
| Engine rooms (including boiler rooms) | 85 % |
| Loading compartments, baggage and provisions rooms | 75 % |
| Double-bottomed areas, fuel bunkers and other compartments in so far as these spaces are to be regarded, in keeping with their intended purpose, as either full or empty, the vessel's waterline being the line corresponding to the deepest subdivision load line. | 0 or 95 %. |

4. Between the collision bulkhead and the stern bulkhead, only those compartments having a length of at least 0,10 $L_F$, but not less than four metres, shall be considered watertight compartments for the purposes of Section 1 above. The inspection body may allow minor exceptions to this rule.

   Where a watertight compartment is longer than required by the foregoing provisions and is subdivided so as to form watertight spaces which also meet the minimum length requirement, those spaces may be taken into account in calculating stability in the event of a leak.

   The length of the first compartment aft of the collision bulkhead may be less than 0,10 $L_F$ or four metres. In such cases, the fore peak and the adjacent compartment shall be taken as jointly floodable in the stability calculation. The distance between the forward perpendicular and the aft transverse bulkhead bounding this compartment may not, however, be less than 0,10 $L_F$ or four metres.

   The distance between the collision bulkhead and the forward perpendicular shall be at least 0,04 $L_F$ and not more than 0,04 $L_F$ + 2 m.

5. Where a passenger vessel has longitudinal watertight subdivisions, asymmetries between the collision bulkhead and the rear bulkhead shall be taken into account as follows:

   (a) provided that the longitudinal bulkheads are at least $B_F$ from the skin plating at the maximum loaded draft line and at least $B_F$, but not less than 1,50 m, from each other, the stability calculation shall allow for the individual flooding of compartments A, B and C and the simultaneous flooding of compartments A + B and B + C (see fig. 1);

   (b) if mid-compartment B has a watertight deck more than 0,50 m from the bottom of the vessel it is not necessary to allow for flooding of compartment D situated above that deck (see fig. 2). The conditions set out above regarding longitudinal bulkheads shall apply.

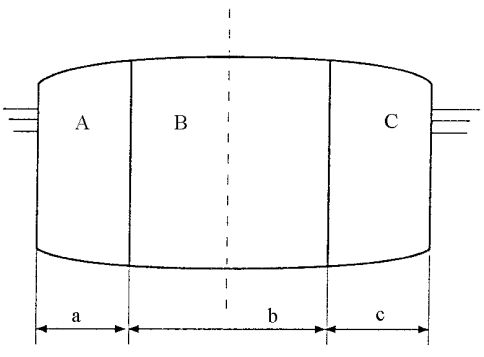


*Figure 1*

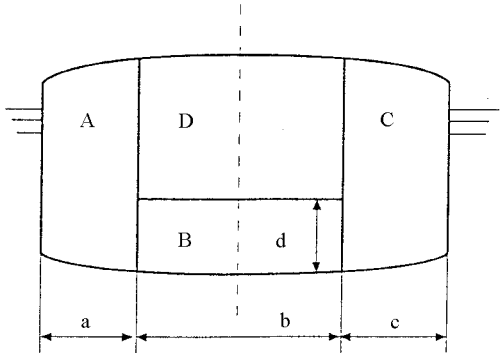


*Figure 2*

a = at least $^1/_5$ $B_F$

b = at least $^1/_6$ $B_F$, and not less than 1,50 m

c = at least $^1/_5$ $B_F$

d = at least 0,50 m.

*Article 15.03*

**Transverse bulkheads**

1. In addition to the bulkheads prescribed in Article 3.03, Section 1, the transverse bulkheads deriving from the subdivision calculation shall be required.

   The prescribed transverse bulkheads shall be watertight and be carried up to the bulkhead deck. Where there is no bulkhead deck these bulkheads shall extend to a height at least 20 cm above the margin line. The requirements of Article 15.04, Section 8 shall be met.

   Passenger spaces and the on-board staff's quarters shall be separated from the engine rooms and boiler rooms by gastight bulkheads.

2. The number of openings in watertight transverse bulkheads as defined in Section 1 above shall be as small as the type of construction and normal operation of the vessel permit. Openings and passageways shall not adversely affect the watertightness of bulkheads.

   Collision bulkheads shall have neither openings nor doors.

   The bulkheads separating engine rooms from passenger spaces or the on-board staff's quarters shall have no doors.

3. Doors in watertight bulkheads which are manually operated and not remotely controlled shall be authorised only in areas not accessible to passengers. They shall remain closed at all times and may be opened only temporarily to allow access. Rapid and safe locking shall be ensured by appropriate devices. The words 'Close door immediately after use' shall appear on both sides of such doors.

   Notwithstanding the first sentence above, manually operated watertight bulkhead doors shall be permitted in passenger areas if:

   (a) the length $L_F$ of the craft does not exceed 40 m;

   (b) the number of passengers does not exceed $L_F$;

   (c) the vessel has only one deck;

   (d) the doors are accessible directly from the deck and are not more than 10 m away from access to the deck;

   (e) the lower edge of the door is at least 30 cm above the floor of the passenger area;

   (f) the two adjacent compartments are equipped with a bilge level alarm system.

4. It shall be possible to close bulkhead doors which remain open for prolonged periods on the spot from either side and from any easily accessible place above the bulkhead deck. Once a door has been remotely closed, it shall be possible to reopen and close it safely on the spot. Closure shall not be impeded by carpeting, foot rails or other obstructions.

   The duration of the remote closing operation shall be not less than 30 seconds and not more than 60 seconds. During the operation, an automatic alarm signal shall sound close to the door. At the point where the remote control operation is carried out, there shall be a device to indicate whether the door is open or closed.

5. Bulkhead doors and their opening and closing devices shall be located in an area bounded on the outside by a vertical plane at a distance of $^1/_5$ of the breadth $B_F$ parallel to the side plating at the maximum loaded draft line. The wheelhouse shall be equipped with a visual alarm system which acts as a monitoring device and is activated whenever the bulkhead door is opened.

6. Open-ended piping and ventilation ducts shall be so installed that, in the event of a leak, no other spaces or tanks are flooded. If several compartments are connected by piping or ventilation ducts, such piping and ducts shall open into an appropriate place above the waterline corresponding to the worst possible flooding. Where this is not the case, transverse bulkheads shall be fitted with remote closing devices operated from above the bulkhead deck.

   Piping which has no open orifice in a compartment shall be considered intact in the event of any damage to that compartment, provided that it is within the safety area defined in Section 5 above and is more than 0,50 m from the bottom.

7. Where openings and doors such as those referred to in Sections 2 to 6 above are authorised, the following operating instructions shall be entered on the inspection certificate:

'The crew shall be instructed that, in the event of danger, all openings and doors in watertight bulkheads are to be hermetically closed without delay.'

8. Transverse bulkheads may be recessed provided that all recess points are within the safety area defined in Section 5 above.

*Article 15.04*

**Intact stability and stability in the event of a leak**

1. The applicant shall show that the intact stability of the vessel is adequate by calculation based on the results of a lateral stability test and, if the inspection body so requests, of a turning test.

2. Proof of adequate intact stability by calculation shall be deemed to be furnished if, when fully rigged, with fuel bunkers, water tanks and waste water collection tasks half filled, while maintaining a residual freeboard and residual safety clearance conforming to Section 7 below, and under the simultaneous effects of:

(a) a lateral displacement of persons under the conditions set out in Section 4 below;

(b) wind pressure as defined in Section 5 below;

(c) the centrifugal force resulting from the turning of the craft under the conditions set out in Section 6 below,

the heel of the vessel does not exceed 12°. Under the sole effect of lateral displacement of persons, this angle shall not exceed 10°.

The inspection body may require the calculation also to be made for other degrees of filling of fuel bunkers and tanks.

3. For vessels with a length $L_F$ of less than 25 m, the proof of adequate intact stability by calculation required in Section 2 above may be replaced by a load test with the weight of half the authorised maximum number of passengers and the most unfavourable loading of fuel bunkers and water tanks. This weight shall be distributed from the side plating over the free deck area for passenger use at a ratio of 3¾ passengers per $m^2$. During this test, the angle of heel shall not exceed 7° and the remaining freeboard and safety clearance shall not be less than 0.05 B + 0,20 m and 0,05 B + 0,10 m respectively.

4. The moment resulting from the lateral displacement of persons Mp shall be the sum of the moments for each deck accessible to passengers. These shall be calculated as follows:

(a) For free decks:

$$Mp_n = c_p \cdot b \cdot P \text{ [kNm]}$$

where:

$c_p$ coefficient (cp = 1,5) [$m/s^2$];

b the greatest usable width of the bridge, measured at a height of 0,50 m;

P total mass in tonnes of the persons admitted on the deck in question.

(b) For deck space occupied by fixed installations:

In calculating the lateral displacement of persons on decks partly occupied by fixed installations, such as benches, tables, dinghies or small shelters, a load of 3¾ passengers per $m^2$ of free deck area shall be used; in the case of benches, a width of 0,50 m and a depth of 0,75 m per passenger should be allowed for.

The calculation shall be made for displacement to starboard and to port.

For vessels with more than one deck, the distribution of the total weight of persons shall be the most unfavourable from the point of view of stability. Cabins, if any, shall be assumed to be unoccupied for the calculation of lateral displacement of persons.

The centre of gravity of a person shall be assumed to be at a height of one metre above the lowest point of the deck at ½ $L_F$ without allowing for the sheer or curvature of the deck and assuming a mass of 75 kg per passenger.

5. The moment resulting from the wind pressure Mw shall be calculated as follows:

$$M_w = p_v \cdot S \left(l_v + \frac{T}{2}\right) \text{[kNm]}$$

where:

$p_v$ specific wind pressure, i.e. 0,1 kN/m$^2$;

S sheer plan of the vessel above the plane of maximum draught in m$^2$;

$l_v$ distance from the centre of gravity of the sheer plan of the vessel S at the plane of maximum draught in m.

6. The moment resulting from the centrifugal force exerted by the turning of the vessel shall be calculated as follows:

$$M_{gi} = C_{gi} \cdot \frac{D}{L_F} \left(\overline{H_g} - \frac{T}{2}\right) \text{[kNm]}$$

where:

$C_{gi}$ a coefficient ($C_{gi}$ = 5) [m$^2$/s$^2$];

$\overline{H_g}$ distance between the centre of gravity and the keel line in m.

Where the angle of heel during turning is verified by a test, the value so determined may be used in the calculation. The test shall be performed with the craft at half maximum speed fully loaded and on the smallest turning radius possible under these conditions.

7. With the vessel at the angle of heel resulting from the forces referred to in Section 2(a) to (c) the remaining freeboard must be not less than 0,20 m.

For vessels whose side glazing can be opened or whose sides contain other openings not guaranteed to be watertight a safety clearance of at least 0,10 m shall be maintained.

8. Proof by calculation of adequate stability in the event of a leak shall be deemed to have been furnished if at all the intermediate stages and the final stage of flooding the righting moment $M_R$ defined by:

$$M_R = C_R \cdot \overline{MG}_{res} \cdot \sin\varphi \cdot D \text{ [kNm]}$$

is greater than the heeling moment $M_g = 0{,}2\ M_p$ [kNm].

where

$C_R$ coefficient ($C_R$ = 10) [m/s$^2$];

$\overline{MG}_{res}$ Reduced metacentric height in m in the flooded state;

$\varphi$ the smaller of the following two angles: angle at which the initial opening of a non-immersed compartment begins to be immersed or angle at which the bulkhead deck begins to be immersed;

$M_p$ Moment resulting from the lateral displacement of persons, as referred to in Section 4.

*Article 15.05*

**Calculation of the number of passengers on the basis of free deck area**

1. If Articles 15.04 and 15.06 have been complied with, the inspection body shall set the authorised maximum number of passengers as follows:

   (a) The calculation shall be based on the sum total free deck area normally reserved on board to accommodate passengers.

   However, the deck areas of cabins and toilet compartments and of areas used permanently or temporarily for the operation of the vessel, even if accessible to passengers, shall not be included in the calculation. Moreover, areas located below the main deck shall not be taken into consideration. However, areas let into the main deck and including large glazing above it may be included in the calculation.

   (b) The following shall be subtracted from the total area calculated in accordance with (a) above:

   — the surfaces of corridors, companionways and other connecting surfaces,

   — surfaces beneath companionways,

   — surfaces permanently occupied by gear or furniture,

   — surfaces beneath dinghies, life-rafts and lifeboats, even where these are placed high enough for passengers to get beneath them,

   — small surfaces, including those between seats and tables, which are effectively unusable.

   (c) A load of 2,5 passengers should be allowed for per $m^2$ of free deck area, as determined in accordance with points (a) and (b); however, this load shall be 2,8 passengers in the case of vessels with a length $L_F$ of less than 25 m.

2. The authorised maximum number of passengers shall be indicated on board by means of easily legible notices affixed in prominent places. In the case of cabin vessels also operated for day excursions, passenger numbers shall be calculated as for a day-excursion vessel and as for a cabin vessel and entered on the certificate.

   Articles 15.02 and 15.04 shall be complied with for each of these passenger numbers.

   In the case of vessels used exclusively for journeys involving overnight accommodation, the number of berths shall be determinant.

*Article 15.06*

**Safety clearance, freeboard and draught marks**

1. The safety clearance shall be at least equal to the sum of:

   (a) the additional lateral draught, measured from the outside plating, resulting from the authorised angle of heel, and

   (b) the residual safety clearance prescribed in Article 15.04, Sections 2 and 7.

   For vessels without a bulkhead deck, the safety clearance shall be at least 0,50 m.

2. The freeboard shall be at least equal to the sum of:

   (a) the additional lateral draught, measured from the outside plating, resulting from the angle of heel calculated in accordance with Article 15.04, Section 2, and

   (b) the residual freeboard prescribed in Article 15.04, Sections 2 and 7.

   The freeboard shall be at least 0,30 m.

3. The plane of maximum draught shall be determined in such a way as to comply with the safety clearance prescribed in Section 1, the freeboard prescribed in Section 2, and Articles 15.02 to 15.04. However, for safety reasons the inspection body may lay down a greater freeboard or a greater safety clearance.

4. Draught marks shall be affixed to each side of the vessel in accordance with Article 4.04. Authorisation will be given for additional pairs of marks or a continuous mark to be affixed. The position of such marks shall be clearly specified in the certificate.

*Article 15.07*

**Passenger installations**

1. Deck areas which are intended for passengers and are not enclosed shall be surrounded by a ship's rail or guard rail at least one metre high. The guard rail shall be fitted in such a way that children cannot fall through it. Openings and installations used to board or leave the vessel and openings used to load or unload it shall be fitted with an appropriate safety device.

   Gangways shall be at least 0,60 m wide and shall be fitted with a railing on each side.

2. (a) Connecting corridors and companionways, and doors and exits intended for use by passengers, shall have a clear width of at least 0,80 m. This may be reduced to 0,70 m for doors to passenger cabins and other small rooms.

   Where a part of the vessel or a room intended for passengers is served by a single connecting corridor or companionway, the clear width thereof shall be at least one metre. On vessels whose length $L_F$ is less than 25 m, the inspection body may authorise a width of 0,80 m.

   In the case of rooms or groups of rooms intended for more than 80 passengers, the sum width of all the exits provided for passengers and which the latter would have to use in an emergency shall be at least 0,01 m per passenger.

   (b) Rooms or groups of rooms designed or arranged for 30 or more passengers or including berths for 12 or more passengers shall have at least two exits. A watertight bulkhead door complying with Article 15.03, Sections 2, 4 or 5 and giving access to an adjacent compartment from which the upper deck may be reached shall be considered to be an exit.

   Such exits shall be appropriately planned. If the total width of the exits referred to at (a) is determined by the number of passengers, the width of each exit shall be at least 0,005 m per passenger. Except in the case of cabin vessels, one of these two exits may be replaced by two emergency exits.

   Rooms located below the main deck shall have at least one direct exit, or where appropriate one emergency exit, giving onto the said deck or to the outside. This requirement does not apply to individual cabins.

   Emergency exits shall have a clear opening of at least 0,36 $m^2$ and a shortest side not less than 0,50 m long.

   (c) Companionways below the main deck shall be located within two vertical planes at a distance of at least $^1/_5$ $B_F$ from the side plating. This distance is not obligatory where there is at least one companionway on each side of the vessel in the same room. Companionways shall be fitted with handrails on each side; in the case of companionways less than 0,90 m wide a single handrail will be sufficient.

3. Doors to passenger day-rooms, except those opening onto corridors, shall be capable of opening outwards or shall be constructed as sliding doors.

   Cabin doors shall be made in such a way that they can also be unlocked from the outside at any time.

4. Evacuation routes and emergency exits shall be clearly signed; these signs shall be lit by the emergency lighting system.

5. On board vessels authorised to carry up to 300 passengers there shall be at least one lavatory per 150 passengers. On board vessels authorised to carry more than 300 passengers there shall be separate lavatories for each sex, at the rate of at least one for every 200 passengers.

6. The entry of non-authorised persons into those parts of the vessel which are not intended for passengers, and in particular access to the wheelhouse and the engine rooms, shall be forbidden. In addition, the words 'No entry' or a corresponding symbol shall appear in a prominent place at the access points to such parts of the vessel.

7. Only toughened glass, laminated glass or a synthetic material authorised for use in fire protection may be used for glazing located in the area accessible to passengers.

*Article 15.08*

**Special requirements for survival equipment**

1. Passenger vessels shall carry the number of lifebuoys indicated in the following table:

| $L_F$ in m | Maximum number of passengers admitted | Number of lifebuoys |
|---|---|---|
| up to 25 | up to 200 | 3 |
| over 25 and up to 35 | over 200 and up to 300 | 4 |
| over 35 and up to 50 | over 300 and up to 600 | 6 |
| over 50 | over 600 and up to 900 | 8 |
| — | over 900 and up to 1 200 | 10 |
| — | over 1 200 | 12 |

The number of lifebuoys shall be determined by reference to the larger of the values resulting from the first and second columns.

Half the prescribed lifebuoys shall be fitted with a buoyant line at least 30 m long.

2. Vessels with a length $L_F$ of less than 25 m shall, in addition to the lifebuoys required under Section 1, carry individual or collective survival equipment both for the entire maximum number of passengers authorised for the vessel's operating mode and for the vessel's service crew. Where buoyancy in the event of a leak has been checked, the requirements referred to in Section 3 shall be applied.

3. Survival equipment shall be stored on board in such a way that in case of need it can be easily and safely reached. Concealed storage places shall be clearly signed.

4. Individual survival equipment are the lifebuoys and life-jackets referred to in Article 10.05 and buoyancy aids and appropriate equipment capable of supporting a person in the water.

The buoyancy aids and appropriate equipment shall:

(a) provide a buoyancy of at least 100 N in fresh water;

(b) be made of a suitable material and be resistant to oil and oil-derived products, and to temperatures of up to 50 °C;

(c) be fitted with appropriate devices enabling them to be grabbed;

(d) have a fluorescent orange colour or have permanently fixed fluorescent surfaces measuring at least 100 $cm^2$.

Inflatable individual survival equipment shall be checked in accordance with the manufacturer's instructions.

5. Collective survival equipment is dinghies, life-rafts and appropriate equipment capable of supporting several persons in the water. These shall:

(a) bear an inscription indicating how they are to be used and the number of passengers for which they are approved;

(b) provide a buoyancy in fresh water of at least 100 N per person;

(c) assume and maintain a stable trim and, in this respect, be fitted with appropriate devices enabling them to be grabbed by the indicated number of persons;

(d) be made of a suitable material and be resistant to oil and oil-derived products, and to temperatures of up to 50 °C;

(e) have a fluorescent orange colour or have permanently fixed fluorescent surfaces measuring at least 100 $cm^2$;

(f) be rapidly and safely launchable from their place of storage by a single person.

6. Inflatable survival equipment shall in addition:

(a) comprise at least two separate air compartments;

(b) inflate automatically or by manual command when launched;

(c) assume and maintain a stable trim whatever load it is supporting, even when only half the air compartments are inflated;

(d) be checked in accordance with the manufacturer's instructions.

*Article 15.09*

**Fire protection and fire-fighting in passenger spaces**

1. Decks separating passenger areas from one another or from the engine rooms and wheelhouse, and bulkheads and walls between passenger areas and engine rooms and between passenger areas and galleys shall be fire-retardant.

Partition walls and doors separating corridors from cabins and cabins from other cabins shall be fire-retardant.

Partition walls between corridors and cabins shall extend from deck to deck or shall extend up to a fire-resistant ceiling.

Where appropriate sprinkler systems have been fitted the prescriptions of the second and third paragraphs of this Section shall not be compulsory.

Fire spaces above ceilings, under floors and behind facings shall be subdivided at no more than 10 m intervals by fire-resistant structural parts.

2. Companionways, exits and emergency exits shall be so disposed that in the event of a fire in any area, the other areas may be evacuated safely.

Companionways, including their steps, shall include a frame made of steel or an equivalent non-flammable material. The steps shall be fire-resistant.

On cabin vessels they shall be located within a stairwell fitted with fire-retardant walls and with automatically closing fire-retardant doors.

A companionway which links only two decks need not be surrounded by a stairwell where one of these decks is surrounded by fire-retardant bulkheads with automatically closing fire-retardant doors or where appropriate sprinkler devices have been installed.

Stairwells shall link directly to the corridors and external decks.

3. Account shall be taken of the increased fire risk in galleys, hairdressing salons and perfume shops in accordance with the prescriptions of the competent authorities.

4. Paint, varnish and other surface treatment products used indoors, as well as materials used to face and insulate, shall be of a fire-resistant type. In the event of fire they shall not give off dangerous amounts of smoke or toxic gas.

Door-opening mechanisms shall function normally for a sufficiently long period in the event of fire.

5. Corridors which are more than 40 m long shall be subdivided by fire-retardant partition walls fitted with automatically closing doors at intervals of no more than 40 m.

6. Automatically closing fire-retardant doors which are left open during normal service shall be closable from a place which is permanently occupied by the vessel's crew and shall be closable on the spot.

7. Ventilation installations shall be built in such a way as to prevent the spread of fire through such installations. It shall be possible to close the air inlet and outlet vents.

Continuous ducts shall be subdivided at intervals of no more than 40 m by fire valves.

Ventilation ducts which pass through stairwell partition walls or engine room bulkheads shall be fitted with fire valves where they pass through such walls.

It shall be possible to switch off built-in ventilators from a central unit located outside the engine room.

8. On cabin vessels all cabins and day-rooms for passengers and crew members as well as the galleys and engine rooms shall be linked to an appropriate fire alarm system. The presence of a fire and its location shall be signalled automatically to a place which is permanently occupied by the vessel's crew.

9. Passenger vessels shall be fitted with a fire-fighting system comprising:

(a) a fixed, powered fire pump;

(b) piping with a sufficient number of hydrants;

(c) a sufficient number of fire hoses.

Fire-fighting installations shall be so arranged and of such dimensions that any point on the vessel may be reached from at least two different hydrants, in each case by using a single fire hose no more than 20 m long. Water pressure at the hydrant shall be at least 3 bar. On the highest deck it shall be possible to achieve a jet length of at least 6 m.

Fire pumps shall not be installed forward of the collision bulkhead. Where the fire pump is installed in the main engine room, a second powered fire pump shall be installed outside that room such as may be used independently of the engine room installations. This pump may be portable.

Normal service and deck wash pumps and deck wash pipes may be encompassed within the fire-fighting installation where appropriate.

On cabin vessels with a length $L_F$ less than 25 m and on day-excursion vessels with a length $L_F$ less than 40 m the following derogations are allowed:

(a) the fire pump need not be a fixed installation;

(b) where the fire pump is installed in the main engine room a second pump is not required;

(c) it is sufficient that every point on the vessel may be reached from one hydrant using a single fire hose no more than 20 m long.

10. In addition to the extinguishers prescribed in Article 10.03, Section 1, the following extinguishers at least shall be carried on board:

(a) one extinguisher for every 120 $m^2$ of gross floor area, rounded up to the next 120 $m^2$, in day-rooms, dining rooms and similar areas;

(b) one extinguisher for every group of 10 cabins, rounded upwards.

These additional extinguishers shall be located around the vessel in such a way that one of them is to hand at all times no matter where a fire breaks out.

*Article 15.10*

**Additional provisions**

1. Lighting shall be provided solely by electric lighting systems.

2. There shall be an emergency electric lighting system with the meaning of Article 9.18, Section 2.

3. Where direct communication is not possible between the wheelhouse and the crew's living quarters, the operating areas, the fore and aft sections of the vessel and the passenger access points, a communication system providing a sure and reliable two-way link shall be provided.

4. Vessels with a length $L_F$ of 40 m or more or authorised to carry more than 75 passengers shall be equipped with loudspeakers capable of reaching all passengers.

5. Cabin vessels shall have an alarm system. This shall comprise:

   (a) an alarm system to warn the vessel command and the crew:

   This alarm shall be given only in areas assigned to vessel command and the crew; it shall be possible for the vessel command to stop the alarm. It shall be possible to trigger the alarm from at least the following places:

   — in each cabin,

   — in the corridors, lifts and stairwells, with the distance to the nearest trigger not exceeding 10 m and with at least one trigger per watertight compartment,

   — in the lounges, dining rooms and similar areas,

   — in the engine rooms, galleys and similar areas exposed to fire risk.

   (b) an alarm system to warn passengers:

   This alarm shall sound clearly and unmistakably in all areas accessible to passengers. It shall be possible to trigger it from the wheelhouse and from a location permanently occupied by the crew.

   Alarm triggers shall be protected against unintentional use.

6. Cabin vessels shall be equipped with a radio-telephone system allowing communication with the public telephone network.

7. The following points and areas at least shall be adequately lit:

   (a) the points where collective survival equipment is stored and those where it is normally prepared for use;

   (b) evacuation routes, passenger access points, corridors, lifts and companionways in the accommodation and the cabin and accommodation areas;

   (c) signs indicating evacuation routes and exits;

   (d) engine rooms and their exits;

   (e) the wheelhouse;

   (f) the room housing the emergency power source;

   (g) the points where extinguishers and fire pumps are located;

   (h) the areas in which passengers and crew muster in the event of danger.

8. On cabin vessels, a safety plan shall be kept on board indicating the tasks to be performed by the crew and staff in the event of an emergency in accordance with the police requirements in force. Tasks shall be indicated for the following cases:

   (a) a leak;

   (b) a fire on board;

   (c) evacuation of passengers;

   (d) a man overboard.

The safety plan shall include a plan of the vessel indicating clearly and precisely:

(a) the survival and safety equipment;

(b) the watertight doors located below deck and the position of their controls, as well as other openings such as those referred to in Article 15.03, Sections 2 and 6;

(c) fire-retardant doors;

(d) fire-dampers;

(e) alarm installations;

(f) Fire alarm system;

(g) fire-fighting installations and extinguishers;

(h) evacuation routes and emergency exits;

(i) the emergency power source;

(j) the ventilation system controls;

(k) connection to the earthing network;

(l) closing controls for fuel supply pipes;

(m) liquefied gas plant;

(n) loudspeaker systems;

(o) radio-telephone installations.

The safety plan and the plan of the vessel shall bear the stamp of the inspection body and be displayed prominently at appropriate locations.

9. On cabin vessels a general evacuation plan shall be displayed for passengers at appropriate locations. The plan may be combined with the safety plan required under Section 8.

The requisite instructions to passengers on what to do in the event of an alarm, fire, damage to the vessel and evacuation and indicating the location of the survival equipment shall be provided in each cabin.

These instructions shall be written in Dutch, English, French and German.

10. In the case of vessels with a wooden, aluminium or synthetic hull, the engine rooms shall be constructed of materials referred to in Article 3.04, Sections 3 and 5, or be equipped with a permanently installed extinguishing system within the meaning of Article 10.03, Section 5.

*Article 15.11*

**Waste water collection and disposal facilities**

1. Passenger vessels with more than 50 passenger berths shall be equipped either with waste water collection tanks or with on-board treatment plant.

2. Waste water collection tanks shall have sufficient volume. They shall be fitted with a device to indicate their content level. To empty the tanks, the vessel shall have its own pumps and pipes with which to evacuate the waste water to berths situated to either side of the vessel. The pipes shall be fitted with waste water evacuation joints in accordance with European standard EN 1306.

3. The on-board treatment plant shall, at all times and without dilution, be able to ensure the exit limit value required by the police provisions in force and shall be fitted with a sampling device.

# Proposal for a Council Decision amending Decision 2000/24/EC so as to establish an EIB special action programme in support of the consolidation and intensification of the EC-Turkey customs union

(2000/C 365 E/09)

*COM(2000) 479 final — 2000/0197(CNS)*

*(Submitted by the Commission on 26 July 2000)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 308 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Whereas:

(1) Council on 23 December 1963 adopted Decision 64/732/EEC on the establishment of an Association Agreement between the EEC and Turkey [1]. The Additional Protocol effective since 1 January 1973 and annexed to the Association Agreement [2] set down the conditions, arrangements and timetables for the progressive establishment of the Customs Union within a period of 22 years.

(2) On 6 March 1995 Council agreed on a global package regarding the future relations with Turkey, including the draft Decision of the EC-Turkey Association Council on the implementation of the final phase of the customs union, and a related Community declaration concerning financial cooperation.

(3) The declaration on financial cooperation specified that the resumed financial cooperation with Turkey shall be based, *inter alia*, on 'additional EIB loans over a five-year period starting in 1996, in order to improve the competitiveness of the Turkish economy following the entry into force of the Customs Union'.

(4) On 25 July 1995, on the basis of the above declaration, the Commission put forward a proposal for a Council Regulation on the implementation of a special measure of financial cooperation with Turkey. In the same proposal, the Commission invited the Council to approve a special EIB lending facility strengthening the competitiveness of the Turkish economy following the entry into force of the Customs Union. The Commission proposal encountered fundamental difficulties during the legislative process and the legal basis has not been approved.

(5) The Luxembourg European Council on 12 and 13 December 1997 called for a strategy to be drawn up to prepare Turkey for accession by bringing it closer to the EU in every field. On 4 March 1998 the Commission submitted to the Council a communication entitled 'the European Strategy for Turkey', which put forward a work programme to consolidate and add substance to the Customs Union and step up cooperation in other areas significant for the further development of relations with Turkey.

(6) The Cardiff European Council on 15 and 16 June 1998 welcomed the European Strategy for Turkey as a platform for developing relations between the European Union and Turkey on a sound and evolutionary basis. Recalling the need for financial support for the European Strategy, the European Council noted the Commission's intention to reflect on ways and means of underpinning the implementation of the strategy, and to table appropriate proposals to this effect.

(7) The Helsinki European Council of 10 and 11 December 1999 decided that Turkey was a candidate State destined to join the Union on the basis of the same criteria as applied to the other candidate States.

(8) In line with the European Strategy for Turkey and the new status of Turkey as candidate State following the Helsinki European Council, the present Decision should establish an EIB special action programme supporting the consolidation and intensification of the EC-Turkey Customs Union. It should facilitate progress in areas that still merit attention as regards the implementation and effective application of certain legislation of relevance for the Customs Union as identified by the regular reports by the Commission on Turkey's progress towards accession and in relevant areas identified by the European Strategy for Turkey.

(9) This Decision replaces the proposal on an EIB special action programme made in 1995. The present Decision, together with Turkey's expected eligibility under the EIB's Pre-Accession Facility, is meant to deliver the EU commitment on special EIB lending in Turkey in the context of the 1995 Customs Union.

[1] OJ 217, 29.12.1964, p. 3685/64.

[2] OJ L 293, 29.12.1972, p. 4.

(10) The EIB's intervention under this Decision should be coherent with the other EIB facilities available in Turkey and support investments assisting the competitiveness of industry in Turkey, in particular the SME sector; investments in infrastructures, covering transport, energy and telecom improving the links between the EU and Turkish infrastructures, including where appropriate and if within the scale of available resources projects related to the TINA Network, the 'Traceca' corridor, and the 'Inogate' energy links; investments supporting direct investment activities by EU companies in Turkey; and where EIB loan finance is an appropriate instrument investments for technical installations facilitating the functioning of the Customs Union.

(11) Council Decision 2000/24/EC [1] grants the EIB a Community guarantee against losses under loans for projects outside the Community (central and eastern Europe, Mediterranean countries, Latin America and Asia and the Republic of South Africa).

(12) Council Decision 2000/24/EC gives recourse to the guarantee fund for external actions established by Council Regulation (EC, Euratom) No 2728/94 of 31 October 1994 [2], amended by Council Regulation (EC, Euratom) No 1149/1999 of 25 May 1999 [3].

(13) The Community guarantee covering the general EIB external lending mandate laid down in Decision 2000/24/EC should be extended to cover an EIB special action programme supporting the consolidation and intensification of the EC-Turkey Customs Union. Decision 2000/24/EC should therefore be amended accordingly.

(14) The provisions of this Decision are based on respect for democratic principles, the rule of law, human rights and fundamental freedoms and respect for international law, which underpin the policies of the European Community and its Member States. The Community attaches great importance to the need for Turkey to improve and promote its democratic practices and respect for fundamental human rights, and more closely involve civil society in that process.

(15) The Treaty does not provide, for the adoption of this Decision, powers other than those under Article 308,

HAS DECIDED AS FOLLOWS:

*Article 1*

The second sentence of the second subparagraph of the first paragraph of Article 1 of Decision 2000/24/EC is hereby amended as follows:

(a) in the introductory part, 'EUR 18 410 million' shall be replaced by 'EUR 18 860 million';

b) the following fifth indent shall be inserted after the 'Republic of South Africa':

'— Special action supporting the consolidation and intensification of the EC-Turkey Customs Union: EUR 450 million.'

*Article 2*

This Decision shall be published in the *Official Journal of the European Communities*. It shall take effect on the day of its adoption.

[1] OJ L 9, 13.1.2000, p. 24.

[2] OJ L 293, 12.11.1994, p. 1.

[3] OJ L 139, 2.6.1999, p. 1.

# Proposal for a Regulation of the European Parliament and of the Council on action by Member States concerning public service requirements and the award of public service contracts in passenger transport by rail, road and inland waterway

(2000/C 365 E/10)

**(Text with EEA relevance)**

*COM(2000) 7 final — 2000/0212(COD)*

*(Submitted by the Commission on 26 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 71 and 89 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The development of the highest possible standards of public service in the provision of passenger transport by road, rail and inland waterway is one of the primary Community objectives under the common transport policy.

(2) Competent authorities in the Member States have recourse to three main mechanisms in pursuing this objective: the conclusion of public service contracts with operators, the granting of exclusive rights to operators and the laying down of minimum standards for public transport operation.

(3) It is important to clarify the legal position of such mechanisms with respect to Community law.

(4) In relation to inland transport, Article 73 of the Treaty refers to the discharge of certain obligations inherent in the concept of public service. Council Regulation (EEC) No 1191/69 of 26 June 1969 on action by Member States concerning the obligations inherent in the concept of a public service in transport by rail, road and inland waterway [1] establishes a Community regulatory framework for public passenger transport, implementing this Article of the Treaty and indicating how competent authorities in the Member States can ensure adequate transport services which contribute to sustainable development, social integration, environmental improvement and regional balance.

(5) Many Member States have introduced legislation providing for the award of fixed-duration exclusive rights and public service contracts, in at least part of their public transport market, on the basis of open, transparent and fair award procedures. In the light of those developments, the application of Community rules on the freedom of establishment, and the application of Community public procurement rules, significant progress has been made towards Community/EEA-wide market access in public transport. As result, trade between Member States has substantially developed and several public transport operators are now providing services in more than one Member State.

(6) However, the opening of the market on the basis of national legislation has led to disparities in the procedures applied and has created legal uncertainty as to the rights of operators and the duties of competent authorities.

(7) Studies carried out on behalf of the Commission [2], and the experience of States where competition in the public transport sector has been in place for a number of years, show that, with appropriate safeguards, the introduction of regulated competition between Community operators in this sector leads to more attractive services at lower costs and is not likely to obstruct the performance of the specific tasks assigned to the operators.

(8) It is important to update the Community legal framework in order to ensure the further development of competition in the provision of public passenger transport services and to take into account the new legal approaches which Member States have introduced in regulating the provision of public passenger transport services. This is in line with the conclusions of the European Council of Lisbon of 28 March 2000 where the Commission, Council and the Member States, each in accordance with their respective powers, were asked to 'speed up liberalisation in areas such as transport'. The updating of the Community legal framework will offer an opportunity to ensure that the smooth opening of the market is guaranteed at Community level and that basic elements of competitive procedures in all Member States are harmonised.

[1] OJ L 156, 28.6.1969, p. 1; Regulation as last amended by Regulation (EEC) No 1893/91 (OJ L 169, 29.6.1991, p. 1).

[2] 'Improved structure and organisation for urban transport operations of passengers in Europe' Isotope consortium, CEC, 1998; 'Examination of Community law relating to the public service obligations and contracts in the field of inland passenger transport', submitted to the European Commission by NEA Transport research and training, 1998.

(9) Article 16 of the Treaty establishes the need to ensure that services of general economic interest operate on the basis of principles and conditions which enable them to fulfil their missions. The development of competition should therefore be accompanied by Community rules that guarantee the protection of the general interest in terms of adequate quality and availability of public transport. In securing this general interest, it is important for consumers and interested parties to have at their disposal integrated information about the services available.

(10) Freedom of establishment is a basic principle of the common transport policy and requires that operators of a Member State established in another Member State be guaranteed effective access to the public transport market of that State in a transparent way and without discrimination.

(11) The Treaty lays down specific rules with regard to restrictions on competition. Article 86(1) of the Treaty, in particular, obliges the Member States to adhere to these rules with regard to public undertakings and undertakings which have been granted exclusive rights. Article 86(2) of the Treaty subjects undertakings entrusted with the operation of services of general economic interest to these rules, under specific conditions.

(12) In order to ensure the application of the principle of non-discrimination and the equal treatment of competing operators, it is essential to define basic common procedures that must be followed by competent authorities in concluding public service contracts or laying down minimum criteria for public transport operation. According to the principles of Community law, competent authorities are required to apply mutual recognition of technical standards and proportionality of selection criteria in implementing these procedures. In accordance with the principle of subsidiarity, such basic common procedures should nevertheless leave it open for competent authorities in the Member States to conclude public service contracts or lay down minimum criteria for public transport operation in ways that take account of specific national or regional circumstances, whether legal or factual.

(13) Studies and experience show that competitive tendering for public service contracts is an effective way of achieving the benefits of competition in terms of cost, efficiency and innovation without obstructing the performance of the specific tasks assigned to the operators in the general public interest.

(14) Mandatory tendering rules for the conclusion of certain contracts are laid down by Council Directive 92/50/EEC of 18 June 1992 relating to the coordination of procedures for the award of public service contracts [1] and Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors [2]. Where such rules are applicable, those aspects of this Regulation that deal with the requirement for contracts to be tendered, and with the methods by which the selection of operators should be conducted, do not apply.

(15) Tendering of public service contracts should not be compulsory where safety standards in the provision of rail services or the coordination of a metro or light rail network would be endangered. Interested parties should nevertheless have the opportunity to comment on plans to award contracts in this way, in time for their views to be taken into account. Where rail contracts awarded in this way are fully integrated with bus services, it should be possible for the bus services to be included in the same contract.

(16) Tendering for public service contracts should also not be compulsory where the contract has a low value. This value should be higher for the tendering of a whole network than for the tendering of a part of a network or of a single route.

(17) Taking into account the specific, commercially viable nature of certain parts of the public transport market, it should also be possible for competent authorities to facilitate new initiatives that arise from the market and that fill gaps not currently served by any operator, by granting an exclusive right to provide services on a particular route, where this is at the operator's request. It is not inappropriate for this grant to be made without tendering, provided that it is for a strictly limited period only and is not renewable.

(18) Where authorities grant an exclusive right but where no direct financial compensation is involved, they should be able to grant it by means of a simplified procedure that nonetheless provides for non-discriminatory competition between operators.

(19) It should be possible for authorities to compensate operators for the cost of complying with minimum criteria for public transport operation, provided that this compensation can be fairly calculated and is not at such a high level that it detracts from the pressure on operators to focus primarily on the requirements of passengers.

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[1] OJ L 209, 24.7.1992, p. 1; Directive as last amended by Directive 97/52/EC (OJ L 328, 28.11.1997, p. 1).

[2] OJ L 199, 9.8.1993 p. 84; Directive as last amended by Directive 98/4/EC (OJ L 101, 1.4.1998, p. 1).

(20) The provisions of this Regulation applicable to operators should also apply in those cases where public transport services are provided by a public administration which does not have a legal personality distinct from that of the public administration that is acting as the competent authority. Any other arrangement, by not applying these provisions to cases where the State acts in an entrepreneurial capacity, would not ensure the non-discriminatory application of Community law.

(21) Studies and experience show that where services are provided under public service contracts whose duration is limited to five years, the performance of the specific tasks assigned to the operators need not be obstructed. To minimise the distortion of competition while protecting the quality of services, public service contracts should normally, therefore, be limited to this duration. However, longer periods may be necessary where the operator has to invest in infrastructure, railway rolling-stock or other vehicles that are tied to specific, geographically defined transport services and that have long payback periods.

(22) In accordance with the principle of non-discrimination, competent authorities should ensure that public service contracts do not cover a wider geographical area than is required by the general interest and in particular, by the need to provide integrated services to significant groups of passengers who habitually use more than one link in the public transport network during the same journey.

(23) Where it is appropriate for competent authorities, in pursuing the general interest, to protect employees in situations where the conclusion of a public service contract may lead to a change of operator, they should have the power to require operators to apply the relevant provisions of Council Directive 77/187/EEC of 14 February 1977 on the approximation of the laws of the Member States relating to the safeguarding of employees' rights in the event of transfers of undertakings, businesses or parts of businesses [1].

(24) It is necessary that the procedures introduced according to this Regulation are transparent and that appeals procedures against decisions of the competent authorities are in place. Authorities should also keep records of their decisions for a period of ten years, in line with the limitation period laid down in Article 15 of Council Regulation (EC) No 659/1999 on State aid procedures [2].

(25) Regulation (EEC) No 1191/69 provides that operating costs and revenues, overheads, assets and liabilities relating to the fulfilment of public service requirements need to be accounted for separately. This requirement should be retained, in a modernised form, in particular to ensure that authorities obtain value for money from public expenditure and that payments made by way of compensation are not misused to distort competition.

(26) Compensation payments which exceed the net costs incurred by an operator as a result of fulfilling a public service requirement are liable to be examined under Community rules on State aids. It is therefore appropriate for the Community to lay down rules establishing when compensation may be considered not to be excessive. Competitive tendering for the conclusion of contracts is an efficient way of ensuring that compensation is not excessive, provided that the results of the tendering reflect fair and realistic market conditions.

(27) Regulation (EEC) No 1191/69 exempts compensation paid pursuant to its provisions from the State aid notification procedure laid down in Article 88(3) of the Treaty; this Regulation establishes new and detailed provisions, designed for the specific circumstances of the public passenger transport sector, including modernised requirements for separate accounting, to ensure that compensation is compatible with Community State aid rules; in addition, it establishes new detailed procedures permitting the Commission to monitor these payments. It is therefore appropriate to continue to exempt compensation paid pursuant to the provisions of this Regulation from the State aid notification procedure.

(28) With a view to improving the operation of this Regulation in the light of experience, the Commission should report on the impact of Community legislation and the application of this Regulation.

(29) As competent authorities in the Member States and operators will need time to adjust to the provisions of this Regulation, provision should be made for the use of transitional arrangements.

(30) As a result of the Community's international obligations, access to the public transport markets of the Member States has, in some circumstances, been granted to certain third-country operators; this Regulation does not restrict this access.

(31) Regulation (EEC) No 1191/69 is superseded by this Regulation and should therefore be repealed.

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[1] OJ L 61, 5.3.1977, p. 26; Directive as amended by Directive 98/50/EC (OJ L 201, 17.7.1998, p. 88).

[2] OJ L 83, 27.3.1999, p. 1.

(32) Council Regulation (EEC) No 1107/70 of 4 June 1970 on the grant of aid for transport by rail, road and inland waterway [1], includes a provision regarding reimbursement for the discharge of obligations arising from the provision of a public service. That provision, which expressly anticipates the entry into force of new Community rules, is now redundant and should be deleted,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**SCOPE AND DEFINITIONS**

*Article 1*

**Scope**

This Regulation shall apply to national and international operation of public passenger transport by rail, road and inland waterway. It lays down the conditions under which competent authorities may compensate transport operators for the cost of fulfilling public service requirements and under which they may grant exclusive rights for the operation of public passenger transport, due regard being had to the pursuit of legitimate public service objectives within a framework of regulated competition.

*Article 2*

**Relationship to public procurement law**

This Regulation shall be without prejudice to the obligations on competent authorities which flow from Directives 92/50/EEC and 93/38/EEC.

Where either of those Directives makes the tendering of a public service contract mandatory, Articles 6(1), 7, 8, 12, 13(1), 13(2) and 14 of this Regulation shall not apply to the award of that contract.

*Article 3*

**Definitions**

For the purposes of this Regulation, the following definitions shall apply:

(a) 'competent authority' means any State body with the power to intervene in public passenger transport markets, or any other body to which such a State power has been assigned;

(b) 'direct award' means the award of a contract to a given operator following a procedure in which no other operator can participate;

(c) 'exclusive right' means the entitlement on the part of an operator to operate a particular type of passenger transport services on a particular route or network or in a particular area, to the exclusion of other potential operators;

(d) 'integrated services' means rail and bus services provided together, directly by an operator, under the terms of a single public service contract; by a single body of employees having the same contractual status; included in a single operating account; and having a single information service, ticketing scheme and timetable;

(e) 'operator' means an undertaking that provides public passenger transport services and that is established under public or private law; or a part, which provides public passenger transport services, of a public administration;

(f) 'payback period' of an asset for an operator means the period during which it is estimated, using appropriate discount rates, that the cost of the asset to the operator, net of any resale value, will exceed the net income that the operator will have received on account of the asset, in particular from passengers and from public authorities;

(g) 'public passenger transport' means transport offered to the general public on a continuing basis;

(h) 'public service contract' means any legally enforceable agreement between a competent authority and an operator for the fulfilment of public service requirements. For the purposes of this Regulation, a public service contract is also:

(i) an agreement that is embodied in a legally enforceable decision, undertaken with an operator's prior consent, through which a competent authority entrusts the operator with the supply of services, or

(ii) the terms that are attached to a decision taken by a competent authority, to entrust an operator forming part of the same public administration with the supply of services;

(i) 'public service requirement' means a requirement adopted by a competent authority in order to secure adequate public passenger transport services;

(j) 'value' of a public passenger transport service, route, contract, compensation scheme or market means the total remuneration, net of VAT, received by the operator or operators, including in particular financial compensation from the public sector and any income from passengers that is not passed on to the competent authority in question.

[1] OJ L 130, 15.6.1970, p. 1, Regulation as last amended by Regulation (EC) No 543/97 (OJ L 84, 26.3.1997, p. 6).

CHAPTER II

## ENSURING THE QUALITY OF PUBLIC PASSENGER TRANSPORT

*Article 4*

1. In applying this Regulation, competent authorities shall secure adequate public passenger transport services that are of high quality and availability, by concluding public service contracts in accordance with Chapter III or by laying down minimum criteria for public passenger transport operation in accordance with Chapter IV.

2. In assessing the adequacy of public passenger transport services, in defining selection and award criteria, and in awarding public service contracts, competent authorities shall take into account at least the following criteria:

(a) consumer protection factors including the accessibility of the services, in terms of their frequency, speed, punctuality, reliability, the extent of the network and the service information that is provided;

(b) the level of tariffs for different groups of users and the transparency of tariffs;

(c) integration between different transport services, including integration of information, ticketing, timetables, consumer rights and the use of interchanges;

(d) accessibility for people with reduced mobility;

(e) environmental factors, including local, national and international standards for the emission of air pollutants, noise and global warming gases;

(f) the balanced development of regions;

(g) the transport needs of people living in less densely populated areas;

(h) passenger health and safety;

(i) the qualifications of the staff; and

(j) how complaints are handled, disputes between passengers and operators are resolved and service shortfalls are redressed.

3. Operators of public passenger transport services shall make available, on request, complete and up-to-date information about the services' timetables, their tariffs and their accessibility for people with different types of mobility handicap. The only charge they shall make shall be to cover the marginal administrative cost of providing the information.

CHAPTER III

## PUBLIC SERVICE CONTRACTS

*Article 5*

### Compulsory use of public service contracts

A public service contract shall be concluded for the payment of all financial compensation for the cost of complying with public service requirements, including compensation taking the form of the use of assets where such use will be charged below market rates, but excluding compensation paid for compliance with general rules for public passenger transport operation in accordance with Article 10.

A public service contract shall also be concluded for the award of all exclusive rights.

*Article 6*

### Award of public service contracts

Where public service contracts are granted under this Regulation, they shall comply with the following requirements:

(a) Contracts shall be put out for competitive tender, except as provided for in Articles 7 and 8.

(b) Contracts shall provide that the operator is responsible, at least, for the cost of supplying the services to which a public service contract relates, including in particular the costs of staffing; energy; and the maintenance and repair of vehicles and rolling-stock.

(c) Contracts shall be limited in time and shall last for no longer than five years. However, the duration of the contract may take into account the payback period, where:

(i) the contract makes the operator responsible for providing railway rolling-stock, other vehicles of a particularly technically advanced nature, or infrastructure, provided that such assets are tied to specific, geographically defined transport services, and

(ii) those assets have a payback period for the operator that is longer than five years.

In such cases, the contract shall also take into account the relative economic importance of the value of the assets in question in comparison with the total estimated value of the services covered by the contract.

(d) Contracts shall require operators to furnish competent authorities, on an annual basis and separately for each route, with information on the services provided, the tariffs charged and the number of passengers carried and complaints received.

*Article 7*

**Direct award of public service contracts**

1. Competent authorities may decide, on a case-by-case basis and subject to paragraph 3, to directly award public service contracts for rail, metro or light rail services if national or international rail safety standards could not be met in any other way.

2. Competent authorities may decide, on a case-by-case basis and subject to paragraph 3, to directly award public service contracts for metro or light rail services if any other arrangement would entail additional costs for maintaining coordination between the operator and the manager of the infrastructure, and if those costs would not be offset by additional benefits.

3. Competent authorities intending to award a contract under the provisions of paragraph 1 or 2 above shall publish, at least one year beforehand and in accordance with Article 13, their preliminary decision to do so and the evidence and analysis on which they have based this preliminary decision.

4. Where an operator, on the date on which this Regulation enters into force, directly provides integrated services, and where the conditions in paragraph 1 or 2 are fulfilled, the competent authority may include the operator's non-rail services, including bus services in the public service contract that will be directly awarded to the operator, provided that the Member State in question gives its approval and informs the Commission of this, with reasoned justification including appropriate comparative performance indicators.

5. Competent authorities may decide, on a case-by-case basis, to directly award public service contracts for services with an estimated average annual value of less than EUR 400 000. If a competent authority incorporates all its public service requirements in a single public service contract, it may decide to directly award this public service contract provided that it has an estimated average annual value of less than EUR 800 000.

No requirement for a given amount of services shall be split up in order to avoid tendering.

6. If an operator proposes a new initiative that will provide a service where none exists, the competent authority may award the exclusive right to provide this new service directly to that operator, provided that the service will not be subject to financial compensation under the terms of any public service contract.

No service may be the subject of the direct award of a public service contract under the terms of the first subparagraph more than once.

*Article 8*

**Award of public service contracts following quality comparison**

A competent authority may, without tendering, award a public service contract for a service that is limited to an individual route and that will not be subject to financial compensation under the terms of any public service contract, provided that:

(a) a notice has been published inviting proposals; and

(b) on that basis the authority has selected, by means of a comparison of the quality of the proposals received, the operator or operators that will provide the best service to the public.

*Article 9*

**Safeguards**

1. A competent authority may require the selected operator to award subcontracts, for a defined proportion of the services covered by the contract, to third parties to which it is not affiliated. This requirement to subcontract may not extend to more than half the value of the services covered by the contract.

2. A competent authority may decide not to award public service contracts to any operator that would, as a consequence, have more than a quarter of the relevant market for public passenger transport services.

3. Where a public service contract includes an exclusive right, the competent authority may require the selected operator to offer to staff previously engaged in providing the services the rights that they would have enjoyed if a transfer had occurred within the meaning of Directive 77/187/EEC. The authority shall list the staff and give details of their contractual rights.

4. Competent authorities may require the selected operator to establish itself in the Member State in question, except where Community legislation adopted pursuant to Article 71 of the Treaty lays down the freedom to provide services. However, competent authorities awarding public service contracts shall not discriminate against potential operators established in other Member States on the grounds that they are not yet established in the Member State in question or have not yet been granted a licence to operate services.

5. Where competent authorities apply any of the conditions in paragraphs 1 to 4, they shall inform potential operators of all the relevant details at the start of the public service contract award procedure.

CHAPTER IV

**MINIMUM CRITERIA FOR PUBLIC PASSENGER TRANSPORT OPERATION**

*Article 10*

Without prejudice to public service contracts concluded in accordance with Chapter III, competent authorities may lay down general rules or minimum criteria to be adhered to by all operators. Those rules or criteria shall be applied without discrimination to all transport services of a similar character in the geographical area for which the authority is responsible. Such general rules or minimum criteria may include compensation for the cost of complying with them, provided that:

(a) if the rule or criterion limits tariffs, it does so only for certain categories of passengers;

(b) in any one year, the amount of compensation for complying with general rules or minimum criteria that is received by any operator in the area covered by the rule or criterion in question shall be no more than one-fifth of the value of that operator's services in that area; and

(c) compensation is available to all operators on a non-discriminatory basis.

CHAPTER V

**PROCEDURAL ISSUES**

*Article 11*

**Notification**

Compensation paid in accordance with this Regulation shall be exempt from the notification procedure laid down in Article 88(3) of the Treaty.

*Article 12*

**Award procedures**

1. The procedure adopted for competitive tendering or quality comparison shall be fair, open and non-discriminatory.

2. The procedure shall include publication in accordance with Article 13.

3. In the case of competitive tendering, the procedure shall include:

(a) selection criteria, taking into account the criteria in Article 4(2), that define the authority's minimum requirements;

(b) award criteria, taking into account the criteria in Article 4(2), that define the grounds on which the authority will choose among offers meeting the selection criteria; and

(c) technical specifications setting out the public service requirements that the contract will cover and identifying any assets to be placed at the disposal of the successful tenderer with the relevant terms and conditions.

There shall be an interval of at least 52 days between the despatch of the call for tenders and the latest date for receipt of tenders.

4. Competent authorities shall include in the information which they supply to potential operators the relevant information they hold, under the terms of public service contracts, about operators' services, tariffs and numbers of passengers during the previous five years.

*Article 13*

**Transparency**

1. Notices, decisions and preliminary decisions made in accordance with this Regulation shall be published in an appropriate manner, stating, in the case of decisions and preliminary decisions, the reasons on which they are based.

2. Competent authorities shall send to the Office for Official Publications of the European Communities, by the most appropriate channels, notices and decisions relating to public service contracts and compensation schemes having an estimated annual value of, respectively, EUR 400 000 or more, or EUR 800 000 or more, for publication in the *Official Journal of the European Communities*.

The higher threshold value cited in the first subparagraph shall apply only if a competent authority has incorporated all its public service requirements in a single public service contract.

3. Competent authorities shall make available, on request:

(a) the terms of any public service contracts they have awarded;

(b) the terms of any general rules for public transport operation they have laid down; and

(c) the information they hold, under the terms of public service contracts, about operators' services, tariffs and numbers of passengers.

4. Authorities shall keep, for at least ten years, a record of every public service contract award procedure sufficient to permit them to justify their decisions at a later date. They shall make available, on request by interested parties, summaries of these records.

5. Member States shall forward to the Commission, by the end of the month of March each year:

(a) a summary for the previous year of the number, estimated value and duration of the public service contracts that competent authorities have awarded, distinguishing between rail, bus and inland waterway services and between contracts awarded following tendering, quality comparison and direct award; and

(b) a summary of the scope and content of the general rules or minimum criteria that were in force during the previous year and for which compensation was provided, and of the amount of compensation paid.

*Article 14*

**Appeals**

1. Member States shall ensure that operators and other interested parties have the right to appeal to a public body against decisions and preliminary decisions of competent authorities under this Regulation. This body shall be independent, in its organisation, funding, legal structure and decision-making, from any competent authority concerned and from any operator.

2. Appeal bodies shall have the power to request relevant information from competent authorities, undertakings and any third party involved within the Member State concerned. This information shall be supplied without undue delay.

3. Appeal bodies shall be required to determine any complaints and to take action to remedy the situation within a maximum period of two months from receipt of all information.

4. Subject to paragraph 5, decisions of appeal bodies shall be binding on all parties covered by such decisions.

5. Member States shall take measures necessary to ensure that decisions taken by appeal bodies are subject to judicial review.

*Article 15*

**Accounting provisions**

1. Services subject to public service contracts concluded with a particular competent authority shall be treated as a separate activity for accounting purposes and shall be operated as a separate accounting division, distinct from any other activities in which the undertaking engages, whether or not those activities are related to passenger transport.

2. Each accounting division shall meet the following conditions:

(a) the operating accounts shall be separate;

(b) the proportions of overheads, assets and liabilities pertaining to each activity shall be attributed according to their actual use;

(c) the cost accounting principles according to which separate accounts are maintained shall be clearly established;

(d) for each activity, expenditure shall be balanced by operating revenue from the services in question and payments from public authorities in compensation for the cost of fulfilling the public service requirements in question, without any possibility of transfer to another activity.

3. Operators receiving compensation for compliance with minimum criteria for transport operation in accordance with Article 10 shall, in their accounts, identify separately the costs they incur in complying with the general rule or criteria in question; the additional revenue they earn as a result of complying with the rule or criteria; and the compensation paid. The compensation paid and the additional revenue earned shall balance the costs incurred, without any possibility of transfer to an activity not subject to the rule or criteria in question.

CHAPTER VI

**FINAL PROVISIONS**

*Article 16*

**Compensation**

Except in the case of public service contracts awarded through competitive tendering, competent authorities shall on no account provide more compensation or apply less stringent procedures than are required by the rules in Annex I.

*Article 17*

**Transitional measures**

1. Member States shall take the necessary measures to ensure that schemes, contracts or arrangements implemented otherwise than in compliance with the provisions of this Regulation cease to be valid within three years of its entry into force.

2. Where an operator, on the date on which this Regulation enters into force, is required by the terms of a public service contract to invest in rail infrastructure, and where the payback period of this infrastructure still has more than three years to run, the competent authority may add up to three years to the transitional period of three years fixed in paragraph 1, taking into account this payback period and the relative economic importance of the assets in question in comparison with the total estimated value of the services covered by the contract.

3. Until the date on which the schemes, contracts and arrangements referred to in paragraphs 1 and 2 cease to be valid, each of them shall continue to be subject to those provisions of Regulation (EEC) No 1191/69 that applied to it before this Regulation entered into force.

*Article 18*

**Operators from countries listed in Annex II**

For the purposes of this Regulation and without prejudice to Article 9(4), operators from the countries listed in Annex II shall be treated as Community companies, in accordance with the terms and conditions of the agreement between each such country and the Community. The Commission shall update the Annex, as changes in the Community's international obligations require, by publishing a notice in the 'L' series of the *Official Journal of the European Communities*.

*Article 19*

**Monitoring by Commission**

1. Member States shall consult the Commission on any laws, regulations or administrative provisions that are necessary for the implementation of this Regulation.

2. The Commission shall prepare a report within five years of its entry into force on how this Regulation has been applied in the Member States, and the consequences for passengers, and shall propose amendments to the Regulation if necessary. The report shall include an examination of the operation of the exemption established in Article 7(4).

*Article 20*

**Repeal and amendment**

1. Regulation (EEC) No 1191/69 is repealed.

2. Article 3(2) of Regulation (EEC) No 1107/70 is deleted.

*Article 21*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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*ANNEX I*

**Rules governing compensation in the absence of competitive tendering**

1. Where a competent authority compensates an operator financially for fulfilling a public service requirement in accordance with this Regulation, and where the compensation is not derived from a public service contract awarded by competitive tendering, the amount of this compensation shall not exceed the net financial effect of fulfilling the public service requirement as calculated in accordance with the rules in this Annex.

2. The net financial effect shall be the sum of:

   (i) the effects of fulfilling the public service requirement on the operator's expenditure (costs avoided minus extra expenditure incurred); and

   (ii) the effects of fulfilling the public service requirement on the operator's income (extra income earned minus income foregone).

3. The net financial effect shall be determined taking into account the effects of fulfilling the public service requirement on the operator's activities as a whole.

4. The net financial effect shall be calculated by comparing the situation in which the public service requirement is fulfilled with the situation that would have occurred if the requirement had not been fulfilled and the operation of the services affected by the requirement had instead been determined on a commercial basis.

5. For the situation that would have occurred if the public service requirement had not been fulfilled (the benchmark case) estimates of tariff rates, passenger figures, and costs should be calculated.

6. The benchmark case may be calculated:

   (i) by using data on the situation before the operator began to fulfil the public service requirement, if circumstances have not changed to a degree that makes it an unreliable guide to present-day tariff rates, passenger figures, and costs; or

(ii) by comparison with data for comparable services that are operated on a commercial basis; or

(iii) by estimating costs and demand for the services.

The calculation of the benchmark case should take due consideration of trends affecting the relevant transport market.

7. Calculation of the effects on revenues of fulfilling a public service requirement shall take into account, in particular, changes in tariffs and in passenger figures. The calculation shall take into account the effect of fulfilling the requirement, and the resulting changes in the quality, quantity and price of services supplied, on the demand for transport services. This assessment shall not be limited to the impact on the segment of the network on which the requirement is directly fulfilled, but shall include effects on other parts of the network.

8. Calculation of the effects on costs of fulfilling a public service requirement shall be analogous to the calculation of the effects on revenues. Where the requirement covers only some of the services that an operator provides, joint costs such as overheads shall be allocated between these services and the others in proportion to the value of each set of services.

9. Costs resulting from the fulfilment of public service requirements shall be calculated on the basis of efficient management of the operator and the provision of transport services of an adequate quality.

The amount of compensation shall be fixed in advance for the duration of the contract or compensation scheme, with the exception that the contract or scheme may provide for the amount of compensation to be adjusted based on predetermined factors. Compensation amounts shall in any case remain fixed for a period of at least one year.

Compensation for complying with public service requirements may only be given where the operator in question, if it were considering its own commercial interests, would not, in the absence of this compensation, fulfil the requirement or would not fulfil it to the same extent or under the same conditions.

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*ANNEX II*

**Countries from which operators shall be treated as Community companies for the purposes of this Regulation in accordance with Article 18**

Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia.

# Proposal for a Regulation of the European Parliament and of the Council concerning the granting of aid for the coordination of transport by rail, road and inland waterway

(2000/C 365 E/11)

**(Text with EEA relevance)**

*COM(2000) 5 final — 2000/0023(COD)*

*(Submitted by the Commission on 28 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 71, 73 and 89 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The elimination of disparities liable to distort the conditions of competition in the transport market is an essential objective of the common transport policy.

(2) Significant progress has now been made in the liberalisation of the inland transport sectors:

(a) in the road haulage sector competition was introduced to international operations on 1 January 1993, and cabotage operations, first introduced on 1 July 1990, are from 1 July 1998 on no longer subject to any quota [1],

(b) the transport of passengers by road is liberalised with the exemption of national regular services [2],

(c) in the railways sector access to infrastructure for international groupings and railway undertakings offering international combined transport services has been introduced, and management independence and separation of accounts for infrastructure and services have been provided for [3],

(d) the inland waterways sector has been progressively liberalised leading to the free conclusion of contracts and free negotiation of prices as regards both national and international inland waterway transport in the Community from 1 January 2000 [4], and

(e) the market for combined transport services has been fully liberalised since 1 July 1993 [5].

(3) However the process of liberalisation in all inland transport sectors is not complete, and moreover harmonised charging mechanisms to compensate for the unpaid costs of transport modes have not yet been established. In those circumstances there is liable to exist State aid which meets the needs of coordination of transport and which for this reason remains compatible with the EC Treaty insofar as the aid does not infringe other provisions of Community law.

[1] Council Regulation (EEC) No 4059/89 of 21 December 1989 laying down the conditions under which non-resident carriers may operate national road haulage services within a Member State (OJ L 390, 30.12.1989, p. 3) replaced by Council Regulation (EEC) No 118/93 of 25 October 1993 laying down the conditions under which non-resident carriers may operate national road haulage services within a Member State (OJ L 279, 12.11.1993, p. 1) and Council Regulation (EEC) No 881/92 of 26 March 1992 on access to the market in the carriage of goods by road within the Community to or from the territory of a Member State or passing across the territory of one or more Member States (OJ L 95, 9.4.1992, p. 1) respectively.

[2] Council Regulation (EEC) No 684/92 of 16 March 1992 on common rules for the international carriage of passengers by coach and bus (OJ L 74, 20.3.1992, p. 1) as last amended by Council Regulation (EC) No 11/98 of 11 December 1997 (OJ L 4, 8.1.1998, p. 1) and Council Regulation (EC) No 12/98 of 11 December 1997 laying down the conditions under which non-resident carriers may operate national road passenger transport services within a Member State (OJ L 4, 8.1.1998, p. 10).

[3] Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways (OJ L 237, 24.8.1991, p. 25).

[4] Council Directive 96/75/EC of 19 November 1996 on the systems of chartering and pricing in national and international inland waterway transport in the Community (OJ L 304, 27.11.1996, p. 12).

[5] Council Directive 92/106/EEC of 7 December 1992 on the establishment of common rules for certain types of combined transport of goods between Member States (OJ L 68, 17.12.1992, p. 38).

(4) Articles 87 to 89 EC Treaty and Council Regulation (EC) No 659/1999 laying down detailed rules for the application of Article 93 (new Article 88) [1] shall apply to aid intended for transport by rail, road, and inland waterway.

(5) Article 73 provides an exemption from the prohibition contained in Article 87(1) and accordingly this Regulation does not prejudge the prior question as to whether there is aid in the sense of Article 87(1). This regulation is also without prejudice to other Treaty articles such as Article 86(2).

(6) Insofar as Article 73 EC Treaty declares aid compatible with the common market which represents reimbursement for the discharge of obligations inherent in the concept of a public service, it is implemented by Council Regulation (EEC) No 1191/69 [2] as modified. Insofar as Article 73 declares aid compatible with the common market which meets the needs of coordination of transport it accordingly remains appropriate to lay down in a Council Regulation the circumstances in which aids shall be considered to meet such needs.

(7) Council Regulation EEC) No 1107/70 [3] was designed to achieve the aims described above; whereas, however, it is now necessary to adapt it to fit the framework on access to the market now in force.

(8) It is now Community policy to encourage public/private partnerships for new transport infrastructure projects, particularly in the case of projects seen as important to the development of the trans-European network [4]. The State aid rules should be applied in such a way as not to penalise those infrastructure projects which contain some private sector participation as against those which do not; whereas, accordingly, it is appropriate to provide a general exception for aid to infrastructure managers rather than one targeted at specific kinds of projects.

(9) Public financing of the management, maintenance or provision of inland transport infrastructure open to all potential users in accordance with Community law and managed by the State does not fall under Article 87(1) EC Treaty as in this case no advantage is conferred to an undertaking competing with other undertakings.

(10) State support granted to an infrastructure manager, public or private but separate from the State, for the management, maintenance or provision of inland transport infrastructure is presumed to be compatible with the common market if that manager was chosen by an open and non-discriminatory tender, as it was thereby assured that the amount of State support represents the market price to achieve the desired result.

(11) However, if any particular aid to a manager of infrastructure does not fall under this presumption of compatability, it should still be permitted as compatible with the EC Treaty to the extent it is necessary to enable the realisation of the project or activity concerned and provided it does not give rise to a distortion of competition to an extent contrary to the common interest. By way of example, State support for the construction and operation of combined transport terminal infrastructure liable to attract significant traffic flows from competing terminals instead of leading to modal shift from road to environmentally friendly modes of transport, is deemed to distort competition to an extent contrary to the common interest.

(12) Furthermore, the requirements of any Community legislation on infrastructure charging that may be in force should be taken into account in assessing the amount of aid that is proportionate. In the rail sector this approach is compatible with Article 7(3) of Council Directive 91/440/EEC, which provides that Member States may accord railway infrastructure managers, having regard to Articles 73, 87 and 88 EC Treaty, financing consistent with the tasks, size and financial requirements, in particular in order to cover new investments, and whereas the same principles should apply to infrastructure managers in all inland transport sectors.

(13) The Community has for some time advocated a policy of achieving a sustainable transport system, which permits and encourages measures to compensate for unpaid additional costs of other competing transport modes, such as infrastructure damage, pollution, noise, congestion, health and accident costs.

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[1] Council Regulation (EC) No 659/99 of 22 March 1999 laying down detailed rules for the application of Article 93 of the Treaty, (OJ L 83, 27.3.1999, p. 1).

[2] Council Regulation (EEC) No 1191/69 of 26 June 1969 on action by Member States concerning the obligations inherent in the concept of a public service in transport by rail, road and inland waterway (OJ L 156, 28.6.1969, p. 1).

[3] Council Regulation (EEC) No 1107/70 of the Council of 4 June 1970 on the granting of aids for transport by rail, road and inland waterway (OJ L 130, 15.6.1970, p. 1).

[4] Council conclusions of the 2031st Council meeting — Transport, paragraphs 4 and 5 on Public-Private Partnerships (PPPs) in the context of trans-European network (TEN) projects, 11007/97 (Press release: Luxembourg 9.10.1997).

(14) With regard to the transport of goods, aid schemes which provide for such measures in connection with the use of infrastructure and which do not disproportionately hamper the attainment of other Community objectives, should be supported. Accordingly Member States should be required to demonstrate with a reasonable degree of transparency that such schemes compensate for specific incremental unpaid costs of competing modes of transport and they should be limited in time. However, until internalisation of specific unpaid external and infrastructure costs is achieved within or across land transport modes, any such State scheme authorised by the Commission may in principle be renewed. With regard to passenger transport this issue can be taken into account when transport operators apply for exclusive rights or financial compensation in accordance with Community legislation and in particular, Council Regulation (EEC) No 1191/69.

(15) Other aid provided in liberalised sectors should be considered under Article 87 EC Treaty, particularly under the notion of development of a sector set out in subparagraph (3)(c) thereof.

(16) Aid granted under this Regulation is notifiable in accordance with Article 87(3) EC Treaty and Council Regulation (EC) No 659/1999 laying down detailed rules for the application of Article 93 (new 88) of the Treaty, except where this Regulation provides otherwise.

(17) Aid for the management, maintenance or provision of infrastructure other than combined transport, inland waterway and road terminals which forms an integral part of an existing open transport network having a single infrastructure manager can be monitored effectively by the Commission on the basis of a periodic general information requirement rather than a specific pre-notification requirement.

(18) However, in the case of aid for the management, maintenance or provision of the aforementioned terminals, or where the infrastructure concerned has a manager separate from the network manager, or where its capacity is wholly or partly reserved to one or more transport undertakings (as opposed to the granting of an access right on open infrastructure), there may be a greater impact on competition and therefore the pre-notification requirement should not be removed.

(19) To ensure transparency and effective monitoring, it is appropriate to establish rules concerning the records that Member States should keep regarding the aid exempted by this Regulation. For the purposes of the annual report to be provided to the Commission by Member States, it is appropriate for the Commission to establish its specific requirements, including, having regard to the wide availability of the necessary technology, information in computerised form.

(20) Council Regulation (EEC) No 1192/69 [1] was introduced to eliminate disparities which arise by reason of the imposition of exceptional financial burdens on, or the grant of benefits to, railway undertakings by public authorities. However, following Council Directive 91/440/EEC Member States are now required to ensure that railway undertakings are afforded a status of independent operators behaving in a commercial manner and adapting to market needs, and therefore such disparities have either been eliminated or should be eliminated.

(21) Article 4, paragraphs (2), (3) and (4) of Council Regulation (EEC) No 1192/69 have become obsolete. Insofar as Member States continue to support railway undertakings under Article 4(1) of Council Regulation (EEC) No 1192/69 for a transitional period, the Commission will have to assure that such support is strictly limited to an amount necessary to compensate railway undertakings for the remaining financial burdens and it is therefore required that such compensation is notified to it under Article 88(3) EC Treaty. The exemption from the notification obligation contained in Regulation (EEC) No 1192/69 should be revoked,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Scope**

This Regulation shall apply to aid, which meets the needs of coordination of transport by rail, road and inland waterway.

*Article 2*

**Definitions**

In this Regulation the following terms have the following meanings:

— *transport infrastructure:* permanent facilities for the movement or transhipment of passengers and goods and associated safety and navigational assets essential for the management of these facilities,

— *infrastructure manager:* any public, private or mixed public/private undertaking managing, maintaining or providing transport infrastructure,

[1] Council Regulation (EEC) No 1192/69 of 26 June 1969 on common rules for the normalisation of the accounts of railway undertakings (OJ L 156, 28.6.1969, p. 8).

— *transport undertaking:* any undertaking wishing to make use of any particular transport infrastructure, whether solely for its own benefit or in order to provide services to other persons or undertakings,

— *specific unpaid external and infrastructure costs:* costs not recovered from the user of transport infrastructure through specific charges. They may include infrastructure damage, pollution, noise, congestion, health and accident costs.

*Article 3*

**Aid for infrastructure**

1. Aid granted to an infrastructure manager for the management, maintenance or provision of inland transport infrastructure, shall be compatible with the EC Treaty provided that the aid compared to the total financing of the project:

(a) is necessary to enable the realisation of the project or activity concerned and

(b) does not give rise to a distortion of competition to an extent contrary to the common interest.

2. Assessment under this Article shall take into account the requirements of any Community legislation on infrastructure charging that may be in force at the time of the grant of the aid concerned.

*Article 4*

**Aid for the use of infrastructure**

1. A scheme for granting aid to transport undertakings for the purpose of the use of infrastructure for goods transport, shall be compatible with the EC Treaty to the extent that:

(a) the scheme has a maximum duration of three years,

(b) it is demonstrated on the basis of a comparative cost analysis that such aid is limited to compensation for specific unpaid external and infrastructure costs for the use of competing transport infrastructure, net of any such unpaid costs for the use of the infrastructure in question,

(c) the scheme provides for aid to be granted on non-discriminatory terms to transport undertakings within the same transport mode, and

(d) the aid does not give rise to a distortion of competition to an extent contrary to the common interest.

2. Assessment under this Article shall take into account the requirements of any Community legislation on the definition or estimation of external costs that may be in force at the time of the grant of the aid concerned.

*Article 5*

**General conditions**

1. Where an undertaking receiving any aid granted under this Regulation is not only engaged in the subsidised activity but also in another economic activity, the funds provided shall be kept in separate accounts and shall be managed without any possibility of transfer to such other activity.

2. In calculating the permissible amount of aid to be granted under any provision of this Regulation any aid granted for the same purpose coming from any other State or Community resources shall be taken into account.

*Article 6*

**Notification**

1. Aid, granted for the management, maintenance or provision of inland transport infrastructure other than terminals for combined transport, inland waterway or road operations shall not be required to be notified in accordance with Article 88(3) EC Treaty where the following conditions are satisfied:

(a) the infrastructure forms an integral part of a network which has the same manager as the infrastructure concerned and access to which is open on non-discriminatory terms to any person or undertaking wishing to use it,

(b) the capacity of the infrastructure is not wholly or partly reserved for the use of one or more transport undertakings.

2. Unimodal railway terminals and stations are considered to form an integral part of the railway network.

*Article 7*

**Information requirements**

1. In relation to aid falling within Article 6, Member States

(a) shall maintain detailed records. Such records shall contain all information necessary to establish that the conditions for exemption, as laid down in this Regulation, are fulfilled. Member States shall maintain a record for 10 years from the date on which the aid was granted. Member States shall, on written request, provide the Commission with copies of such records within a period of 20 working days, or such longer period as may be fixed in the Commission's request and

(b) are hereby required to provide the Commission on an annual basis, not later than 31 March for the preceding calendar year, with a summary information on aid schemes implemented and individual aid granted outside such schemes in the form provided for in the Annex and in particular with:

— a description of the supported project including the exact amount of the aid, the overall project costs, the identity of the beneficiary and the timing,

— future plans or arrangements for management of the infrastructure concerned and for access to the infrastructure concerned, and

— any other information likely to be relevant to a State aid assessment.

2. The first date on which such information will be provided shall be 31 March of the year following the first full calendar year to elapse after the entry into force of this Regulation. The information provided on that date should relate to the period from the date of entry into force of this Regulation until the end of such calendar year and should also be provided in a computerised form.

*Article 8*

**Monitoring of this Regulation**

An Advisory Committee is hereby established subject to Article 79 EC Treaty. It shall be composed of representatives of the Member States and chaired by the representative of the Commission. The Committee may examine and give an opinion on all general questions regarding the operation of this Regulation.

*Article 9*

**Revocation**

1. Council Regulation (EEC) No 1107/70, as modified, is hereby revoked.

2. Articles 4(2), 4(3), 4(4), 13(2) and 13(3) of Council Regulation (EEC) No 1192/69, as modified, shall be deleted.

*Article 10*

**Transitional arrangements and entry into force**

1. Aid measures, which by virtue of Article 5 of Regulation (EEC) No 1107/70, as amended, have been exempted from the procedure provided for in Article 88(3) of the Treaty, shall remain exempted for a period of 12 months after the entry into force of this Regulation.

2. Member States shall amend such aid measures during this period so as to be made compatible with Article 6 of this Regulation and shall inform the Commission thereof.

3. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*. This Regulation shall be binding in its entirety and directly applicable in all Member States.

*ANNEX*

**Form accompanying the summary information on any individual aid granted or aid schemes implemented**

Member State (Region):

Date of implementation (aid scheme) or grant (individual aid):

Name and address of responsible authority:

Title of aid scheme implemented or name of beneficiary granted individual aid:

Objective of aid:

Legal basis:

Budget:

Aid intensity

Duration:

Other information (optional):

# Proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment

(2000/C 365 E/12)

**(Text with EEA relevance)**

*COM(2000) 347 final — 2000/0158(COD)*

*(Submitted by the Commission on 28 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The objectives of the Community's environment policy are, in particular, to preserve, protect and improve the quality of the environment, protect human health and utilise national resources prudently and rationally. That policy is based on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

(2) The Community programme of policy and action in relation to the environment and sustainable development ('Fifth Environmental Action Programme') [1] states that the achievement of sustainable development calls for significant changes in current patterns of development, production, consumption and behaviour and advocates, *inter alia*, the reduction of wasteful consumption of natural resources and the prevention of pollution. It mentions waste electrical and electronic equipment (WEEE) as one of the target areas to be regulated, in view of the application of the principles of prevention, recovery and safe disposal of waste.

(3) The Commission communication of 30 July 1996 on review of the Community strategy for waste management [2] states that, where the generation of waste cannot be avoided, it should be reused or recovered for its material or energy.

(4) The Council, in its Resolution of 24 February 1997 on the Community strategy for waste management [3], invited the Commission to develop, as soon as possible, an appropriate follow-up to the projects of the priority waste streams programme, including WEEE.

(5) The European Parliament, in its resolution of 14 November 1996 [4] asked the Commission to present proposals for Directives on a number of priority waste streams, including electrical and electronic waste, and to base such proposals on the principle of producer responsibility. The European Parliament, in the same resolution, requests the Council and the Commission to put forward proposals for cutting the volume of waste.

(6) Council Directive 75/442/EEC of 15 July 1975 on waste [5], as last amended by Commission Decision 96/350/EC [6], provides that specific rules for particular instances or supplementing those of Directive 75/442/EEC on the management of particular categories of waste may be laid down by means of individual Directives.

(7) The amount of WEEE generated in the Community is growing rapidly, the content of hazardous components in electrical and electronic equipment is a major concern during the waste management phase and recycling of WEEE is not undertaken to a sufficient extent.

(8) The objective of improving the management of WEEE cannot be achieved effectively by Member States acting individually. In particular, different national applications of the producer responsibility principle lead to substantial disparities in the financial burden on economic operators. Having different national policies on the management of WEEE hampers the effectiveness of national recycling policies.

(9) The provisions of this Directive should apply to products and producers irrespective of the selling technique, including distance and electronic selling.

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[1] OJ C 138, 17.5.1993, p. 5.

[2] COM(96) 399 final.

[3] OJ C 76, 11.3.1997, p. 1.

[4] OJ C 362, 2.12.1996, p. 241.

[5] OJ L 194, 25.7.1975, p. 39.

[6] OJ L 135, 6.6.1996, p. 32.

(10) This Directive should cover all electrical and electronic equipment used by consumers and electrical and electronic equipment intended for professional use which are likely to end up in the municipal waste stream. This Directive should apply without prejudice to Community legislation on safety and health requirements and specific Community waste management legislation, in particular Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances ([1]), as amended by Commission Directive 98/101/EC ([2]).

(11) It is necessary to draw up as quickly as possible provisions concerning the design and manufacture of electrical and electronic equipment to minimise their impact on the environment during their life cycle. In the interest of overall consistency between Directives relevant to electrical and electronic equipment, those provisions should be drawn up in accordance with the principles set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards ([3]).

(12) Separate collection is the precondition to ensure specific treatment and recycling of WEEE and is necessary to achieve the chosen level of protection of human and animal health and the environment in the Community. Consumers have to actively contribute to the success of such collection and should be encouraged to return WEEE. For this purpose, convenient facilities should be set up for the return of WEEE, including public collection points, where private households should be able to return their waste free of charge.

(13) A collection target for WEEE used by private households should be fixed in order to attain the chosen level of protection and harmonised environmental objectives of the Community and more specifically to ensure that Member States strive to set up efficient collection schemes.

(14) Specific treatment for WEEE is indispensable in order to avoid the dispersion of pollutants into the recycled material or the waste stream. Such treatment is the most effective means of ensuring compliance with the chosen level of protection of the environment of the Community. Recycling facilities should comply with certain minimum standards to prevent negative environmental impacts associated with the treatment of WEEE.

(15) A high level of recovery, in particular re-use or recycling, should be achieved and producers encouraged to integrate recycled material in new equipment.

(16) Basic principles with regard to the financing of WEEE management have to be set at Community level and financing schemes have to contribute to high collection rates as well as to the implementation of the principle of producer responsibility. In order to achieve the benefits of the producer responsibility concept most efficiently, producers should be encouraged to fulfil their responsibility individually, provided that they contribute to the financing of the management of waste from products put on the market before the entry into force of the financing obligation introduced by this Directive.

(17) Users of electrical and electronic equipment from private households should have the possibility of returning WEEE free of charge. Producers should therefore finance the treatment, recovery and disposal of WEEE. In order to reduce costs for producers resulting from the management of waste from products already on the market ('historical waste'), a transitional period should be laid down. The responsibility for the financing of the management of historical waste should be shared by all existing producers and fulfilled through either individual or collective systems. Collective systems should not have the effect of excluding niche and low-volume producers, importers and new entrants.

(18) Information to users about the collection systems and their role in the management of WEEE is indispensable for the success of WEEE collection. Such information implies the proper marking of electrical and electronic equipment which could end up in rubbish bins or similar means of municipal waste collection.

(19) Information on treatment facilities provided by producers is important to facilitate the management, and in particular the treatment, of WEEE.

(20) Information about the numbers and weight of items of electrical and electronic equipment put on the market in the Community and the rates of collection and recycling of WEEE is necessary to monitor the success of collection schemes.

(21) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([4]), they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

([1]) OJ L 78, 26.3.1991, p. 38.

([2]) OJ L 1, 5.1.1999, p. 1.

([3]) OJ C 136, 4.6.1985, p. 1.

([4]) OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Objectives**

The purpose of this Directive is, as a first priority, the prevention of waste electrical and electronic equipment (WEEE), and in addition, the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all economic operators involved in the life cycle of electrical and electronic equipment and in particular operators directly involved in the treatment of waste electrical and electronic equipment.

*Article 2*

**Scope**

1. This Directive shall apply to electrical and electronic equipment falling under the categories set out in Annex I A.

2. Article 4(1), (3), (4) and (5), and Articles 7 and 9 shall not apply to electrical and electronic equipment falling under categories 8, 9 and 10 of Annex I A.

3. This Directive shall apply without prejudice to Community legislation on safety and health requirements and specific Community waste management legislation.

*Article 3*

**Definitions**

For the purposes of this Directive, the following definitions shall apply:

(a) 'electrical and electronic equipment' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields falling under the categories set out in Annex I A and designed for use with a voltage rating not exceeding 1 000 volt for alternating current and 1 500 volt for direct current;

(b) 'waste electrical and electronic equipment' or 'WEEE' means electrical or electronic equipment which is waste within the meaning of Article 1(a) of Directive 75/442/EEC, including all components, sub-assemblies and consumables, which are part of the product at the time of discarding;

(c) 'prevention' means measures aimed at reducing the quantity and the harmfulness to the environment of WEEE and materials and substances contained therein;

(d) 're-use' means any operation by which WEEE is used for the same purpose for which it was conceived, including the continued use of WEEE which is returned to collection points, distributors, recyclers or manufacturers;

(e) 'recycling' means the reprocessing in a production process of the waste materials for the original purpose or for other purposes, but excluding energy recovery;

(f) 'energy recovery' means the use of combustible waste as a means of generating energy through direct incineration with or without other waste but with recovery of the heat;

(g) 'recovery' means any of the applicable operations provided for in Annex II.B to Directive 75/442/EEC;

(h) 'disposal' means any of the applicable operations provided for in Annex II.A to Directive 75/442/EEC;

(i) 'treatment' means any activity after the WEEE has been handed over to a facility for depollution, disassembly, shredding, recovery or disposal and any other operation carried out for the recovery and/or the disposal of the WEEE;

(j) 'producer' means any person who:

(i) manufactures and sells electrical and electronic equipment under his own brand, irrespective of the selling technique used, including distance and electronic selling,

(ii) resells under his own brand equipment produced by other suppliers, irrespective of the selling technique used, including distance and electronic selling, or

(iii) imports electrical and electronic equipment on a professional basis into a Member State;

(k) 'distributor' means anyone who provides a product on a commercial basis to the party who is going to use that product;

(l) 'WEEE from private households' means WEEE which comes from private households and from commercial, industrial, institutional and other sources which, because of its nature and quantity, is similar to that from private households;

(m) 'dangerous substance or preparation' means any substance or preparation which has to be considered dangerous under Council Directive 67/548/EEC [1] or Directive 1999/45/EC of the European Parliament and of the Council [2].

[1] OJ L 196, 16.8.1967, p. 1.

[2] OJ L 200, 30.7.1999, p. 1.

*Article 4*

**Separate collection**

1. Member States shall ensure that systems are set up so that final holders and distributors can return WEEE from private households free of charge. They shall ensure the availability and accessibility of the necessary collection facilities, taking into account the population density.

2. Member States shall ensure that distributors, when supplying a new product, offer to take back free of charge similar WEEE from private households provided that the equipment is free from contaminants, including radioactive and biological contaminants.

3. Member States shall ensure that producers provide for the collection of WEEE from holders other than private households. They shall be allowed on a voluntary and individual basis to set up and operate take-back systems for WEEE from private households.

4. Member States shall ensure that all WEEE collected is transferred to authorised treatment facilities. The collection and transportation of separately collected WEEE shall be carried out in a way which ensures the suitability for re-use and recycling of those components or whole appliances which might be re-used and/or recycled.

5. Member States shall endeavour to achieve by 31 December 2005 at the latest a minimum rate of separate collection of four kilograms on average per inhabitant per year of WEEE from private households.

As soon as it is possible, on the basis of the information required under Article 11, to formulate a collection target of WEEE from private households as a percentage of the amount of electrical and electronic equipment sold to private households, the European Parliament and the Council, acting on a proposal from the Commission and taking account of technical and economic experience in the Member States, shall establish such a compulsory target.

*Article 5*

**Treatment**

1. Member States shall ensure that producers set up systems to provide for the treatment of WEEE. To ensure compliance with Article 4 of Directive 75/442/EEC, the treatment shall, as a minimum, include the removal of all fluids and a selective treatment in accordance with Annex II to the present Directive provided that the re-use and recycling of components or whole appliances is not hindered.

2. Member States shall ensure that any establishment or undertaking carrying out treatment operations obtains a permit from the competent authorities, in compliance with Articles 9 and 10 of Directive 75/442/EEC.

The derogation from the permit requirement referred to in Article 11(1)(b) of Directive 75/442/EEC may apply to recovery operations concerning WEEE if an inspection is carried out by the competent authorities before the registration in order to ensure compliance with Article 4 of Directive 75/442/EEC.

The inspection shall verify:

(a) the type and quantities of waste to be treated;

(b) the general technical requirements to be complied with;

(c) the safety precautions to be taken.

The inspection shall be carried out once a year and the results shall be communicated by the Member States to the Commission.

3. Member States shall ensure that any establishment or undertaking carrying out treatment operations stores and treats WEEE in compliance with the technical requirements set out in Annex III.

4. Member States shall ensure that the permit referred to in paragraph 2 includes all conditions necessary for compliance with the requirements of paragraphs 1 and 3 as well as Article 6.

5. The treatment operation may also be undertaken outside the respective Member State or the Community provided that the shipment of WEEE is in compliance with Council Regulation (EEC) No 259/93 [1].

*Article 6*

**Recovery**

1. Member States shall ensure that producers set up systems to provide for the recovery of separately collected WEEE in compliance with this Directive.

2. Member States shall ensure that, by 31 December 2005 at the latest, the following targets for separately collected waste are met by producers:

(a) For WEEE falling under category 1 (large household appliances) of Annex I A, the rate of recovery shall be increased to a minimum of 80 % by an average weight per appliance and component, material and substance re-use and recycling shall be increased to a minimum of 75 % by an average weight per appliance;

[1] OJ L 30, 6.2.1993, p. 1.

(b) For WEEE falling under categories 2, 4, 6 and 7 of Annex I A, with the exception of equipment that contains cathode-ray tubes, the rate of recovery shall be increased to a minimum of 60 % by weight of the appliances and component, material and substance re-use and recycling shall be increased to a minimum of 50 % by weight of the appliances;

(c) For WEEE falling under category 3 of Annex I A, with the exception of equipment that contains cathode-ray tubes, the rate of recovery shall be increased to a minimum of 75 % by weight of the appliances and component, material and substance re-use and recycling shall be increased to a minimum of 65 % by weight of the appliances;

(d) For gas discharge lamps, the rate of component, material and substance re-use and recycling shall reach a minimum of 80 % by weight of the lamps;

(e) For WEEE containing a cathode-ray tube, the rate of recovery shall be increased to a minimum of 75 % by an average weight per appliance and component, material and substance re-use and recycling shall be increased to a minimum of 70 % by an average weight per appliance.

3. By 31 December 2004 at the latest, the detailed rules for monitoring compliance by Member States with the targets referred to in paragraph 2 of this Article shall be adopted in accordance with the procedure referred to in Article 14(2).

4. The European Parliament and the Council, acting on a proposal from the Commission, shall establish targets for recovery, re-use and recycling for the years beyond 2008.

*Article 7*

**Financing in respect of WEEE from private households**

1. Member States shall ensure that holders of WEEE from private households can return such waste free of charge in accordance with Article 4.

2. Member States shall ensure that, five years after the entry into force of this Directive, producers provide for the financing of the collection of WEEE from private households deposited at collection facilities, set up under Article 4(1), as well as of the treatment, recovery and environmentally sound disposal of WEEE.

3. The financing referred to in paragraph 2 may be provided by means of collective or individual systems. There shall be no discrimination between producers who opt for collective systems and those who opt for individual systems.

The responsibility for the financing of the management of waste from products put on the market before the expiry of the period referred to in paragraph 2 ('historical waste') shall be shared by all existing producers. Where a producer who opts for an individual system cannot prove that he is discharging his responsibility with respect to a fair share of the historical waste, he shall contribute to the financing of an alternative system.

*Article 8*

**Financing in respect of WEEE from users other than private households**

Member States shall ensure that the financing of the costs for the collection, treatment, recovery and environmentally sound disposal of WEEE from users other than private households is covered by agreements between the producer and the user of the equipment at the time of purchase.

*Article 9*

**Information for users**

1. Member States shall ensure that users of electrical and electronic equipment in private households are given the necessary information about:

(a) the return and collection systems available to them;

(b) their role in contributing to re-use, recycling and other forms of recovery of WEEE;

(c) the meaning of the symbol shown in Annex IV.

2. Member States shall encourage consumers to contribute to collection, treatment and recovery of WEEE.

3. Member States shall ensure that, with a view to achieving a high rate of collection, producers appropriately mark electrical and electronic equipment which might normally be disposed of in rubbish bins or similar means of municipal waste collection with the symbol shown in Annex IV. In exceptional cases, where this is necessary because of the size or the function of the product, the symbol shall be printed on the packaging of the electrical and electronic equipment.

*Article 10*

**Information for treatment facilities**

Member States shall ensure that producers provide such information as is needed by treatment facilities to identify the different electrical and electronic equipment components and materials, and the location of dangerous substances and preparations in the electrical and electronic equipment.

*Article 11*

**Information requirements**

1. Member States shall provide to the Commission information on an annual basis on the quantities and categories of electrical and electronic equipment put on the market, collected and recycled within the Member States, both by numbers and by weight.

2. Member States shall ensure that the information required under paragraph 1 is transmitted to the Commission by 1 January 2007 and on a three-yearly basis thereafter. The information shall be provided in a format which shall be established within one year after the entry into force of this Directive in accordance with the procedure referred to in Article 14(2).

*Article 12*

**Reporting obligation**

Without prejudice to the requirements of Article 11, Member States shall send a report to the Commission on the implementation of this Directive at three-year intervals. The report shall be drawn up on the basis of a questionnaire or outline drafted by the Commission in accordance with the procedure laid down in Article 6 of Council Directive 91/692/EEC [1] with a view to establishing databases on WEEE and their treatment. The questionnaire or outline shall be sent to the Member States six months before the start of the period covered by the report. The report shall be made available to the Commission within nine months of the end of the three-year period covered by it.

The first report shall cover a period of three years from 1 January 2006.

The Commission shall publish a report on the implementation of this Directive within nine months after receiving the reports from the Member States.

*Article 13*

**Adaptation to scientific and technical progress**

Any amendments which are necessary in order to adapt Annexes II, III and IV to scientific and technical progress shall be adopted in accordance with the procedure referred to in Article 14(2).

*Article 14*

**Committee**

1. The Commission shall be assisted by the committee instituted by Article 18 of Directive 75/442/EEC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 15*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2004 (18 months after the date of adoption) at the latest. They shall immediately inform the Commission thereof.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of all existing laws, regulations and administrative provisions adopted in the field covered by this Directive.

*Article 16*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 17*

**Addressees**

This Directive is addressed to the Member States.

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[1] OJ L 377, 31.12.1991, p. 48.

*ANNEX I A*

**Categories of electrical and electronic equipment covered by this Directive**

1. Large household appliances
2. Small household appliances
3. IT & telecommunication equipment
4. Consumer equipment
5. Lighting equipment
6. Electrical and electronic tools
7. Toys
8. Medical equipment systems (with the exception of all implanted and infected products)
9. Monitoring and control instruments
10. Automatic dispensers

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*ANNEX I B*

**Indicative list of products which fall under the categories of Annex I A**

1. **Large household appliances**

Large cooling appliances

Refrigerators

Freezers

Washing machines

Clothes dryers

Dish-washing machines

Cooking

Electric stoves

Electric hot plates

Microwaves

Heating appliances

Electric heaters

Electric fans

Air conditioners

2. **Small household appliances**

Vacuum cleaners

Carpet sweepers

Irons

Toasters

Fryers

Coffee grinders

Electric knives

Coffee machines

Hair dryers

Tooth brushes

Shavers

Clocks

Scales

3. **IT & telecommunication equipment**

Centralised data processing:

Mainframes

Minicomputers

Printer units

Personal computing:

Personal computers (CPU, mouse, screen and keyboard included)

Lap-top computers (CPU, mouse, screen and keyboard included)

Note-book computers

Note-pad computers

Printers

Copying equipment

Electrical and electronic typewriters

Pocket and desk calculators

User terminals and systems

Facsimile

Telex

Telephones

Pay telephones

Cordless telephones

Cellular telephones

Answering systems

4. **Consumer equipment**

Radio sets (clock radios, radio-recorders)

Television sets

Videocameras

Video recorders

Hi-fi recorders

Audio amplifiers

Musical instruments

5. **Lighting equipment**

Luminaires

Straight fluorescent lamps

Compact fluorescent lamps

High intensity discharge lamps, including high-pressure sodium lamps and metal halide lamps

Low-pressure sodium lamps

Other lighting equipment

6. **Electrical and electronic tools**

Drills

Saws

Sewing machines

7. **Toys**

Electric trains or car-racing sets

Hand-held video game consoles

Video games

8. **Medical equipment systems (with the exception of all implanted and infected products)**

Radiotherapy equipment

Cardiology

Dialysis

Pulmonary ventilators

Nuclear medicine

Laboratory equipment for in-vitro diagnosis

Analysers

Freezers

9. **Monitoring and control instruments**

Smoke detectors

Heating regulators

Thermostats

10. **Automatic dispensers**

Automatic dispensers for hot drinks

Automatic dispensers for hot or cold bottles or cans

Automatic dispensers for solid products

*ANNEX II*

**Selective treatment for materials and components of waste electrical and electronic equipment in accordance with Article 5.1**

1. As a minimum, the following substances, preparations and components have to be removed from any separately collected WEEE:

   — PCB containing capacitors

   — Mercury containing components, such as switches

   — Batteries

   — Printed circuit boards

   — Toner cartridges, liquid and pasty, as well as colour toner

   — Plastic containing brominated flame retardants

   — Asbestos waste

   — Cathode-ray tubes

   — CFC, HCFC or HFCs

   — Gas-discharge lamps

   — Liquid crystal displays of a surface greater than 100 square centimetres and all those back-lighted with gas-discharge lamps

   These substances, preparations and components shall be disposed of or recovered in compliance with Article 4 of Council Directive 75/442/EEC.

2. The following components of WEEE that is separately collected has to be treated as indicated:

   — Cathode-ray tubes: The fluorescent coating has to be removed

   — Equipment containing CFC, HCFC or HFCs: The CFC present in the foam and the refrigerating circuit must be properly extracted and destroyed. HCFC or HFCs present in the foam and the refrigerating circuit must be properly extracted and destroyed or recycled

   — Gas-discharge lamps: The mercury shall be removed

*ANNEX III*

**Technical requirements in accordance with Article 5.3**

1. Sites for storage of WEEE (without prejudice to the requirements of Directive 1999/31/EC on the landfill of waste):

   — Impermeable surfaces

   — Weatherproof covering

2. Sites for treatment of WEEE:

   — Balances to measure the weight of the treated waste

   — Impermeable surfaces and waterproof covering for appropriate areas

   — Appropriate storage for disassembled spare parts

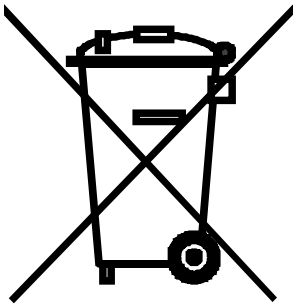
   — Appropriate containers for storage of batteries, PCB/PCT containing condensators and other hazardous waste

   — Equipment for the treatment of water, including rainwater

*ANNEX IV*

**Symbol for the marking of electrical and electronic equipment**

The symbol indicating separate collection for electrical and electronic equipment consists of the crossed-out wheeled bin, as shown below. The symbol must be printed visibly, legibly and indelibly.



# Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(2000/C 365 E/13)

**(Text with EEA relevance)**

*COM(2000) 347 final — 2000/0159(COD)*

*(Submitted by the Commission on 28 July 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The disparities between the laws or administrative measures adopted by the Member States as regards the restriction of the use of hazardous substances in electrical and electronic equipment could create barriers to trade and distort competition in the Community and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to approximate the laws of the Member States in this field.

(2) The objectives and principles of the Community's environment policy are, in particular, to prevent, reduce and as far as possible eliminate pollution.

(3) The Commission Communication of 30 July 1996 on the review of the Community strategy for waste management [1] stresses the need to reduce the content of hazardous substances in waste and points out the potential benefits of Community-wide rules limiting the presence of such substances in products and in production processes.

(4) The Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium [2] invites the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented. The Resolution stresses that the use of cadmium should be limited to cases where suitable and safer alternatives do not exist.

(5) The available evidence indicates that measures on the collection, treatment, recycling and disposal of waste electrical and electronic equipment (WEEE) as set out in Directive ... of the European Parliament and of the Council on waste electrical and electronic equipment are necessary to reduce the waste management problems linked to the heavy metals concerned and the flame retardants polybrominated biphenyls (PBB) and polybrominated diphenyl ether (PBDE). In spite of those measures, however, significant parts of WEEE will continue to be found in the current disposal routes. Even if WEEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, PBB and PBDE would be likely to pose risks to health or the environment.

(6) Taking into account technical and economic feasibility, the most effective way of ensuring the significant reduction of risks to health and the environment related to those substances which can achieve the chosen level of protection in the Community is the substitution of those substances in electrical and electronic equipment by safe or safer materials.

(7) The substances covered by this Directive are scientifically well researched and evaluated and have been subject to different measures both at Community and national level.

(8) The measures provided for in this Directive take into account existing international guidelines and recommendations and are based on an assessment of available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human and animal health and the environment, having regard to the risks which the absence of measures would be likely to create in the Community. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information.

[1] COM(96) 399 final.

[2] OJ C 30, 4.2.1988, p. 1.

(9) This Directive should apply without prejudice to Community legislation on safety and health requirements and specific Community waste management legislation, in particular Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances [1], as amended by Commission Directive 98/101/EC [2].

(10) The technical development of electrical and electronic equipment without heavy metals, PBDE and PBB should be taken into account.

(11) Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view or if the negative environmental or health impacts caused by substitution are likely to outweigh the human, animal and environmental benefits of the substitution. The health and safety of users of electrical and electronic equipment should also not be jeopardised by the substitution of the hazardous substances in electrical and electronic equipment.

(12) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Objectives**

The purpose of this Directive is to approximate the laws of the Member States on the restrictions of the use of hazardous substances in electrical and electronic equipment and to contribute to the environmentally sound recovery and disposal of waste electrical and electronic equipment.

*Article 2*

**Scope**

1. This Directive shall apply to electrical and electronic equipment falling under the categories set out in Annex I A to Directive . . . [on waste electrical and electronic equipment].

2. Article 4 shall not apply to electrical and electronic equipment falling under categories 8, 9 and 10 of Annex I A to Directive . . . [on waste electrical and electronic equipment].

3. This Directive shall apply without prejudice to Community legislation on safety and health requirements and specific Community waste-management legislation.

*Article 3*

**Definitions**

For the purposes of this Directive, the following definitions shall apply:

(a) 'electrical and electronic equipment' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 Volts for alternating current and 1 500 Volts for direct current;

(b) 'producer' means any person who manufactures and sells electrical and electronic equipment under his own brand, who resells under his own brand equipment produced by other suppliers or who imports that equipment on a professional basis into a Member State.

*Article 4*

**Prevention**

1. Member States shall ensure that with effect from 1 January 2008 the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ether (PBDE) in electrical and electronic equipment is substituted by other substances.

2. Paragraph 1 shall not apply to the applications of lead, mercury, cadmium and hexavalent chromium listed in the Annex.

*Article 5*

**Adaptation to scientific and technical progress**

1. Any amendments which are necessary in order to adapt the Annex to scientific and technical progress for the following purposes shall be adopted in accordance with the procedure referred to in Article 7(2):

(a) establishing, as necessary, maximum concentration values up to which the presence of the substances referred to in Article 4(1) in specific materials and components of electrical and electronic equipment shall be tolerated;

(b) exempting materials and components of electrical and electronic equipment from Article 4(1) if the use of the substances referred to therein in those materials and components is technically or scientifically unavoidable or where the negative environmental and/or health impacts caused by substitution are likely to outweigh the environmental benefits thereof;

[1] OJ L 78, 26.3.1991, p. 38.

[2] OJ L 1, 5.1.1999, p. 1.

[3] OJ L 184, 17.7.1999, p. 23.

(c) deleting materials and components of electrical and electronic equipment from the Annex if the use of the substances referred to in Article 4(1) in these materials and components is avoidable, provided that the negative environmental and/or health impacts caused by substitution do not outweigh the possible environmental benefits thereof.

2. Before the Annex is amended pursuant to paragraph 1, the Commission shall consult producers of electrical and electronic equipment.

*Article 6*

**Review**

By 31 December 2003 at the latest, the Commission shall review the measures provided for in this Directive to take into account, as necessary, new scientific evidence.

*Article 7*

**Committee**

1. The Commission shall be assisted by the committee instituted by Article 18 of Directive 75/442/EEC ([1]).

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 8*

**Transposition**

1. Member States shall bring into force the law, regulations and administrative provisions necessary to comply with this Directive by 30 June 2004 [18 months after the date of adoption] at the latest. They shall immediately inform the Commission thereof.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of all existing laws, regulations and administrative provisions adopted in the field covered by this Directive.

*Article 9*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 10*

**Addressees**

This Directive is addressed to the Member States.

([1]) OJ L 194, 25.7.1975, p. 39.

*ANNEX*

**Applications of lead, mercury, cadmium and hexavalent chromium, which are exempted from the requirements of Article 4(4)**

— Mercury in compact fluorescent lamps not exceeding 5 mg per lamp

— Mercury in straight fluorescent lamps not exceeding 10 mg per lamp

— Mercury in lamps not specifically mentioned in this Annex

— Mercury in laboratory equipment

— Lead as radiation protection

— Lead in glass of cathode ray tubes, light bulbs and fluorescent tubes

— Lead as an alloying element in steel containing up to 0,3 % lead by weight, aluminium containing up to 0,4 % lead by weight and as a copper alloy containing up to 4 % lead by weight

— Lead in electronic ceramic parts

— Cadmium oxide on the surface of selenium photocells

— Cadmium passivation as an anti-corrosion in specific applications

— Cadmium, mercury and lead in hollow cathode lamps for atomic absorption spectroscopy and other instruments to measure heavy metals

— Hexavalent chromium as an anti-corrosion of the carbon steel cooling system in absorption refrigerators.

# Proposal for a Directive of the European Parliament and of the Council on a common regulatory framework for electronic communications networks and services

(2000/C 365 E/14)

**(Text with EEA relevance)**

*COM(2000) 393 final — 2000/0184(COD)*

*(Submitted by the Commission on 23 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The current regulatory framework for telecommunications has been successful in creating the conditions for effective competition in the telecommunications sector during the transition from monopoly to full competition.

(2) On 10 March 1999 the Commission presented a Communication to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the convergence of the telecommunications, media and information technology sectors, and the implications for regulation — Results of the public consultation on the Green Paper ([1]).

(3) On 10 November 1999 the Commission presented a Communication to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on next steps in radio spectrum policy — Results of the public consultation on the Green Paper ([2]).

(4) On 10 November 1999, the Commission presented a Communication to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions entitled 'Towards a new framework for electronic communications infrastructure and associated services — The 1999 Communications Review' ([3]). In that Communication, the Commission reviewed the existing regulatory framework for telecommunications, in accordance with its obligation under Article 8 of Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision ([4]), as amended by Directive 97/51/EC of the European Parliament and of the Council ([5]). It also presented a series of policy proposals for a new regulatory framework for electronic communications infrastructure and associated services for public consultation.

(5) On 26 April 2000 the Commission presented a Communication to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the results of the public consultation on the 1999 Communications Review and Orientations for the new Regulatory Framework ([6]). The Communication summarised the public consultation and set out certain key orientations for the preparation of a new framework for electronic communications infrastructure and associated services.

(6) The Lisbon European Council of 23-24 March 2000 highlighted the potential for growth, competitiveness and job creation of the shift to a digital, knowledge-based economy. In particular, it emphasised the importance for Europe's businesses and citizens of access to an inexpensive, world-class communications infrastructure and a wide range of services.

(7) The convergence of the telecommunications, media and information technology sectors means all transmission networks and services should be covered by a single regulatory framework. That regulatory framework consists of this Directive, four specific Directives: Directive (. . ./. . ./EC of the European Parliament and of the Council on the authorisation of electronic communications networks and services), Directive (. . ./. . ./EC of the European Parliament and of the Council on access to, and interconnection of, electronic communications networks and associated facilities), Directive (. . ./. . ./EC of the European Parliament and of the Council on universal service and users' rights relating to electronic communications networks and services), Directive (. . ./. . ./EC of the European Parliament and of the Council on the processing of personal data and the protection of privacy in the electronic communications sector) and Regulation ((EC) No . . ./. . . of the European Parliament and of the Council on unbundled access to the local loop) (hereinafter referred to as 'the Specific

([1]) COM(1999) 108.

([2]) COM(1999) 538.

([3]) COM(1999) 539.

([4]) OJ L 192, 24.7.1990, p. 1.

([5]) OJ L 295, 29.10.1997, p. 23.

([6]) COM(2000) 239.

Measures'). It is necessary to separate the regulation of transmission from the regulation of content. This framework does not therefore cover the content of services delivered over electronic communications networks using electronic communications services, such as broadcasting content, financial services and certain information society services. The content of television programmes is covered by Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities ([1]), as amended by Directive 97/36/EC of the European Parliament and of the Council ([2]). The separation between the regulation of transmission and the regulation of content does not prejudice the taking into account of the links existing between them.

(8) This Directive does not cover equipment within the scope of Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ([3]), but does cover consumer equipment used for digital television.

(9) Information society services are covered by Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of Information Society services, in particular electronic commerce, in the internal market (Directive on Electronic Commerce) ([4]).

(10) In accordance with Article 14 of the Treaty, the internal market comprises an area without internal frontiers in which the free movement of electronic communications services is ensured.

(11) In accordance with the principle of the separation of regulatory and operational functions, Member States should guarantee the independence of the national regulatory authority or authorities with a view to ensuring the impartiality of their decisions. This requirement of independence is without prejudice to the institutional autonomy and constitutional obligations of the Member States or to the principle of neutrality with regard to the rules in Member States governing the system of property ownership laid down in Article 295 of the Treaty. National regulatory authorities should be in possession of all the necessary resources, in terms of staffing, expertise, and financial means, for the performance of their tasks.

(12) Any party who is the subject of a decision by a national regulatory authority should have the right to appeal to an independent body established by the Member States. The appellate body should be able to consider the facts of the case and, pending the outcome of the appeal, the decision of the national regulatory authority should stand. This appeal procedure is without prejudice to the rights of legal entities or natural persons under national law.

(13) National regulatory authorities need to gather information from market players in order to carry out their tasks effectively. Such information may also need to be gathered on behalf of the Commission, to allow it to fulfil its obligations under Community law. Requests for information should be proportionate and not impose an undue burden on undertakings. Information gathered by national regulatory authorities should be publicly available, except in so far as it is confidential. National regulatory authorities should have the same rights and duties of confidentiality in respect of exchange of information as a 'competent authority' for the purposes of Council Regulation No 17 of 6 February 1962: First Regulation implementing Articles 85 and 86 of the Treaty ([5]), as last amended by Regulation (EC) No 1216/1999 ([6]).

(14) It is important that national regulatory authorities consult all interested parties on proposed decisions and take account of their comments before adopting a final decision. In order to ensure that decisions at national level do not have an adverse effect on the single market or other Treaty objectives, national regulatory authorities should also notify certain draft decisions to the Commission and other national regulatory authorities to give them the opportunity to comment and to allow the Commission to require amendment or suspension of these decisions if necessary. This procedure is without prejudice to the notification procedure provided for in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules of Information Society services ([7]), as amended by Directive 98/48/EC ([8]), and the Commission's prerogatives under the Treaty in respect of infringements of Community law.

(15) National regulatory authorities should have a harmonised set of objectives and principles to underpin their actions. These should be the only objectives and principles governing the actions of the national regulatory authorities in carrying out their tasks under this regulatory framework.

([1]) OJ L 298, 17.10.1989, p. 23.
([2]) OJ L 202, 30.7.1997, p. 60.
([3]) OJ L 91, 7.4.1999, p. 10.
([4]) OJ L 178, 17.7.2000, p. 1.
([5]) OJ 13, 21.2.1962, p. 204/62.
([6]) OJ L 148, 15.6.1999, p. 5.
([7]) OJ L 204, 21.7.1998, p. 37.
([8]) OJ L 217, 5.8.1998, p. 18.

(16) Radio spectrum is an essential input for radio-based electronic communications services and, in so far as it relates to such services, should therefore be allocated and assigned by national regulatory authorities according to transparent, non-discriminatory and objective criteria. It is important that the allocation and assignment of radio spectrum is managed as efficiently as possible, in a manner consistent with the need to balance the requirements of commercial and non-commercial use of radio spectrum. Secondary trading of radio spectrum can be an effective means of increasing efficient use of spectrum, as long as there are sufficient safeguards in place to protect the public interest, in particular the need to ensure transparency and regulatory supervision of such transactions. Decision (. . .) of the European Parliament and of the Council on a regulatory framework for radio spectrum policy in the Community establishes a framework for harmonisation of radio spectrum, and action taken under this Directive should seek to facilitate the work under that Decision.

(17) Access to numbering resources on the basis of transparent, objective and non-discriminatory criteria is essential for undertakings to compete in the electronic communications sector. All elements of national numbering plans should be managed by national regulatory authorities, including point codes used in network addressing. Where there is a need for harmonisation of numbering resources in the Community, this should be carried out by the Commission using its executive powers. Access by end-users to all numbering resources in the Community is a vital precondition for a single market. It should include freephone, premium rate and other non-geographic numbers, except where the called subscriber has chosen, for commercial reasons, to limit access from certain geographical areas. Tariffs charged to parties calling from outside the Member State concerned need not be the same as for those parties calling from inside that Member State. Numbering requirements in Europe, the need for the provision of pan-European and new services and the globalisation and synergy of the electronic communications market require the Community to harmonise national positions in accordance with the Treaty in international organisations and fora where numbering decisions are taken.

(18) Timely, non-discriminatory procedures should be in place for the granting of rights of way, to guarantee the conditions for fair and effective competition. This Directive is without prejudice to national laws governing expropriation of property.

(19) Facility sharing can be of benefit for town planning, public health or environmental reasons, and should be encouraged by national regulatory authorities on the basis of voluntary agreements. Compulsory facility sharing may be appropriate in some circumstances, but should be imposed on undertakings only after full public consultation.

(20) There is a need for *ex-ante* obligations in certain circumstances in order to ensure the development of competitive market. The definition of significant market power in the Directive 97/33/EC of the European Parliament and of the Council of 30 June 1997 on interconnection in telecommunications with regard to ensuring universal service and interoperability through application of the principles of Open Network Provision (ONP) [1], as amended by Directive 98/61/EC [2], has proved effective in the initial stages of market opening as the threshold for ex-ante obligations, but now needs to be adapted to suit more complex and dynamic markets. For this reason, the definition used in this Directive is now based on the concept of dominance as defined in the case law of the Court of Justice and the Court of First Instance of the European Communities. Except in other cases mandated by international obligations of the Community and its Member States, *ex ante* regulatory obligations designed to ensure effective competition are justified only for undertakings which have financed infrastructure on the basis of special or exclusive rights in areas where there are legal, technical or economic barriers to market entry, in particular for the construction of network infrastructure, or which are vertically integrated entities owning or operating network infrastructure for delivery of services to customers and also providing services over that infrastructure, to which their competitors necessarily require access.

(21) It is essential that such regulatory obligations should only be imposed where there is not effective competition and where national and Community competition law remedies are not sufficient to address the problem. It is necessary therefore for the Commission to draw up guidelines at Community level for national regulatory authorities to follow in assessing whether competition is effective in a given market and in assessing significant market power. Those guidelines will also address the issue of newly emerging markets, where *de facto* the market leader is likely to have a substantial market share but should not be subjected to inappropriate obligations. National regulatory authorities will need to cooperate with each other where the relevant market is found to be transnational.

(22) The Community and the Member States have taken commitments in relation to standards and the regulatory framework of telecommunications networks and services in the World Trade Organisation.

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[1] OJ L 199, 26.7.1997, p. 32.

[2] OJ L 268, 3.10.1998, p. 37.

(23) Standardisation should remain primarily a market-driven process. However, there may still be situations where it is appropriate to require compliance with specified standards at Community level to ensure interoperability in the single market. At national level, Member States are subject to the provisions of Directive 98/34/EC. Directive 95/47/EC of the European Parliament and of the Council of 24 October 1995 on the use of standards for the transmission of television signals [1] did not mandate any specific digital television transmission system or service requirement. Through the Digital Video Broadcasting Group, European market actors have developed a family of television transmission systems that have been standardised by the European Telecommunications Standards Institute (ETSI) and have become International Telecommunications Union Recommendations.

(24) In the event of a dispute between undertakings in the same Member State in an area covered by this Directive or the Specific Measures, an aggrieved party should be able to call on the national regulatory authority to resolve the dispute. National regulatory authorities should be able to impose a solution on the parties.

(25) In addition to the rights of recourse granted under national or Community law, there is a need for a simple procedure to resolve cross-border disputes which lie outside the competence of a single national regulatory authority. This procedure, to be initiated at the request of either party in a dispute, but with the agreement of all parties, should be responsive, inexpensive and transparent. Where the Commission decides to establish a working group to assist it in resolving cross-border disputes, it should ensure that the group's membership is independent of the parties involved.

(26) A single Committee should replace the 'ONP Committee' instituted by Article 9 of Directive 90/387/EEC and the Licensing Committee instituted by Article 14 of Directive 97/13/EC of the European Parliament and of the Council of 10 April 1997 on a common framework for general authorisations and individual licences in the field of telecommunications services [2].

(27) National regulatory authorities and national competition authorities should have the right to exchange information, in order to allow them to cooperate fully together.

(28) A high-level group composed of national regulatory authorities should be established. The primary function of this group should be to assist the Commission in securing the uniform application of this Directive and the Specific Measures in order to ensure consistency between Member States. Expert groups may be established to consider specific issues, for example in relation to consumer protection

(29) The provisions of this Directive should be reviewed periodically, in particular with a view to determining the need for modification in the light of changing technological or market conditions.

(30) In accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], measures for the implementation of this Directive should be adopted by use of the advisory procedure provided for in Article 3 of that Decision or the regulatory procedure provided for in Article 5 of that Decision, as appropriate.

(31) In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, the objective of achieving a harmonised framework for the regulation of electronic communications services, electronic communications networks and associated facilities cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effect of the action, be better achieved by the Community. This Directive confines itself to the minimum required in order to achieve that objective and does not go beyond what is necessary for that purpose.

(32) The following Directives and Decisions should be repealed:

— Directive 90/387/EEC;

— Council Decision 91/396/EEC of 29 July 1991 on the introduction of a single European emergency call number [4];

— Council Directive 92/44/EEC of 5 June 1992 on the application of open network provision to leased lines [5], as last amended by Commission Decision 98/80/EC [6];

— Council Decision 92/264/EEC of 11 May 1992 on the introduction of a standard international telephone access code in the Community [7];

— Directive 95/47/EC;

— Directive 97/13/EC;

— Directive 97/33/EC;

[1] OJ L 281, 23.11.1995, p. 51.

[2] OJ L 117, 7.5.1997, p. 15.

[3] OJ L 184, 17.7.1999, p. 23.

[4] OJ L 217, 6.8.1991, p. 31.

[5] OJ L 165, 19.6.1992, p. 27.

[6] OJ L 14, 20.1.1998, p. 27.

[7] OJ L 137, 20.5.1992, p. 21.

— Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector [1],

— Directive 98/10/EC of the European Parliament and of the Council of 26 February 1998 on the application of open network provision (ONP) to voice telephony and on universal service for telecommunications in a competitive environment [2],

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

**SCOPE, AIM AND DEFINITIONS**

*Article 1*

**Scope and aim**

1. This Directive establishes a harmonised framework for the regulation of electronic communications services, electronic communications networks and associated facilities. It lays down the duties of national regulatory authorities and establishes a set of procedures to ensure the harmonised application of the regulatory framework throughout the Community.

2. This Directive as well as the Specific Measures are without prejudice to obligations imposed by national law in accordance with Community law or by Community law in respect of services delivered using electronic communications networks and services.

3. This Directive is without prejudice to the provisions of Directive 1999/5/EC.

*Article 2*

**Definitions**

For the purposes of this Directive:

(a) 'electronic communications network' means transmission systems and, where applicable, switching or routing equipment and other resources which permit the conveyance of signals by wire, by radio, by optical or by other electromagnetic means, including satellite networks, fixed (circuit- and packet-switched, including Internet) and mobile terrestrial networks, networks used for radio and television broadcasting, and cable TV networks, irrespective of the type of information conveyed;

(b) 'electronic communications service' means services provided for remuneration which consist wholly or mainly in the transmission and routing of signals on electronic communications networks, including telecommunications services and transmission services in networks used for broadcasting, but excluding services providing, or exercising editorial control over, content transmitted using electronic communications networks and services;

(c) 'public communications network' means an electronic communications network used wholly or mainly for the provision of publicly available electronic communications services;

(d) 'associated facilities' means those facilities associated with an electronic communications network and/or an electronic communications service, to which access is necessary for the competitive provision of electronic communications services on equal terms;

(e) 'national regulatory authority' means the body or bodies charged by a Member State with any of the regulatory tasks assigned in this Directive and the Specific Measures;

(f) 'user' means a legal entity or natural person using or requesting publicly available electronic communications services;

(g) 'consumer' means any natural person who uses a publicly available electronic communications service for purposes which are outside his or her trade, business or profession;

(h) 'universal service' means a set of services, defined in Directive (on universal service and users' rights relating to electronic communications networks and services), of specified quality which is available to all users regardless of their geographical location and, in the light of specific national conditions, at an affordable price;

(i) 'subscriber' means any natural person or legal entity who or which is party to a contract with the provider of publicly available electronic communications services for the supply of such services;

(j) 'Specific Measures' means Directive 2000/. . ./EC (on the authorisation of electronic communications networks and services), Directive 2000/. . ./EC (on access to, and interconnection of, electronic communications networks and associated facilities), Directive 2000/. . ./EC (on universal service and users' rights relating to electronic communications networks and services), Directive 2000/. . ./EC (on the processing of personal data and the protection of privacy in the electronic communications sector) and Regulation (EC) No . . . (on unbundled access to the local loop);

(k) 'Communications Committee' means the committee established under Article 19;

(l) 'High-Level Communications Group' means the group established under Article 21.

[1] OJ L 24, 30.1.1998, p. 1;

[2] OJ L 101, 1.4.1998, p. 24.

CHAPTER II

## NATIONAL REGULATORY AUTHORITIES

*Article 3*

### National Regulatory Authorities

1. Member States shall ensure that each of the tasks assigned to national regulatory authorities in this Directive and the Specific Measures is undertaken by a competent body.

2. Member States shall guarantee the independence of national regulatory authorities by ensuring that they are legally distinct from and functionally independent of all organisations providing electronic communications networks, equipment or services. Member States that retain ownership or control of undertakings providing electronic communications networks and/or services shall ensure full and effective structural separation of the regulatory function from activities associated with ownership or control.

3. Member States shall ensure that national regulatory authorities exercise their powers impartially and transparently.

4. Member States shall publish the tasks to be undertaken by national regulatory authorities in an easily accessible form, in particular where those tasks are assigned to more than one body. Member States shall in addition publish the procedures for consultation and cooperation between those authorities, and between those authorities and national authorities entrusted with the implementation of competition law and national authorities entrusted with the implementation of consumer law, on matters of common interest. Member States shall ensure that there is no overlap between the tasks of those authorities.

5. National regulatory authorities and national competition authorities shall have the right to exchange information. In order to facilitate cooperation and the mutual exchange of information, national regulatory authorities shall have the same rights and duties of confidentiality in respect of exchange of information as a 'competent authority' for the purposes of Regulation No 17.

6. Member States shall notify to the Commission all national regulatory authorities assigned tasks under this Directive and the Specific Measures, and their respective responsibilities.

*Article 4*

### Right of appeal

1. Member States shall ensure that a mechanism exists at national level under which a user or undertaking providing electronic communications networks and/or services has the right of appeal against a decision of a national regulatory authority to a body that is independent of government and the national regulatory authority concerned. The appeal body shall be able to consider not only the procedure according to which the decision was reached, but also the facts of the case. Pending the outcome of any such appeal, the decision of the national regulatory authority shall stand.

2. The Member States shall ensure that decisions taken by appeal bodies can be effectively enforced.

3. Where the appeal body is not judicial in character, written reasons for its decision shall always be given. Furthermore, in such a case, its decision shall be subject to review by a court or tribunal.

4. The members of the appeal body shall be appointed and leave office under the same conditions as members of the judiciary as regards the authority responsible for their appointment, their period of office and their removal. At least the presiding member of the appeal body shall have the same legal and professional qualifications as members of the judiciary. The appeal body shall take its decisions following a procedure in which both sides are heard, and its decisions shall, by means determined by each Member State, be legally binding.

*Article 5*

### Provision of information

1. Member States shall ensure that undertakings providing electronic communications networks and services provide all the information necessary for national regulatory authorities to ensure compliance with Community law. The information requested by the national regulatory authority shall be proportionate to the performance of that task. The national regulatory authority shall give the reasons justifying its request for information.

2. Member States shall ensure that national regulatory authorities provide the Commission on request with the information necessary for it to carry out its tasks under the Treaty. The information requested by the Commission shall be proportionate to the performance of those tasks. Where appropriate, the Commission shall make information submitted to one national regulatory authority available to another such authority in the same or another Member State. Where information has been submitted in confidence, the Commission and the national regulatory authorities concerned shall maintain the confidentiality of the information provided.

3. Member States shall ensure that, acting in accordance with national rules on public access to information and subject to Community and national rules on commercial confidentiality, national regulatory authorities publish such information as would contribute to an open and competitive market.

4. National regulatory authorities shall publish the terms governing public access to information as referred to in paragraph 3, including detailed guidelines and procedures for obtaining such access. Any decision to refuse access to information shall give reasons and shall be made public.

*Article 6*

**Consultation and transparency mechanism**

1. Member States shall ensure that where national regulatory authorities intend to take measures in accordance with this Directive or the Specific Measures, they give interested parties the chance to comment within a reasonable period. National regulatory authorities shall publish their national consultation procedures.

2. Where a national regulatory authority intends to take measures under Article 8 or Article 14(4) and (5) of this Directive or Article 8(2) of Directive 2000/. . ./EC (on access to and interconnection of electronic communications networks and associated facilities), it shall communicate the draft measure to the Commission and the national regulatory authorities in other Member States, together with the reasoning on which the measure is based. National regulatory authorities may make comments to the national regulatory authority concerned within the period for consultation determined in accordance with paragraph 1.

3. The national regulatory authority concerned shall take the utmost account of comments of other national regulatory authorities, and shall communicate the resulting draft measure to the Commission without delay.

4. The measure shall take effect one month after the date of communication to the Commission unless the Commission notifies the national regulatory authority concerned that it has serious doubts as to the compatibility of the measure with Community law and in particular the provisions of Article 7. In such cases, the measure shall not take effect for a further two months. Within that period the Commission shall take a final decision, and if necessary, require the national regulatory authority concerned to amend or withdraw the draft measure. If the Commission does not take a decision within that period, the draft measure may be adopted by the national regulatory authority.

5. In exceptional circumstances, where a national regulatory authority considers that there is an urgent need to act, by way of derogation from the procedure set out in paragraphs 1 to 4, in order to safeguard competition and protect the interests of users, it may adopt measures immediately. It shall, without delay, communicate those measures, with full reasons, to the Commission and the other national regulatory authorities. The Commission shall verify the compatibility of those measures with Community law and in particular the provisions of Article 7. If necessary, the Commission shall require the national regulatory authority to amend or abolish those measures.

6. Omission on the part of the Commission to take action under paragraphs 4 and 5 shall not prejudice or in any way limit its rights to act under Article 226 of the Treaty in relation to any decision or measure of a national regulatory authority.

CHAPTER III

**DUTIES OF NATIONAL REGULATORY AUTHORITIES**

*Article 7*

**Policy Objectives and Regulatory Principles**

1. Member States shall ensure that in carrying out the regulatory tasks specified in this Directive and the Specific Measures, the national regulatory authorities take all reasonable measures which are aimed exclusively at achieving the objectives set out in paragraphs 2, 3 and 4. Those measures shall be proportionate to those objectives.

Member States shall ensure that in carrying out the regulatory tasks specified in this Directive and the Specific Measures, in particular those designed to ensure fair competition, national regulatory authorities take the utmost account of the need for regulation to be technologically neutral; i.e. that it neither imposes nor discriminates in favour of the use of a particular type of technology.

2. The national regulatory authorities shall promote an open and competitive market for electronic communications networks, electronic communications services and associated facilities by:

(a) ensuring that users derive maximum benefit in terms of choice, price, quality and value for money;

(b) ensuring that there is no distortion or restriction of competition in the electronic communications sector;

(c) encouraging efficient investment in infrastructure; and

(d) ensuring the efficient allocation and assignment of radio spectrum.

3. The national regulatory authorities shall contribute to the development of the internal market by:

(a) removing remaining obstacles to the provision of electronic communications networks, associated facilities and electronic communications services at European level;

(b) encouraging the establishment and development of trans-European networks and the interoperability of pan-European services; and

(c) ensuring that, in similar circumstances, there is no discrimination in the treatment of undertakings providing electronic communications networks and services.

4. The national regulatory authorities shall promote the interests of European citizens by:

(a) ensuring that all citizens have affordable access to a universal service specified in Directive 2000/. . ./EC (on universal service and users' rights relating to electronic communications networks and services);

(b) ensuring a high level of protection for consumers in their dealings with suppliers, in particular by ensuring the availability of simple and inexpensive dispute resolution procedures;

(c) ensuring a high level of protection of personal data and privacy;

(d) requiring transparency of tariffs and conditions for using publicly available electronic communications services; and

(e) addressing the needs of specific social groups, in particular disabled users.

*Article 8*

**Management of radio spectrum**

1. Member States shall ensure the effective management of radio spectrum for electronic communication services in their territory. They shall ensure that the allocation and assignment of radio spectrum by national regulatory authorities is based on objective, transparent, non-discriminatory and proportionate criteria.

2. National regulatory authorities shall promote the harmonisation of use of radio spectrum across the Community, consistent with the need to ensure effective and efficient use thereof.

3. National regulatory authorities may use auctions or administrative pricing of spectrum in pursuit of the objectives set out in Article 7.

4. Member States may make provision for undertakings to trade rights to use radio spectrum with other undertakings only where such rights to use radio spectrum have been assigned by national regulatory authorities by auction. Decisions to make provision for trading of such rights of use in specific frequency bands shall be subject to the procedure set out in Article 6.

5. Member States shall ensure that an undertaking's intention to trade rights to use radio spectrum is notified to the national regulatory authority responsible for spectrum assignment and that any sales transaction takes place under the supervision and with the consent of that authority. National regulatory authorities shall ensure that interested parties are aware of an intended sale of rights to use radio spectrum in order that they have the opportunity to make an offer for such rights of use. National regulatory authorities shall ensure that competition is not distorted as a result of any such transaction. Where radio spectrum use has been harmonised through Decision 2000/. . ./EC (on a regulatory framework for radio spectrum policy in the Community) or other Community measures, any such trading shall not result in change of use of that radio spectrum.

6. Decisions to allocate rights of use of spectrum shall be subject to the procedure set out in Article 6.

*Article 9*

**Numbering, naming and addressing**

1. Member States shall ensure that national regulatory authorities control the allocation and assignment of all national numbering resources and the management of the national numbering plan. Member States shall ensure that adequate numbers and numbering ranges are provided for all publicly available electronic communications services.

2. National regulatory authorities shall ensure that numbering plans and procedures are applied in a manner that gives equal treatment to all providers of publicly available electronic communications services. In particular, Member States shall ensure that an undertaking allocated a range of numbers does not discriminate against other providers of electronic communications services as regards the number sequences used to give access to their services.

3. Member States shall ensure that the national numbering plans, and all subsequent additions or amendments thereto, are published, subject only to limitations imposed on the grounds of national security.

4. National regulatory authorities shall support the harmonisation of numbering resources within the Community where that is necessary to support the development of pan-European services. Any such harmonisation shall take place in accordance with the procedure referred to in Article 19(2).

5. National regulatory authorities shall ensure that users from other Member States are able to access non-geographic numbers within their territory, except where a called subscriber has chosen for commercial reasons to limit access by calling parties located in specific geographical areas.

6. In order to ensure full global interoperability of services, the Community shall take all necessary steps to ensure the coordination of Member States' positions in international organisations and forums in which decisions are taken on issues relating to the numbering, naming and addressing of electronic communications networks and services.

*Article 10*

**Rights of way**

1. Member States shall ensure that the procedures used for the granting of rights to install facilities on, over or under public or private property are available to all providers of publicly available electronic communications networks on the basis of transparent and publicly available terms and conditions applied without discrimination and without delay.

2. Member States shall ensure that where local authorities retain ownership or control of undertakings operating electronic communications networks and/or services, there is effective structural separation of the function responsible for granting rights of way from activities associated with ownership or control.

*Article 11*

**Co-location and facility sharing**

1. Where an undertaking providing electronic communications networks has the right under national legislation to install facilities on, over or under public or private property, or may take advantage of a procedure for the expropriation or use of property, national regulatory authorities shall encourage the sharing of such facilities or property, in particular where undertakings are deprived of access to viable alternatives because of the need to protect the environment, public health, public security or to meet town and country planning objectives.

2. Agreements for co-location or facility sharing shall normally be a matter for commercial and technical agreement between the parties concerned. The national regulatory authority may intervene to resolve disputes, as provided for in Article 17.

3. National regulatory authorities may impose the sharing of facilities or property (including physical co-location) on an undertaking operating an electronic communications network only after an appropriate period of public consultation during which all interested parties must be given an opportunity to express their views. Such sharing arrangements may include rules for apportioning the costs of facility or property sharing.

*Article 12*

**Accounting separation and financial reports**

1. Member States shall require undertakings providing public communications networks or publicly available electronic communications services which have special or exclusive rights for the provision of services in other sectors in the same or another Member State to:

(a) keep separate accounts for the activities associated with the provision of electronic communications networks or services, to the extent that would be required if these activities were carried out by legally independent companies, so as to identify all elements of cost and revenue, with the basis of their calculation and the detailed attribution methods used, related to their activities associated with the provision of electronic communications networks or services including an itemised breakdown of fixed asset and structural costs, or

(b) have structural separation for the activities associated with the provision of electronic communications networks or services.

A Member State may choose not to apply the requirements referred to in the first subparagraph to undertakings the annual turnover of which in activities associated with electronic communications networks or services in that Member State is less than EUR 50 million.

2. Undertakings providing public communications networks or publicly available electronic communications services shall provide financial information to their national regulatory authority promptly on request and to the level of detail required. National regulatory authorities may publish such information as would contribute to an open and competitive market, while respecting Community and national rules on commercial confidentiality.

3. The financial reports of undertakings providing public communications networks or publicly available electronic communications services shall be drawn up and submitted to independent audit and published. The audit shall be carried out in accordance with the relevant Community and national rules. This requirement shall also apply to the separate accounts required under paragraph 1(a).

CHAPTER IV

**GENERAL PROVISIONS**

*Article 13*

**Undertakings with significant market power**

1. Where the Specific Measures require national regulatory authorities to determine whether operators have significant market power, paragraphs 2 and 3 shall apply.

2. An undertaking shall be deemed to have significant market power if, either individually or jointly with others, it enjoys a position of economic strength affording it the power to behave to an appreciable extent independently of competitors, customers and ultimately consumers.

3. Where an undertaking has significant market power on a specific market, it may also be deemed to have significant market power on a closely related market, where the links between the two markets are such as to allow the market power held in one market to be leveraged into the other market, thereby strengthening the market power of the undertaking.

*Article 14*

**Market analysis procedure**

1. After consultation with national regulatory authorities through the High-Level Communications Group, the Commission shall issue a Decision on Relevant Product and Service Markets (hereinafter 'the Decision'), addressed to Member States. The Decision shall identify those product and service markets within the electronic communications sector, the characteristics of which may be such as to justify the imposition of regulatory obligations set out in the Specific Measures, without prejudice to markets that may be defined in specific cases under competition law. The Commission shall also publish Guidelines on market analysis and the calculation of significant market power (hereinafter 'the Guidelines').

The Commission may indicate in the Decision those markets which are transnational. In such markets, the national regulatory authorities concerned shall jointly conduct the market analysis and decide on any imposition of regulatory obligations under paragraphs 2 to 5 in a concerted fashion.

National regulatory authorities shall seek and receive the prior agreement of the Commission before using market definitions that are different from those identified in the Decision or before imposing sector-specific regulatory obligations on markets other than those identified in the Decision.

The Commission shall regularly review the Decision.

2. Within two months of the date of adoption of the Decision or any updating thereof, national regulatory authorities shall carry out an analysis of the product and service markets identified in the Decision, in accordance with the Guidelines. Member States shall ensure that national competition authorities are fully associated with that analysis. The national regulatory authorities' analysis of each market shall be published.

3. Where a national regulatory authority is required under Articles 16, 25 or 27 of Directive 2000/. . ./EC (on universal service and users' rights relating to electronic communications networks and services), or Articles 7 or 8 of Directive 2000/. . ./EC (on access to and interconnection of electronic communications networks and associated facilities) to determine whether to impose, maintain or withdraw obligations on undertakings, it shall determine on the basis of its market analysis referred to in paragraph 2 whether a market identified in the Decision is effectively competitive in a specific geographic area in accordance with the Guidelines.

4. Where a national regulatory authority concludes that the market is effectively competitive, it shall not impose sector-specific regulatory obligations set out in the Specific Measures. In cases where such sector-specific regulatory obligations already exist, it shall withdraw such obligations placed on undertakings in that specific market. An appropriate period of notice shall be given to parties affected by such a withdrawal of obligations.

5. Where a national regulatory authority determines that a market identified in the Decision is not effectively competitive in a specific geographic area in accordance with the Guidelines, it shall impose the sector-specific regulatory obligations set out in the Specific Measures, or maintain such obligations where they already exist.

6. Measures taken pursuant to paragraphs 4 and 5 shall be subject to the procedure set out in Article 6.

*Article 15*

**Standardisation**

1. The Commission shall draw up and publish in the *Official Journal of the European Communities* a List of standards and/or specifications to serve as a basis for encouraging the harmonised provision of electronic communications networks, electronic communications services and associated facilities. Where necessary, the Commission may, acting in accordance with the procedure referred to in Article 19(2), request that standards be drawn up by European standardisation bodies.

2. Member States shall encourage the use of the standards and/or specifications referred to in paragraph 1, for the provision of services, technical interfaces and/or network functions, to the extent strictly necessary to ensure interoperability and to improve freedom of choice for users.

As long as standards and/or specifications have not been published in accordance with paragraph 1, Member States shall encourage the implementation of standards and/or specifications adopted by European standardisation bodies such as ETSI or the Joint European Standards Institution CEN/CENELEC.

In the absence of such standards and/or specifications, Member States shall encourage the implementation of international standards or recommendations adopted by the International Telecommunications Union (ITU), the International Organisation for Standardisation (ISO) or the International Electrotechnical Committee (IEC).

Where international standards exist, Member States shall take all reasonable measures to ensure that European standardisation bodies, such as ETSI or CEN/CENELEC use them, or the relevant parts of them, as a basis for the standards they develop, except where such international standards or relevant parts would be ineffective.

3. If the standards and/or specifications referred to in paragraph 1 have not been adequately implemented so that interoperability of services in one or more Member States cannot be ensured, the implementation of such standards and/or specifications may be made compulsory in accordance with paragraph 4, to the extent strictly necessary to ensure such interoperability and to improve freedom of choice for users.

4. Where the Commission intends to make the implementation of certain standards and/or specifications compulsory, it shall publish a notice in the *Official Journal of the European Communities* and invite public comment by all parties concerned. The Commission, acting in accordance with the procedure referred to in Article 19(3), shall make implementation of the relevant standards compulsory by making reference to them as compulsory standards in the List of standards and/or specifications referred to in paragraph 1.

5. Where the Commission considers that standards and/or specifications referred to in paragraph 1 no longer contribute to the provision of harmonised electronic communications services, it shall, acting in accordance with the procedure referred to in Article 19(2), remove them from the List of standards and/or specifications referred to in paragraph 1.

6. Where the Commission considers that standards and/or specifications referred to in paragraph 4 no longer contribute to the provision of harmonised electronic communications services, it shall, acting in accordance with the procedure referred to in Article 19(3), remove them from the List of standards and/or specifications referred to in paragraph 1.

*Article 16*

**Harmonisation measures**

1. The Commission may, where appropriate, acting in accordance with the procedure referred to in Article 19(2), issue Recommendations to Member States. Member States shall ensure that national regulatory authorities take the utmost account of those Recommendations in carrying out their tasks. Where a national regulatory authority chooses not to follow a Recommendation, it shall publish its reasoning.

2. Where the Commission finds, *inter alia*, that divergence in regulation at national level creates a barrier to the single market, or where the High-Level Communications Group advises that a binding harmonisation measure is necessary, the Commission may, acting in accordance with the procedure referred to in Article 19(3), adopt binding harmonisation measures.

*Article 17*

**Dispute resolution between undertakings**

1. In the event of a dispute arising in the field covered by this Directive or the Specific Measures between undertakings providing electronic communications networks or services in a single Member State, the national regulatory authority concerned shall, at the request of either party, issue a binding decision within two months to resolve the dispute. Member States shall ensure that all parties cooperate fully with the national regulatory authority.

2. In resolving a dispute, the national regulatory authority shall take into account, *inter alia*:

(a) user interests,

(b) regulatory obligations or constraints imposed on any of the parties,

(c) the desirability of stimulating innovative market offerings, and of providing users with a wide range of electronic communications services at a national and at a Community level,

(d) where appropriate, the availability of technically and commercially viable alternatives to the services or facilities requested,

(e) the need to maintain the integrity of electronic communications networks and the interoperability of services,

(f) the nature of the request in relation to the resources available to meet the request,

(g) the relative market positions of the parties,

(h) the public interest (e.g. the protection of the environment, public health and safety),

(i) the promotion of competition,

(j) the need to maintain a universal service.

3. The decision of the national regulatory authority shall be published. The parties concerned shall be given a full statement of the reasons on which it is based.

4. The procedure referred to in paragraphs 1, 2 and 3 shall not preclude either party bringing an action for damages before the national courts.

*Article 18*

**Resolution of cross-border disputes**

1. In the event of a cross-border dispute arising in the field covered by this Directive or the Specific Measures between parties in different Member States, which lies outside the competence of a single national regulatory authority, the procedure set out in paragraphs 2 to 5 shall be available.

2. Any party may refer the dispute to the national regulatory authorities concerned. The national regulatory authorities shall coordinate their efforts in order to bring about a resolution of the dispute, in accordance with Article 17(2).

3. If the dispute is not resolved within two months of its referral to the national regulatory authorities concerned, either party may, with the agreement of all parties, submit to the Commission, with copies to all parties involved, a request for a decision on the dispute. In so doing, the parties renounce any further action under national law.

4. When the Commission receives a request as referred to in paragraph 3, it shall examine the case, assisted, where it considers it appropriate, by an expert working group, and issue a decision within three months. Member States shall ensure that all parties fully implement the decision.

5. In the event that no decision is issued under paragraph 4, the parties shall be free to take further action under national law.

*Article 19*

**Committee**

1. The Commission shall be assisted by a committee, composed of representatives of the Member States and chaired by the representative of the Commission ('the Communications Committee').

2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 20*

**Exchange of information**

1. The Commission shall, where appropriate, inform the Communications Committee of the outcome of regular consultations with the representatives of network operators, service providers, users, consumers, manufacturers and trade unions.

2. The Communications Committee shall, taking account of the Community's electronic communications policy, foster the exchange of information between the Member States and between the Member States and the Commission on the situation and the development of regulatory activities regarding electronic communications networks and services.

*Article 21*

**High-Level Communications Group**

1. A High-Level Communications Group is hereby set up. It shall have advisory status and act independently.

2. The Group shall be composed of representatives designated by the national regulatory authorities. It shall elect its chairman. The Group's secretariat shall be provided by the Commission. The Group shall draw up its own rules of procedure, in agreement with the Commission.

3. Some tasks referred to in paragraph 4 may be carried out by expert groups created for that purpose. Representatives of national competition authorities and other relevant authorities shall be invited where appropriate to participate in the work of the Group and the expert groups.

4. The Group and/or the expert groups shall:

(a) examine any question concerning the application of the national measures adopted under this Directive and the Specific Measures in order to promote the uniform application of such measures in all Member States;

(b) adopt agreed positions on the detailed application of Community legislation, with a view to facilitating pan-European services;

(c) advise the Commission on drawing up the Decision on Relevant Product and Service Markets referred to in Article 14;

(d) consider issues brought to their attention by Member States, national regulatory authorities, market players, or users, and propose solutions where appropriate;

(e) inform the Commission of any difficulties encountered in implementation of this Directive and the Specific Measures;

(f) endorse codes of practice, drawn up by the Group or the expert groups or by other interested parties, for use in Member States, on issues related to the application of Community legislation in the sector;

(g) monitor and publicise, if appropriate by means of a database, the activities of national regulatory authorities throughout the Community, in particular national consultations on specific regulatory issues and subsequent decisions by national regulatory authorities.

5. The Group shall inform the Commission of any divergences between the laws or practices of Member States which are likely to affect the Community market for electronic communications networks or services. The Group may, on its own initiative, give opinions or make recommendations on all matters relating to electronic communications networks or services in the Community.

6. The Group's opinions and recommendations shall be forwarded to the Commission and to the Communications Committee. The Commission shall inform the Group of what action, if any, it intends to take in response to its opinions and recommendations.

7. The Group and the expert groups shall take the utmost account of the views of interested parties, including consumers, users, network operators, service providers, manufacturers and relevant associations at Community level.

8. The Group shall submit an annual report of its activities and those of the expert groups to the European Parliament, the Council and the Commission. The report shall be made public.

*Article 22*

**Publication of information**

1. Member States shall ensure that up-to-date information pertaining to the application of this Directive and the Specific Measures is made publicly available in a manner that guarantees all interested parties easy access to that information. They shall publish a notice in their national Official Gazette describing how and where the information is published. The first such Notice shall be published before 1 January 2002, and thereafter a Notice shall be published whenever there is any change in the information contained therein.

2. Member States shall send to the Commission a copy of all such Notices at the time of publication. The Commission shall distribute the information to the Communications Committee and the High-Level Communications Group as appropriate.

*Article 23*

**Review procedures**

The Commission shall periodically review the functioning of this Directive and report to the European Parliament and to the Council, on the first occasion not later than three years after the date of entry into force of this Directive. For this purpose, the Commission may request from the Member States information, which shall be supplied without delay.

CHAPTER V

**FINAL PROVISIONS**

*Article 24*

**Repeal**

The following Directives and Decisions are repealed with effect from 1 January 2002:

— Directive 90/387/EEC;

— Decision 91/396/EEC;

— Directive 92/44/EEC, without prejudice to Articles 3, 4, 6, 7, 8 and 10 thereof;

— Decision 92/264/EEC;

— Directive 95/47/EC;

— Directive 97/13/EC;

— Directive 97/33/EC, without prejudice to Articles 4, 6, 7, 8, 11, 12 and 14 thereof;

— Directive 97/66/EC;

— Directive 98/10/EC, without prejudice to Articles 16 and 17 thereof.

*Article 25*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive and of any subsequent amendments to those provisions.

*Article 26*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 27*

**Addressees**

This Directive is addressed to the Member States.

*ANNEX*

**LIST OF MARKETS TO BE INCLUDED IN THE INITIAL COMMISSION DECISION ON PRODUCT AND SERVICE MARKETS (ARTICLE 14)**

1. **Markets referred to in Directive (. . .) on universal service and users' rights relating to electronic communications networks and services**

Article 16 (Retail tariff regulation) and Article 25(2) (Carrier selection)

— the provision of connection to and use of the public telephone network at fixed locations

Article 27 (Leased lines)

— the provision of leased lines to end-users

2. **Markets referred to in Directive (. . .) on access to, and interconnection of, electronic communications networks and associated facilities**

*Article 7 — Markets defined under the former regulatory framework, where obligations should be reviewed*

Interconnection (Directive 97/33/EC, as amended by Directive 98/61/EC)

— call origination in the fixed public telephone network;

— call termination in the fixed public telephone network;

— transit services in the fixed public telephone network;

— call origination on public mobile telephone networks;

— call termination on public mobile telephone networks;

— leased line interconnection (interconnection of part circuits).

Network access and special network access (Directive 97/33/EC, Directive 98/10/EC)

— access to the fixed public telephone network, including unbundled access to the local loop;

— access to public mobile telephone networks, including carrier selection.

Wholesale leased line capacity (Directive 92/44/EEC as amended by Directive 97/51/EC)

— wholesale provision of leased line capacity to other suppliers of electronic communications networks or services.

3. **Markets referred to in Regulation (. . .) on unbundled access to the local loop**

— services provided over unbundled (copper) loops.

# Proposal for a Regulation of the European Parliament and of the Council on unbundled access to the local loop

(2000/C 365 E/15)

**(Text with EEA relevance)**

*COM(2000) 394 final — 2000/0185(COD)*

*(Submitted by the Commission on 23 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The conclusions of the special European Council of Lisbon of 23 and 24 March 2000 note that, for Europe to fully seize the growth and job potential of the digital, knowledge-based economy, businesses and citizens must have access to an inexpensive, world-class communications infrastructure and a wide range of services. The Member States, together with the Commission, are called upon 'to work towards introducing greater competition in local access networks before the end of 2000 and unbundling the local loop, in order to help bring about a substantial reduction in the costs of using the Internet'. The Feira European Council of 20 June 2000 endorsed the proposed *e*Europe Action Plan [1] which identifies unbundled access to the local loop as a short-term priority.

(2) The 'local loop' is the physical copper line circuit in the local access network connecting the customer's premises to the operator's local switch, concentrator or equivalent facility. As noted in the Commission's Fifth Report on the implementation of the telecommunications regulatory package [2], the local access network remains one of the least competitive segments of the liberalised telecommunications market. New entrants do not have wide-spread alternative network infrastructures and are unable, with traditional technologies, to match the economies of scale and scope of operators notified as having significant market power in the fixed public telephone network market ('notified operators'). This results from the fact that operators rolled out their old copper local access networks over significant periods of time protected by exclusive rights and were able to fund investment costs through monopoly rents.

(3) The European Parliament Resolution of 13 June 2000 on the Commission communication on the 1999 Communications review [3] stresses the importance of enabling the sector to develop infrastructures which promote the growth of electronic communications and e-commerce and the importance of regulating in a way that supports this growth. It notes that the unbundling of the local loop is currently mainly relevant to the copper infrastructure of a dominant entity and that investment in alternative infrastructures must have the possibility of ensuring a reasonable rate of return, since that might facilitate the expansion of these infrastructures in areas where their penetration is still low.

(4) The provision of new loops with high capacity optical fibre directly to major users is a specific market that is developing under competitive conditions with new investments. This Regulation therefore does not address unbundled access to fibre local loops.

(5) It would not be economically viable for new entrants to duplicate the incumbent's copper local loop access infrastructure in its entirety and within a reasonable time. Alternative infrastructures such as cable television, satellite, wireless local loops do not generally offer the same functionality or ubiquity.

(6) It is appropriate to mandate unbundled access to the copper local loops only of notified operators. The Commission has already published an initial list of operators of fixed public telephone networks notified by the national regulatory authorities as having significant market power [4].

[1] COM(2000) 330 final.

[2] COM(1999) 537.

[3] AS-0145/2000.

[4] OJ C 112, 23.4.1999, p. 2.

(7) Although commercial negotiation is the preferred method for reaching agreement on technical and pricing issues for local loop access, experience shows that in most cases regulatory intervention is necessary due to imbalance in negotiating power between the new entrant and the notified operator, and lack of other alternatives. Notified operators should provide information and unbundled access to third parties under the same conditions and of the same quality as they provide for their own services or those of their subsidiaries or partners. To this end, the publication by the notified operator of an adequate reference offer for unbundled access to the local loop, within a short time-frame and ideally on Internet, and under the supervisory control of the national regulatory authority, would contribute to creating transparent and non-discriminatory market conditions. In certain circumstances the national regulatory authority may, in accordance with Community law, intervene at its own initiative to impose terms, including pricing rules, designed to ensure interoperability of services, maximise economic efficiency and benefit end-users.

(8) Costing and pricing rules for local loops and associated facilities (such as co-location and leased transmission capacity) should be transparent, non-discriminatory and be objective to ensure fairness. Pricing rules should ensure that the local loop provider is able to cover its appropriate costs in this regard plus a reasonable return. Pricing rules for local loops should foster fair and sustainable competition and ensure that there is no distortion of competition, in particular no margin squeeze between prices of wholesale and retail services of the notified operator. In this regard, it is considered important that competition authorities be consulted.

(9) In Recommendation 2000/417/EC of 25 May 2000 on unbundled access to the local loop: enabling the competitive provision of a full range of electronic communications services including broadband multimedia and high-speed Internet [1] and the Communication of 26 April 2000 [2], the Commission set out detailed guidance to assist national regulatory authorities on the fair regulation of different forms of unbundled access to the local loop and on the application of existing Community law.

(10) In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, the objective of achieving a harmonised framework for unbundled access to the local loop in order to enable the competitive provision of an inexpensive, world-class communications infrastructure and a wide range of services for all businesses and citizens in the Community cannot be achieved by the Member States in a secure, harmonised and timely manner and can therefore be better achieved by the Community. This Regulation confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Scope**

(1) This Regulation shall apply to unbundled access to the local loops of network operators that have been notified to the Commission by the national regulatory authority as having significant market power in the provision of fixed public telephone networks and services in accordance with the relevant Community provisions (hereinafter referred to as 'notified operators').

(2) This Regulation shall apply without prejudice to the obligation under the relevant Community provisions for notified operators to comply with the principle of non-discrimination when using the fixed public telephone network to provide high-speed access and transmission services to third parties under the same conditions as to its own services.

*Article 2*

**Definitions**

For the purposes of this Regulation:

(a) 'local loop' means the physical copper line circuit in the local access network connecting the customer's premises to the fixed public telephone network operator's local switch, concentrator or equivalent facility;

(b) 'unbundled access to the local loop' means full unbundled access to the local loop and shared access to the local loop; it does not entail a change in ownership of the copper local loop;

(c) 'full unbundled access to the local loop' means the provision of access to the copper local loop of the incumbent operator, in such a way that the new entrant has exclusive use of the full frequency spectrum of the copper line and can offer a full range of voice and data services to end-users;

[1] OJ L 156, 29.6.2000, p. 44.

[2] COM(2000) 237.

(d) 'shared access to the local loop' means the provision of access to the non-voice frequency spectrum of a copper line over which the basic telephone service is being provided to the end-user by the incumbent operator allowing a new entrant to deploy technologies — such as asymmetrical digital subscriber line (ADSL) systems — to provide the end-user with additional services such as high-speed Internet access;

(e) 'co-location' means the provision of physical space and technical conditioning necessary to reasonably accommodate and connect the equipment of a new entrant to access the local loop.

*Article 3*

**Provision of unbundled access**

1. Notified operators shall make available to third parties, by 31 December 2000 at the latest, unbundled access to the local loop, under transparent, fair and non-discriminatory conditions. Notified operators shall provide competitors with the same facilities as they provide to themselves or to their associated companies, and with the same conditions and timescales.

2. Notified operators shall provide physical access for third parties to any technically feasible point of the copper local loop or sub-loop where the new entrant can co-locate and connect its own network equipment and facilities in order to deliver services to its customer, either in the local switch, concentrator or equivalent facility.

3. Notified operators shall publish, by 31 December 2000 at the latest, a reference offer for the unbundled access to the local loops and associated facilities including co-location, sufficiently unbundled, and containing a description of the component offerings and the associated terms and conditions, including prices, taking account of the list in the Annex to Recommendation 2000/417/EC.

*Article 4*

**Regulatory supervision**

1. For as long as the level of competition in the local access network is insufficient to prevent excessive pricing, national regulatory authorities shall ensure that the prices for unbundled access to the local loop charged by notified operators follow the principle of cost orientation. National regulatory authorities shall be competent where justified to impose changes in the reference offer for the unbundled access to the local loop, including prices.

In adopting pricing rules and price decisions on unbundled access to the local loop, national regulatory authorities shall ensure that they foster fair and sustainable competition.

2. National regulatory authorities shall be competent to resolve disputes between undertakings concerning issues included in this Regulation, in a prompt, fair and transparent manner.

*Article 5*

**Entry into force**

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

# Proposal for a Directive of the European Parliament and of the Council on access to, and interconnection of, electronic communications networks and associated facilities

(2000/C 365 E/16)

**(Text with EEA relevance)**

*COM(2000) 384 final — 2000/0186(COD)*

*(Submitted by the Commission on 25 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Directive (. . ./. . ./EC of the European Parliament and of the Council of . . . on a common regulatory framework for electronic communications networks and services) lays down the objectives of a regulatory framework to cover electronic communications networks and services in the Community, including fixed and mobile telecommunications networks, cable television networks, networks used for terrestrial broadcasting, satellite networks and Internet networks, whether used for voice, fax, data or images. Such networks may have been authorised by Member States under Directive (. . ./. . ./EC of the European Parliament and of the Council of . . . on the authorisation of electronic communications networks and services) or have been authorised under previous regulatory measures. The provisions of this Directive apply to those networks that are used for the commercial provision of publicly available electronic communications services or for transmission of broadcasting signals. This Directive covers access and interconnection arrangements between service suppliers. It does not apply to networks used for the provision of communications services available only to a specific end-user or to a closed user group, nor does it deal with access for end-users or others who are not supplying publicly available services.

(2) The term 'access' has a wide range of meanings, and it is therefore necessary to define precisely how that term is used in this Directive, without prejudice to how it may be used in other Community measures. The term 'operator' implies control of the relevant network or facilities, but does not imply ownership; a network operator may own the underlying network or facilities or may rent some or all of them.

(3) Directive 95/47/EC of the European Parliament and of the Council of 24 October 1995 on the use of standards for the transmission of television signals [1] did not mandate any specific digital television transmission system or service requirement, and this opened an opportunity for the market actors to take the initiative and develop suitable systems. Through the Digital Video Broadcasting Group, European market actors have developed a family of television transmission systems that have been adopted by broadcasters throughout the world. These transmissions systems have been standardised by the European Telecommunications Standards Institute (ETSI) and have become International Telecommunications Union Recommendations. In relation to wide-screen digital television, the 16:9 aspect ratio is the reference format for wide-format television services and programmes, and is now established in Member States' markets as a result of Council Decision 93/424/EEC of 22 July 1993 on an action plan for the introduction of advanced television services in Europe [2].

(4) In an open and competitive market, there should be no restrictions that prevent undertakings from negotiating access and interconnection arrangements between themselves, in particular on cross border agreements, subject to the competition rules of the Treaty. In markets where there continue to be large differences in negotiating power between undertakings, and where some undertakings rely on infrastructure provided by others for delivery of their services, it is appropriate to establish a framework to ensure that the market functions effectively. National regulatory authorities should have the power to secure, where commercial negotiation fails, adequate access and interconnection and interoperability of services in the interest of end-users. This would be the case for example if network operators were to unreasonably restrict end-user choice for access to Internet portals and services. The use of *ex-ante* rules by national regulatory authorities should be limited to those areas where *ex-post* application of the remedies available under competition law cannot achieve the same results in the same time-scale.

[1] OJ L 281, 23.11.1995, p. 51.

[2] OJ L 196, 5.8.1993, p. 48.

(5) National legal or administrative measures that link the terms and conditions for access or interconnection to the activities of the party seeking interconnection, and specifically to the degree of its investment in network infrastructure, and not to the interconnection or access services provided, may cause market distortion and may therefore not be compatible with competition rules. In any case national regulatory authorities should take into account the case-law of the Court of Justice and Court of First Instance of the European Communities and may not confirm pricing practices or prices contrary to Article 81(1) or Article 82 of the Treaty.

(6) Network operators who control access to their own customers do so on the basis of unique numbers or addresses from a published numbering or addressing range. Other network operators need to be able to deliver traffic to those customers, and so need to be able to interconnect directly or indirectly to each other. The existing rights and obligations to negotiate interconnection should therefore be maintained. It is also appropriate to maintain the obligations formerly laid down in Directive 95/47/EC requiring all electronic communications networks used for the distribution of digital television services to be capable of distributing widescreen television services and programmes, so that users are able to receive such programmes in the format in which they were transmitted.

(7) Directive 95/47/EC provided an initial regulatory framework for the nascent digital television industry which should be maintained, including in particular the obligation to provide conditional access on fair, reasonable and non-discriminatory terms. Technological and market developments make it necessary to review these obligations on a regular basis, in particular to determine whether there is justification for extending obligations to new gateways, such as electronic programme guides (EPGs) and applications program interfaces (APIs) for the benefit of European citizens.

(8) In order to ensure continuity of existing agreements and to avoid a legal vacuum, it is necessary to ensure that obligations for access and interconnection imposed under Articles 4, 6, 7, 8, 11, 12 and 14 of Directive 97/33/EC of the European Parliament and of the Council of 30 June 1997 on interconnection in telecommunications with regard to ensuring universal service and interoperability through application of the principles of Open Network Provision (ONP) [1], as amended by Directive 98/61/EC [2], obligations on special access imposed under Article 16 of Directive 98/10/EC of the European Parliament and of the Council of 26 February 1998 on the application of open network provision (ONP) to voice telephony and on universal service for telecommunications in a competitive environment [3], and obligations concerning the provision of leased line transmission capacity under Council Directive 92/44/EEC of 5 June 1992 on the application of open network provision to leased lines [4], as last amended by Commission Decision 98/80/EC [5], are initially carried over into the new regulatory framework, but are subject to immediate review in the light of prevailing market conditions. Such a review should also extend to those organisations covered by Regulation (EC) No .../... of the European Parliament and of the Council of ... on unbundled access to the local loop. The review should be carried out using an economic market analysis based on competition law methodology. The aim is to reduce *ex-ante* sector-specific rules progressively as competition in the market develops. However, the procedure also takes account of the possibility of new bottlenecks arising as a result of technological development, which may require *ex-ante* regulation, for example in the area of broadband access networks. It may well be the case that competition develops at different speeds in different market segments and in different Member States, and national regulatory authorities should be able to relax regulatory obligations in those markets where competition is delivering the desired results. In order to ensure that market players in similar circumstances are treated in similar ways in different Member States, the Commission should be able to ensure harmonised application of the provisions of this Directive. The Community and its Member States have taken commitments on interconnection of telecommunications networks in the context of the World Trade Organisation agreement on basic telecommunications that need to be respected.

(9) Directive 97/33/EC laid down a range of obligations to be imposed on undertakings with significant market power, namely transparency, non-discrimination, accounting separation, access, and price control, including cost orientation. This range of possible obligations should be maintained but, in addition, they should be established as a set of maximum obligations that can be applied to undertakings, in order to avoid over-regulation. Exceptionally, in order to comply with international commitments or Community law it may be appropriate to impose obligations for access or interconnection on all market players, as is currently the case for conditional access systems for digital television services. In all cases, *ex-ante* regulation is only justified where the remedies available under competition rules cannot achieve the desired results as quickly.

[1] OJ L 199, 26.7.1997, p. 32.

[2] OJ L 268, 3.10.1998, p. 37.

[3] OJ L 101, 1.4.1998, p. 24.

[4] OJ L 165, 19.6.1992, p. 27.

[5] OJ L 14, 20.1.1998, p. 27.

(10) Transparency of terms and conditions for access and interconnection, including prices, serve to speed up negotiation, avoid disputes and give confidence to market players that a service is not being provided on discriminatory terms. Openness and transparency of technical interfaces can be particularly important in ensuring interoperability.

(11) The principle of non-discrimination ensures that undertakings with market power do not distort competition, in particular where they are vertically integrated undertakings that supply services to competitors with whom they compete on downstream markets.

(12) Accounting separation allows internal price transfers to be rendered visible, and allows national regulatory authorities to check compliance with obligations for non-discrimination where applicable. In this regard the Commission published Recommendation 98/322/EC of 8 April 1998 on interconnection in a liberalised telecommunications market (Part 2 — accounting separation and cost accounting) ([1]).

(13) Mandating access to network infrastructure can be justified as a means of increasing competition, but national regulatory authorities need to balance the rights of an infrastructure owner to exploit its infrastructure for its own benefit, and the rights of other service providers to access facilities that are essential for the provision of competing services. The imposition by national regulatory authorities of mandated access that increases competition in the short term should not reduce incentives for competitors to invest in alternative facilities that will secure more competition in the long term. The Commission has published a Notice on the application of the competition rules to access agreements in the telecommunications sector ([2]), which addresses these issues.

(14) Price control may be necessary when market analysis in a particular market reveals inefficient competition. The regulatory intervention may be relatively light, such as an obligation that prices for carrier selection are reasonable as laid down in Directive 97/33/EC, or much heavier such as an obligation that prices are cost oriented to provide full justification for those prices where competition is not sufficiently strong to prevent excessive pricing. In particular, operators with significant market power should avoid a price squeeze whereby the difference between their retail prices and the interconnection prices charged to competitors who provide similar retail services is not adequate to ensure sustainable competition. In its Recommendation 98/195/EC of 8 January 1998 on interconnection in a liberalised telecommunications market (Part 1 — interconnection pricing) ([3]), the Commission recommended the use of long-run average incremental costs as the basis for interconnection prices in the Community that serves to promote efficiency and sustainable competition.

(15) Publication of information by Member States will ensure that market players and potential market entrants understand their rights and obligations, and know where to find the relevant detailed information. Publication in the National Gazette helps interested parties in other Member States to find the relevant information.

(16) In order to determine the correct application of Community law, the Commission needs to know which undertakings have been designated as having significant market power and what obligations have been placed upon market players by national regulatory authorities. In addition to national publication of this information, it is therefore necessary for Member States to send this information to the Commission.

(17) Given the pace of technological and market developments, the implementation of this Directive should be reviewed within three years of its entry into force to determine if it is meeting its objectives.

(18) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([4]), they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

**SCOPE, AIM AND DEFINITIONS**

*Article 1*

**Scope and aim**

1. Within the framework set out in Directive (on a common regulatory framework for electronic communications networks and services), this Directive harmonises the way in which Member States regulate access to, and interconnection of, electronic communications networks and associated facilities. The aim is to establish a regulatory framework, in accordance with internal market principles, for the market between suppliers of networks and services that will result in sustainable competition, interoperability of services and consumer benefits.

([1]) OJ L 141, 13.5.1998, p. 6.

([2]) OJ C 265, 22.8.1998, p. 2.

([3]) OJ L 73, 12.3.1998, p. 42.

([4]) OJ L 184, 17.7.1999, p. 23.

2. The Directive establishes rights and obligations for undertakings owning or operating public communications networks and associated facilities, and undertakings seeking interconnection and/or access to those networks or associated facilities. It sets out objectives for national regulatory authorities with regard to network access and interconnection, and lays down procedures to ensure that obligations imposed by national regulatory authorities are reviewed and where appropriate withdrawn once the desired objectives have been achieved.

*Article 2*

**Definitions**

The definitions in Directive (on a common regulatory framework for electronic communications networks and services) shall apply, where relevant.

The following definitions shall also apply:

(a) 'access' means the making available of facilities and/or services, to another undertaking, under defined conditions, on either an exclusive or non-exclusive basis, for the purpose of providing electronic communications services. It covers *inter alia*: access to network elements and associated facilities and services, which may involve the connection of equipment, by wire or wireless means; access to physical infrastructure including buildings, ducts and masts; access to software systems including operational support systems; access to number translation or systems offering equivalent functionality; access to mobile networks, in particular for roaming; access to conditional access systems for digital television services. Interconnection is a specific type of access implemented between public network operators. Access in this Directive does not refer to access by end-users;

(b) 'interconnection' means the physical and logical linking of public electronic communications networks used by the same or a different undertaking in order to allow the users of one undertaking to communicate with users of the same or another undertaking, or to access services provided by another undertaking. Services may be provided by the parties involved or other parties who have access to the network;

(c) 'operator' means an undertaking providing, operating or controlling a publicly available electronic communications network or an associated facility such as a conditional access system, by means of which it can restrict or deny service providers' access to the end-user or the end-user's choice of services;

(d) 'wide-screen digital television service' means a television service that consists wholly or partially of programmes produced and edited to be displayed in a full-height wide-screen format using anamorphic expansion. The 16:9 format is the reference format for wide-screen television services;

(e) 'end-user' means a user not providing publicly available electronic communications networks or services.

CHAPTER II

**GENERAL FRAMEWORK FOR REGULATING ACCESS AND INTERCONNECTION**

*Article 3*

**General framework for access and interconnection**

1. Member States shall ensure that there are no restrictions which prevent undertakings in the same Member State or in different Member States from negotiating between themselves agreements on technical and commercial arrangements for access and/or interconnection, in accordance with Community law. The undertaking requesting access or interconnection does not need to be authorised to operate in the Member State where access or interconnection is requested, where it is not providing services in that Member State.

2. Without prejudice to Article 26 of Directive (on universal service and users' rights relating to electronic communications networks and services), Member States shall not maintain legal or other administrative measures obliging operators, when granting network access or interconnection, to offer different terms and conditions to different undertakings for the same services, and/or imposing obligations that are not related to the actual access and interconnection services provided.

*Article 4*

**Rights and obligations for undertakings**

1. All undertakings authorised to operate electronic communications networks for the provision of publicly available electronic communications services shall have a right and, when requested by other undertakings so authorised, an obligation to negotiate interconnection with each other for the purpose of providing the services in question, in order to ensure provision and interoperability of services throughout the Community.

2. Electronic communications networks used for the distribution of digital television services shall be capable of distributing wide-screen television services and programmes. Network operators that receive and re-distribute wide-screen television services or programmes shall maintain that wide-screen format.

3. Without prejudice to Article 11 of Directive on (authorisation of electronic communications networks and services), national regulatory authorities shall ensure that undertakings that acquire information from another undertaking during the process of negotiating access or interconnection arrangements use that information solely for the purpose for which it was supplied and respect at all times the confidentiality of information transmitted or stored. The information shall not be passed on to any other party, in particular other departments, subsidiaries or partners, for whom such information could provide a competitive advantage.

*Article 5*

**Powers and responsibilities of the national regulatory authorities with regard to access and interconnection**

1. National regulatory authorities shall, acting in pursuit of the objectives set out in Article 7 of Directive (on a common regulatory framework for electronic communications networks and services), encourage and secure adequate network access and interconnection, and interoperability of services, exercising their responsibility in a way that promotes efficiency, sustainable competition, and gives the maximum benefit to end-users.

2. Member States shall ensure that national regulatory authorities are empowered to impose the obligations identified in Articles 6 to 13 of this Directive on operators that have been designated as having significant market power in a relevant market. In the absence of agreement between undertakings on access and interconnection arrangements, Member States shall ensure that the national regulatory authority is empowered to intervene at the request of either of the parties involved or at its own initiative, taking account of the policy objectives and procedures included in Articles 6, 7 and 13 to 18 of Directive (on a common regulatory framework for electronic communications networks and services).

CHAPTER III

**OBLIGATIONS ON OPERATORS AND MARKET REVIEW PROCEDURES**

*Article 6*

**Conditional access systems and other associated facilities**

1. Member States shall ensure that, in relation to conditional access to digital television services broadcast to viewers in the Community, irrespective of the means of transmission, the conditions laid down in Part I of the Annex apply.

2. Conditions relating to access to other associated facilities referred to in Part II of the Annex may be adopted in accordance with the procedure referred to in Article 14(2).

3. In the light of market and technological developments, the Annex may be amended in accordance with the procedure referred to in Article 14(2).

*Article 7*

**Review of former obligations for access and interconnection**

1. Member States shall maintain all obligations on undertakings providing publicly available electronic communications networks concerning access and interconnection that were in force prior to the date of entry into force of this Directive under Articles 4, 6, 7, 8, 11, 12 and 14 of Directive 97/33/EC, Article 16 of Directive 98/10/EC, Articles 7 and 8 of Directive 92/44/EC and Article 3 of Regulation (on unbundled access to the local loop), until such time as these obligations have been reviewed and a determination made in accordance with paragraph 3.

2. The relevant markets for the obligations referred to in paragraph 1 will be included in the initial Decision on Relevant Product and Service Markets to be published by the Commission in accordance with the procedure laid down in Article 14 of Directive (on a common regulatory framework for electronic communications networks and services).

3. Member States shall ensure that, immediately following the entry into force of this Directive, and periodically thereafter, national regulatory authorities undertake a market analysis, in accordance with the procedure laid down in Article 14 of Directive (on a common regulatory framework for electronic communications networks and services) to determine whether to maintain, amend or withdraw these obligations. An appropriate period of notice shall be given to parties affected by such amendment or withdrawal of obligations.

*Article 8*

**Imposition, amendment or withdrawal of obligations**

1. Where an operator is deemed to have significant market power on a specific market as a result of a market analysis carried out in accordance with Article 14 of Directive (on a common regulatory framework for electronic communications networks and services), national regulatory authorities shall impose one or more of the obligations set out in Articles 9 to 13 of this Directive as appropriate, in order to avoid distortions of competition. The specific obligation(s) imposed shall be based on the nature of problem identified.

2. National regulatory authorities may, without prejudice to the provisions of Article 6, impose on operators, including operators other than those with significant market power, the obligations set out in Article 9 to 13 in relation to interconnection, in order to comply with international commitments.

Exceptionally, with the prior agreement of the Commission, national regulatory authorities may impose on operators with significant market power obligations for access or interconnection that go beyond those set out in Articles 9 to 13 of this Directive, provided that all such obligations are justified in the light of the objectives laid down in Article 1 of this Directive and in Article 7 of Directive (on a common regulatory framework for electronic communications networks and services), and are proportionate to the aim pursued.

3. In relation to the first subparagraph of paragraph 2, national regulatory authorities shall notify decisions to impose, modify or withdraw obligations on market players to the Commission, in accordance with the procedures in Article 6(2), (3) and (4) of Directive on (a common regulatory framework for electronic communications networks and services).

*Article 9*

**Obligation of transparency**

1. National regulatory authorities may, in accordance with the provisions of Article 8, impose obligations for transparency in relation to interconnection and/or network access, requiring operators to make publicly available specified information, such as technical specifications, network characteristics, terms and conditions for supply and use, and prices.

2. In particular, where an operator has obligations of non-discrimination, national regulatory authorities may require that operator to publish a reference offer, sufficiently unbundled, giving a description of the relevant offerings broken down into components according to market needs, and the associated terms and conditions including prices.

3. National regulatory authorities may specify the precise information to be made available, the level of detail required and the manner of publication.

*Article 10*

**Obligation of non-discrimination**

1. A national regulatory authority may, in accordance with the provisions of Article 8, impose obligations of non-discrimination, in relation to interconnection and/or network access.

2. Obligations of non-discrimination shall ensure, in particular, that the operator applies similar conditions in similar circumstances to other undertakings providing similar services, and provides services and information to others under the same conditions and of the same quality as they provide for their own services, or those of their subsidiaries or partners.

*Article 11*

**Obligation of accounting separation**

1. A national regulatory authority may, in accordance with the provisions of Article 8, impose obligations for accounting separation in relation to specified activities related to interconnection and/or network access.

In particular, a national regulatory authority may require a vertically integrated company to make transparent its wholesale prices and its internal transfer prices, in situations where a market analysis indicates that the operator concerned provides input facilities that are essential to other service providers, while competing itself on the same downstream market.

2. To facilitate the verification of compliance with obligations of transparency, national regulatory authorities shall have the power to require that accounting records, including data on revenues received from third parties, are provided on request. National regulatory authorities may publish such information as would contribute to an open and competitive market, while respecting national and Community rules on commercial confidentiality.

*Article 12*

**Obligations of access to, and use of, specific network facilities**

1. A national regulatory authority may, in accordance with the provisions of Article 8, impose obligations on operators to grant access to, and use of, specific facilities and/or associated services, *inter alia* in situations where the national regulatory authority considers that denial of access would hinder the emergence of a sustainable competitive market at the retail level, or would not be in the end-user's interest.

Operators may be required *inter alia*:

(a) to give third parties access to specified network elements and/or facilities;

(b) not to withdraw access to facilities already granted;

(c) to provide resale of specified services;

(d) to grant open access to technical interfaces, protocols or other key technologies that are indispensable for the interoperability of services;

(e) to provide collocation or other forms of facility sharing, including duct, building or mast sharing;

(f) to provide specified services needed to ensure interoperability of end-to-end services to users, including facilities for intelligent network services or roaming on mobile networks;

(g) to provide access to operational support systems or similar software systems necessary to ensure fair competition in the provision of services;

(h) to interconnect networks or network facilities.

National regulatory authorities may attach to those obligations conditions covering fairness, reasonableness, timeliness, transparency and/or non-discrimination.

2. When imposing the obligations referred to in paragraph 1, national regulatory authorities shall take account in particular of:

(a) the technical and economic viability of using or installing competing facilities, in the light of the rate of market development;

(b) the feasibility of providing the access proposed, in relation to the capacity available;

(c) the initial investment by the facility owner, bearing in mind the risks involved in making the investment;

(d) the need to safeguard competition in the long term;

(e) where appropriate, any relevant intellectual property rights.

*Article 13*

**Price control and cost accounting obligations**

1. A national regulatory authority may, in accordance with the provisions of Article 8, impose price controls, including obligations for cost orientation of prices and obligations concerning cost accounting systems, for the provision of specific types of interconnection and/or network access, in situations where a market analysis indicates that a potential lack of effective competition means that the operator concerned might be capable of sustaining prices at an excessively high level, or applying a price squeeze, to the detriment of end users. National regulatory authorities shall take into account the investment made by the operator and the risks involved.

2. National regulatory authorities shall ensure that any pricing methodology that is mandated serves to promote efficiency and sustainable competition and maximise consumer benefits.

3. Where an operator has an obligation regarding the cost orientation of its prices, the burden of proof that charges are derived from costs including a reasonable rate of return on investment shall lie with the operator concerned. National regulatory authorities may require an operator to provide full justification for its prices, and may, where appropriate, require prices to be adjusted.

4. National regulatory authorities shall ensure that, where implementation of a cost accounting system is mandated in order to support price controls, a description of the cost accounting system is made publicly available, showing at least the main categories under which costs are grouped and the rules used for the allocation of costs. Compliance with the cost accounting system shall be verified by a qualified independent body. A statement concerning compliance shall be published annually.

CHAPTER IV

**PROCEDURAL PROVISIONS**

*Article 14*

**Committee**

1. The Commission shall be assisted by the Communications Committee instituted by Article 19 of Directive (on a common regulatory framework for electronic communications networks and services).

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 15*

**Publication of, and access to, information**

1. Member States shall ensure that the specific obligations imposed on undertakings under this Directive are published and that the specific product/service and geographical markets are identified. They shall ensure that up-to-date information is made publicly available in a manner that guarantees all interested parties easy access to that information.

2. Member States shall send to the Commission a copy of all such information published. The Commission shall make this information available in a readily accessible form, and shall distribute the information to the Communications Committee and the High Level Communications Group as appropriate.

*Article 16*

**Notification**

1. Member States shall notify to the Commission by 31 December 2001 at the latest the national regulatory authorities responsible for the tasks set out in this Directive.

2. National regulatory authorities shall notify to the Commission the names of operators deemed to have significant market power for the purposes of this Directive, and the obligations imposed upon them under this Directive. Any changes affecting the obligations imposed upon undertakings or of the undertakings affected under the provisions of this Directive shall be notified to the Commission without delay.

*Article 17*

**Review**

The Commission shall periodically review the functioning of this Directive and report to the European Parliament and to the Council, on the first occasion not later than three years after the date of entry into force of this Directive. For this purpose, the Commission may request from Member States information, which shall be supplied promptly on request.

*Article 18*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive and of any subsequent amendments to those provisions.

*Article 19*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 20*

**Addressees**

This Directive is addressed to the Member States.

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*ANNEX*

**Conditions for access to digital television services broadcast to viewers in the Community**

Part I — Conditions for conditional access systems to be applied in accordance with Article 6(1).

In relation to conditional access to digital television services broadcast to viewers in the Community, irrespective of the means of transmission, Member States must ensure in accordance with Article 6 that the following conditions apply:

(a) conditional access systems operated on the market in the Community shall have the necessary technical capability for cost-effective transcontrol allowing the possibility for full control by network operators at local or regional level of the services using such conditional access systems;

(b) all operators of conditional access services, irrespective of the means of transmission, who produce and market access services to digital television services shall:

— offer to all broadcasters, on a fair, reasonable and non-discriminatory basis compatible with Community competition law, technical services enabling the broadcasters' digitally-transmitted services to be received by viewers authorised by means of decoders administered by the service operators, and comply with Community competition law,

— keep separate financial accounts regarding their activity as conditional access providers;

(c) when granting licences to manufacturers of consumer equipment, holders of industrial property rights to conditional access products and systems shall ensure that this is done on fair, reasonable and non-discriminatory terms. Taking into account technical and commercial factors, holders of rights shall not subject the granting of licences to conditions prohibiting, deterring or discouraging the inclusion in the same product of:

— a common interface allowing connection with several other access systems, or

— means specific to another access system, provided that the licensee complies with the relevant and reasonable conditions ensuring, as far as he is concerned, the security of transactions of conditional access system operators.

Part II — Other associated facilities to be considered under the review procedure in Article 6(2).

— Access to application program interfaces (APIs);

— Access to electronic programme guides (EPGs).

# Proposal for a Directive of the European Parliament and of the Council concerning the processing of personal data and the protection of privacy in the electronic communications sector

(2000/C 365 E/17)

**(Text with EEA relevance)**

*COM(2000) 385 final — 2000/0189(COD)*

*(Submitted by the Commission on 25 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] requires Member States to ensure the rights and freedoms of natural persons with regard to the processing of personal data, and in particular their right to privacy, in order to ensure the free flow of personal data in the Community.

(2) Confidentiality of communications is guaranteed in accordance with the international instruments relating to human rights, in particular the European Convention for the Protection of Human Rights and Fundamental Freedoms, and the constitutions of the Member States.

(3) Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector [2] translated the principles set out in Directive 95/46/EC into specific rules for the telecommunications sector. Directive 97/66/EC should be adapted to developments in the markets and technologies for electronic communications services in order to provide an equal level of protection of personal data and privacy for users of publicly available electronic communications services, regardless of the technologies used.

(4) New advanced digital technologies are currently being introduced in public communications networks in the Community, which give rise to specific requirements concerning the protection of personal data and privacy of the user. The development of the information society is characterised by the introduction of new electronic communications services. Access to digital mobile networks has become available and affordable for a large public. These digital networks have large capacities and possibilities for processing personal data. The successful cross-border development of these services is partly dependent on the confidence of users that their privacy will not be at risk.

(5) The Internet is overturning traditional market structures by providing a common, global infrastructure for the delivery of a wide range of electronic communications services. Publicly available electronic communications services over the Internet open new possibilities for users but also new risks for their personal data and privacy.

(6) In the case of public communications networks, specific legal, regulatory, and technical provisions should be made in order to protect fundamental rights and freedoms of natural persons and legitimate interests of legal persons, in particular with regard to the increasing capacity for automated storage and processing of data relating to subscribers and users.

(7) Legal, regulatory, and technical provisions adopted by the Member States concerning the protection of personal data, privacy and the legitimate interests of legal persons, in the electronic communication sector, should be harmonised in order to avoid obstacles to the internal market for electronic communication in accordance with Article 14 of the Treaty. Harmonisation should be limited to requirements necessary to guarantee that the promotion and development of new electronic communications services and networks between Member States are not hindered.

(8) The Member States, providers and users concerned, together with the competent Community bodies, should cooperate in introducing and developing the relevant technologies where this is necessary to apply the guarantees provided for by this Directive and taking particular account of the objectives of minimising the processing of personal data and of using anonymous or pseudonymous data where possible.

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[1] OJ L 281, 23.11.1995, p. 31.

[2] OJ L 24, 30.1.1998, p. 1.

(9) In the electronic communications sector, Directive 95/46/EC applies, in particular for all matters concerning protection of fundamental rights and freedoms, which are not specifically covered by the provisions of this Directive, including the obligations on the controller and the rights of individuals. Directive 95/46/EC applies to non-publicly available electronic communications services.

(10) Like Directive 95/46/EC, this Directive does not address issues of protection of fundamental rights and freedoms related to activities which are not governed by Community law. It is for Member States to take such measures as are necessary for the protection of public security, defence, State security (including the economic well-being of the State when the activities relate to State security matters) and the enforcement of criminal law. This Directive does not affect the ability of Member States to carry out lawful interception of electronic communications if necessary for any of these purposes.

(11) Subscribers of a publicly available electronic communications service may be natural or legal persons. By supplementing Directive 95/46/EC, this Directive is intended to protect the fundamental rights of natural persons and particularly their right to privacy, as well as the legitimate interests of legal persons. It does not entail an obligation for Member States to extend the application of Directive 95/46/EC to the protection of the legitimate interests of legal persons, which is ensured within the framework of the applicable Community and national legislation.

(12) The application of certain requirements relating to presentation and restriction of calling and connected line identification and to automatic call forwarding to subscriber lines connected to analogue exchanges should not be made mandatory in specific cases where such application would prove to be technically impossible or would require a disproportionate economic effort. It is important for interested parties to be informed of such cases and the Member States should therefore notify them to the Commission.

(13) Service providers should take appropriate measures to safeguard the security of their services, if necessary in conjunction with the provider of the network, and inform subscribers of any special risks of a breach of the security of the network. Such risks may especially occur for electronic communications services over an open network such as the Internet. It is particularly important for subscribers and users of such services to be fully informed by their service provider of the existing security risks which are outside the scope of possible remedies by the service provider. Service providers who offer publicly available electronic communications services over the Internet should inform users and subscribers of measures they can take to protect the security of their communications for instance by using specific types of software or encryption technologies. Security is appraised in the light of Article 17 of Directive 95/46/EC.

(14) Measures should be taken to prevent unauthorised access to communications in order to protect the confidentiality of communications, including both the contents and any data related to such communications, by means of public communications networks and publicly available electronic communications services. National legislation in some Member States only prohibits intentional unauthorised access to communications.

(15) The data relating to subscribers processed within electronic communications networks to establish connections and to transmit information contain information on the private life of natural persons who have a right to respect for their correspondence. The legitimate interests of legal persons should also be protected. Such data may only be stored to the extent that is necessary for the provision of the service for the purpose of billing and for interconnection payments, and for a limited time. Any further processing of such data which the provider of the publicly available electronic communications services may want to perform for the marketing of its own electronic communications services or for the provision of value added services, may only be allowed if the subscriber has agreed to this on the basis of accurate and full information given by the provider of the publicly available electronic communications services about the types of further processing it intends to perform and about the subscriber's right not to give or to withdraw his consent to such processing. Traffic data used for marketing of own communications services or for the provision of value added services should also be erased or made anonymous after the provision of the service. Service providers should always keep subscribers informed of the types of data they are processing and the purposes and duration for which this is done.

(16) The introduction of itemised bills has improved the possibilities for the subscriber to check the accuracy of the fees charged by the service provider but, at the same time, it may jeopardise the privacy of the users of publicly available electronic communications services. Therefore, in order to preserve the privacy of the user, Member States should encourage the development of electronic communication service options such as alternative payment facilities which allow anonymous or strictly private access to publicly available electronic communications services, for example calling cards and facilities for payment by credit card.

(17) In digital mobile networks location data giving the geographic position of the terminal equipment of the mobile user are processed to enable the transmission of communications. Such data are traffic data covered by Article 6. However, in addition, digital mobile networks may have the capacity to process location data which are more precise than is necessary for the transmission of communications and which are used for the provision of value added services such as services providing individualised traffic information and guidance to drivers. The processing of such data for value added services should only be allowed where subscribers have given their consent. Even in cases where subscribers have given their consent, they should have a simple means to temporarily deny the processing of location data, free of charge.

(18) It is necessary, as regards calling line identification, to protect the right of the calling party to withhold the presentation of the identification of the line from which the call is being made and the right of the called party to reject calls from unidentified lines. There is justification for overriding the elimination of calling line identification presentation in specific cases. Certain subscribers, in particular helplines and similar organisations, have an interest in guaranteeing the anonymity of their callers. It is necessary, as regards connected line identification, to protect the right and the legitimate interest of the called party to withhold the presentation of the identification of the line to which the calling party is actually connected, in particular in the case of forwarded calls. The providers of publicly available electronic communications services should inform their subscribers of the existence of calling and connected line identification in the network and of all services which are offered on the basis of calling and connected line identification as well as the privacy options which are available. This will allow the subscribers to make an informed choice about the privacy facilities they may want to use. The privacy options which are offered on a per-line basis do not necessarily have to be available as an automatic network service but may be obtainable through a simple request to the provider of the publicly available electronic communications service.

(19) Safeguards should be provided for subscribers against the nuisance which may be caused by automatic call forwarding by others and, in such cases, it should be possible for subscribers to stop the forwarded calls being passed on to their terminals by simple request to the provider of the publicly available electronic communications service.

(20) Directories of subscribers to electronic communications services are widely distributed and publicly available. The right to privacy of natural persons and the legitimate interest of legal persons require that subscribers are able to determine whether their personal data are published in a directory and, if so, which. Providers of public directories should inform the subscribers included in such directories of the purposes of the directory and of any particular usage which may be made of electronic versions of public directories especially through search functions embedded in the software, such as reverse search functions enabling users of the directory to discover the name and address of the subscriber on the basis of a telephone number only.

(21) Safeguards should be provided for subscribers against intrusion of their privacy by means of unsolicited calls, telefaxes, electronic mails and other forms of communications for direct marketing purposes. Member States may limit such safeguards to subscribers who are natural persons.

(22) The functionalities for the provision of electronic communications services may be integrated in the network or in any part of the terminal equipment of the user, including the software. The protection of the personal data and the privacy of users of publicly available electronic communications services should be independent of the configuration of the various components necessary to provide the service and of the distribution of the necessary functionalities between these components. Directive 95/46/EC covers any form of processing of personal data regardless of the technology used. The existence of specific rules for electronic communications services alongside general rules for other components necessary for the provision of such services may not facilitate the protection of personal data and privacy in a technology neutral way. It may therefore be necessary to adopt measures requiring manufacturers of certain types of equipment used for electronic communications services to construct their product in such a way as to incorporate safeguards to ensure that the personal data and privacy of the user and subscriber are protected. The adoption of such measures in accordance with Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity [1] will ensure that the introduction of technical features of electronic communication equipment including software for data protection purposes is harmonised in order to be compatible with the implementation of the internal market.

(23) In particular, similarly to what is provided for by Article 13 of Directive 95/46/EC, Member States can restrict the scope of subscribers' obligations and rights in certain circumstances, for example by ensuring that the provider of a publicly available electronic communications service may override the elimination of the presentation of calling line identification in conformity with national legislation for the purposes of preventing or detecting criminal offences or of State security.

[1] OJ L 91, 7.4.1999, p. 10.

(24) Where the rights of users and subscribers are not respected, national legislation should provide for judicial remedies. Penalties should be imposed on any person, whether governed by private or public law, who fails to comply with the national measures taken under this Directive.

(25) It is useful, in the field of application of this Directive, to draw on the experience of the Working Party on the Protection of Individuals with regard to the Processing of Personal Data set up by Article 29 of Directive 95/46/EC.

(26) To facilitate compliance with the provisions of this Directive, certain specific arrangements are needed for processing of data already under way on the date on which national legislation implementing this Directive enters into force,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Scope and aim**

1. This Directive harmonises the provisions of the Member States required to ensure an equivalent level of protection of fundamental rights and freedoms, and in particular the right to privacy, with respect to the processing of personal data in the electronic communication sector and to ensure the free movement of such data and of electronic communication equipment and services in the Community.

2. The provisions of this Directive particularise and complement Directive 95/46/EC for the purposes mentioned in paragraph 1. Moreover, they provide for protection of legitimate interests of subscribers who are legal persons.

3. This Directive shall not apply to activities which fall outside the scope of the EC Treaty, such as those covered by Titles V and VI of the Treaty on European Union, and in any case to activities concerning public security, defence, State security (including the economic well-being of the State when the activities relate to State security matters) and the activities of the State in areas of criminal law.

*Article 2*

**Definitions**

Save as otherwise provided, the definitions in Directive 95/46/EC and in Directive 2001/.../EC of the European Parliament and of the Council of . . . (on a common regulatory framework for electronic communications networks and services), shall apply.

The following definitions shall also apply:

(a) 'user' means any natural person using a publicly available electronic communications service, for private or business purposes, without necessarily having subscribed to this service;

(b) 'traffic data' means any data processed in the course of or for the purpose of the transmission of a communication over an electronic communications network;

(c) 'location data' means any data processed in an electronic communications network, indicating the geographic position of the terminal equipment of a user of a publicly available electronic communications service;

(d) 'communication' means any information exchanged or transmitted between a finite number of parties by means of a publicly available electronic communications service;

(e) 'call' means a connection established by means of a publicly available telephone service allowing two-way communication in real time.

*Article 3*

**Services concerned**

1. This Directive shall apply to the processing of personal data in connection with the provision of publicly available electronic communications services in public communications networks in the Community.

2. Articles 8, 10 and 11 shall apply to subscriber lines connected to digital exchanges and, where technically possible and if it does not require a disproportionate economic effort, to subscriber lines connected to analogue exchanges.

3. Cases where it would be technically impossible or require a disproportionate economic effort to fulfil the requirements of Articles 8, 10 and 11 shall be notified to the Commission by the Member States.

*Article 4*

**Security**

1. The provider of a publicly available electronic communications service must take appropriate technical and organisational measures to safeguard security of its services, if necessary in conjunction with the provider of the public electronic communications network with respect to network security. Having regard to the state of the art and the cost of their implementation, these measures shall ensure a level of security appropriate to the risk presented.

2. In case of a particular risk of a breach of the security of the network, the provider of a publicly available electronic communications service must inform the subscribers concerning such risk and any possible remedies, including the costs involved.

*Article 5*

**Confidentiality of the communications**

1. Member States shall ensure the confidentiality of communications and the related traffic data by means of a public communications network and publicly available electronic communications services, through national legislation. In particular, they shall prohibit listening, tapping, storage or other kinds of interception or surveillance of communications and the related traffic data, by persons other than users, without the consent of the users concerned, except when legally authorised to do so, in accordance with Article 15(1).

2. Paragraph 1 shall not affect any legally authorised recording of communications and the related traffic data in the course of lawful business practice for the purpose of providing evidence of a commercial transaction or of any other business communication.

*Article 6*

**Traffic data**

1. Traffic data relating to subscribers and users processed for the purpose of the transmission of a communication and stored by the provider of a public communications network or service must be erased or made anonymous upon completion of the transmission, without prejudice to the provisions of paragraphs 2, 3 and 4.

2. Traffic data which are necessary for the purposes of subscriber billing and interconnection payments may be processed. Such processing is permissible only up to the end of the period during which the bill may lawfully be challenged or payment pursued.

3. For the purpose of marketing its own electronic communications services or for the provision of value added services to the subscriber, the provider of a publicly available electronic communications service may process the data referred to in paragraph 1 to the extent and for the duration necessary for such services, if the subscriber has given his consent.

4. The service provider must inform the subscriber of the types of traffic data which are processed for the purposes mentioned in paragraphs 2 and 3 and of the duration of such processing.

5. Processing of traffic data, in accordance with paragraphs 1 to 4, must be restricted to persons acting under the authority of providers of the public communications networks and services handling billing or traffic management, customer enquiries, fraud detection, marketing the provider's own electronic communications services or providing a value added service, and must be restricted to what is necessary for the purposes of such activities.

6. Paragraphs 1, 2, 3 and 5 shall apply without prejudice to the possibility for competent authorities to be informed of traffic data in conformity with applicable legislation with a view to settling disputes, in particular interconnection or billing disputes.

*Article 7*

**Itemised billing**

1. Subscribers shall have the right to receive non-itemised bills.

2. Member States shall apply national provisions in order to reconcile the rights of subscribers receiving itemised bills with the right to privacy of calling users and called subscribers, for example by ensuring that sufficient alternative privacy enhancing modalities for communications or payments are available to such users and subscribers.

*Article 8*

**Presentation and restriction of calling and connected line identification**

1. Where presentation of calling-line identification is offered, the calling user must have the possibility, using a simple means and free of charge, of preventing the presentation of the calling-line identification on a per-call basis. The calling subscriber must have this possibility on a per-line basis.

2. Where presentation of calling-line identification is offered, the called subscriber must have the possibility, using a simple means and free of charge for reasonable use of this function, of preventing the presentation of the calling line identification of incoming calls.

3. Where presentation of calling line identification is offered and where the calling line identification is presented prior to the call being established, the called subscriber must have the possibility, using a simple means, of rejecting incoming calls where the presentation of the calling line identification has been prevented by the calling user or subscriber.

4. Where presentation of connected line identification is offered, the called subscriber must have the possibility, using a simple means and free of charge, of preventing the presentation of the connected line identification to the calling user.

5. The provisions of paragraph 1 shall also apply with regard to calls to third countries originating in the Community. The provisions of paragraphs 2, 3 and 4 shall also apply to incoming calls originating in third countries.

6. Member States shall ensure that where presentation of calling and/or connected line identification is offered, the providers of publicly available electronic communications services inform the public thereof and of the possibilities set out in paragraphs 1 to 4.

*Article 9*

**Location data**

1. Where electronic communications networks are capable of processing location data other than traffic data, relating to users or subscribers of their services, these data may only be processed when they are made anonymous, or with the consent of the users or subscribers to the extent and for the duration necessary for the provision of a value added service. The service provider must inform the users or subscribers, prior to obtaining their consent, of the type of location data which will be processed, of the purposes and duration of the processing and whether the data will be transmitted to a third party for the purpose of providing the value added service.

2. Where consent of the users or subscribers has been obtained for the processing of location data other than traffic data, the user or subscriber must continue to have the possibility, using a simple means and free of charge, of temporarily refusing the processing of such data for each connection to the network or for each transmission of a communication.

3. Processing of location data in accordance with paragraphs 1 and 2 must be restricted to persons acting under the authority of the provider of the electronic communications service or of the third party providing the value added service, and must be restricted to what is necessary for the purposes of providing the value added service.

*Article 10*

**Exceptions**

Member States shall ensure that there are transparent procedures governing the way in which a provider of a public communications network and/or a publicly available electronic communications service may override:

(a) the elimination of the presentation of calling line identification, on a temporary basis, upon application of a subscriber requesting the tracing of malicious or nuisance calls. In this case, in accordance with national law, the data containing the identification of the calling subscriber will be stored and be made available by the provider of a public communications network and/or publicly available electronic communications service;

(b) the elimination of the presentation of calling line identification and the temporary denial or absence of consent of a subscriber or user for the processing of location data, on a per-line basis for organisations dealing with emergency calls and recognised as such by a Member State, including law enforcement agencies, ambulance services and fire brigades, for the purpose of responding to such calls.

*Article 11*

**Automatic call forwarding**

Member States shall ensure that any subscriber has the possibility, using a simple means and free of charge, of stopping automatic call forwarding by a third party to the subscriber's terminal.

*Article 12*

**Directories of subscribers**

1. Member States shall ensure that subscribers are informed, free of charge, about the purpose(s) of a printed or electronic directory of subscribers available to the public or obtainable through directory enquiry services, in which their personal data can be included and of any further usage possibilities based on search functions embedded in electronic versions of the directory.

2. Member States shall ensure that subscribers are given the opportunity, free of charge, to determine whether their personal data are included in public directories, and if so, which, to the extent that such data are relevant for the purpose of the directory as determined by the provider of the directory, and to verify, correct or withdraw such data.

3. Paragraphs 1 and 2 shall apply to subscribers who are natural persons. Member States shall also ensure, in the framework of Community law and applicable national legislation, that the legitimate interests of subscribers other than natural persons with regard to their entry in public directories are sufficiently protected.

*Article 13*

**Unsolicited communications**

1. The use of automated calling systems without human intervention (automatic calling machines), facsimile machines (fax) or electronic mail for the purposes of direct marketing may only be allowed in respect of subscribers who have given their prior consent.

2. Member States shall take appropriate measures to ensure that, free of charge, unsolicited communications for purposes of direct marketing, by means other than those referred to in paragraph 1, are not allowed either without the consent of the subscribers concerned or in respect of subscribers who do not wish to receive these communications, the choice between these options to be determined by national legislation.

3. Paragraphs 1 and 2 shall apply to subscribers who are natural persons. Member States shall also ensure, in the framework of Community law and applicable national legislation, that the legitimate interests of subscribers other than natural persons with regard to unsolicited communications are sufficiently protected.

*Article 14*

**Technical features and standardisation**

1. In implementing the provisions of this Directive, Member States shall ensure, subject to paragraphs 2 and 3, that no mandatory requirements for specific technical features are imposed on terminal or other electronic communication equipment which could impede the placing of equipment on the market and the free circulation of such equipment in and between Member States.

2. Where provisions of this Directive can be implemented only by requiring specific technical features in electronic communications networks, Member States shall inform the Commission in accordance with the procedure provided for by Directive 98/34/EC of the European Parliament and the Council ([1]).

3. Where required, the Commission shall adopt measures to ensure that terminal equipment incorporates the necessary safeguards to guarantee the protection of personal data and privacy of users and subscribers, in accordance with Directive 1999/5/EC and Council Decision 87/95/EEC ([2]).

*Article 15*

**Application of certain provisions of Directive 95/46/EC**

1. Member States may adopt legislative measures to restrict the scope of the rights and obligations provided for in Article 5, Article 6, Article 8(1) to (4), and Article 9 of this Directive when such restriction constitutes a necessary measure to safeguard national security, defence, public security, the prevention, investigation, detection and prosecution of criminal offences or of unauthorised use of the electronic communication system, as referred to in Article 13(1) of Directive 95/46/EC.

2. The provisions of Chapter III on Judicial Remedies, Liability and Sanctions of Directive 95/46/EC shall apply with regard to national provisions adopted pursuant to this Directive and with regard to the individual rights derived from this Directive.

3. The Working Party on the Protection of Individuals with regard to the Processing of Personal Data instituted by Article 29 of Directive 95/46/EC shall also carry out the tasks laid down in Article 30 of that Directive with regard to matters covered by this Directive, namely the protection of fundamental rights and freedoms and of legitimate interests in the electronic communications sector.

*Article 16*

**Transitional arrangements**

Article 12 shall not apply to editions of directories published before the national provisions adopted pursuant to this Directive entering into force.

*Article 17*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive and of any subsequent amendments to those provisions.

*Article 18*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 19*

**Addressees**

This Directive is addressed to the Member States.

([1]) OJ L 204, 21.7.1998, p. 37.

([2]) OJ L 36, 7.2.1987, p. 310.

# Proposal for a Directive of the European Parliament and of the Council on the authorisation of electronic communications networks and services

(2000/C 365 E/18)

**(Text with EEA relevance)**

*COM(2000) 386 final — 2000/0188(COD)*

*(Submitted by the Commission on 28 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The outcome of the public consultation on the 1999 review of the regulatory framework for electronic communications, as reflected in the Commission communication of 26 April 2000 [1], has confirmed the need for a more harmonised and less onerous market access regulation for electronic communications services and networks throughout the Community.

(2) Convergence between different electronic communications services and networks and their technologies requires the establishment of an authorisation system covering all similar services in a similar way regardless of the technologies used.

(3) The least onerous system possible should be used to allow the provision of electronic communications services and networks in order to stimulate the development of new electronic communications services and to allow service providers and consumers to benefit from the economies of scale of the single market.

(4) Those aims can be best achieved by general authorisation of all electronic communications services and networks without requiring any explicit decision or administrative act by the national regulatory authority and by limiting any procedural requirements to notification only.

(5) It is necessary to include the rights of undertakings under general authorisations explicitly in such authorisations in order to ensure a level playing field throughout the Community and to facilitate cross border negotiation of interconnection between public communications networks.

(6) The granting of specific rights may continue to be necessary for the use of radio frequencies and numbers, including short codes, from the national numbering plan. Rights to numbers may also be allocated from a European numbering plan, including for example the virtual country code '3883' which has been attributed to Member countries of the European Conference of Post and Telecommunications (CEPT). Those rights of use should not be restricted except where this is unavoidable in view of the scarcity of radio frequencies and the need to ensure the efficient use thereof.

(7) The conditions which may be attached to the general authorisation and to the specific rights of use, should be limited to what is strictly necessary to ensure compliance with essential requirements and obligations under Community law.

(8) Specific obligations which may be imposed on providers of electronic communications services and networks in accordance with Community law by virtue of their significant market power as defined in Directive .../.../EC of the European Parliament and of the Council of ... (on a common regulatory framework for electronic communications networks and services) should be imposed separately from the general rights and obligations under the general authorisation.

(9) The general authorisation should contain only conditions which are specific to the electronic communications sector. It should not be made subject to conditions which are already applicable by virtue of other existing national law which is not specific to the electronic communications sector.

(10) Where the demand for radio frequencies in a specific range exceeds their availability, appropriate and transparent procedures should be followed for the assignment of such frequencies in order to avoid any discrimination and optimise use of those scarce resources.

(11) Where the harmonised assignment of radio frequencies to particular undertakings has been agreed at European level, Member States should strictly implement such agreements in the granting of rights of use of radio frequencies from the national frequency usage plan.

[1] COM(2000) 239.

(12) Providers of electronic communications services and networks may need a confirmation of their rights under the general authorisation with respect to interconnection and rights of way, in particular to facilitate negotiations with other, regional or local, levels of government or with service providers in other Member States. For this purpose the national regulatory authorities should provide declarations to undertakings upon request or automatically in response to a notification under the general authorisation.

(13) The penalties for non-compliance with conditions under the general authorisation should be commensurate with the infringement. Save in exceptional circumstances, it would not be proportionate to withdraw the right to provide electronic communications services or the right to use radio frequencies or numbers where an undertaking did not comply with one or more of the conditions under the general authorisation. This is without prejudice to urgent measures which Member States may need to take in case of serious threats to public safety, security or health or to economic and operational interests of other undertakings. This Directive should also be without prejudice to any claims for compensation for damages between undertakings under national law.

(14) Subjecting service providers to reporting and information obligations can be cumbersome, both for the undertaking and for the national regulatory authority concerned. Such obligations should therefore be proportionate, objectively justified and limited to what is strictly necessary. It is not necessary to require systematic and regular proof of compliance with all conditions under the general authorisation or attached to rights of use. Undertakings have a right to know the purposes for which the information they should provide will be used. The provision of information should not be a condition for market access. This Directive should be without prejudice to Member States' obligations to provide any information necessary for the defence of Community interests within the context of international agreements.

(15) Administrative charges may be imposed on providers of electronic communications services in order to finance the activities of the national regulatory authority in managing the authorisation system and for the granting of rights of use. Such charges should be limited to cover the actual administrative costs for those activities. For this purpose transparency should be created in the income and expenditure of national regulatory authorities by means of annual reporting about the total sum of charges collected and the administrative costs incurred. This will allow undertakings to verify that administrative costs and charges are in balance. Administrative charges should not act as a barrier to market entry. Such charges should therefore be distributed in proportion to the turnover on the relevant services of the undertaking concerned as calculated over the accounting year preceding the year of the administrative charge. Small and medium-sized undertakings should not be required to pay administrative charges.

(16) In addition to administrative charges, usage fees may be levied for the use of radio frequencies and numbers as an instrument to ensure the optimal use of such resources. Such fees should not hinder the development of innovative services and competition in the market.

(17) Member States may need to amend rights, conditions, procedures, charges and fees relating to general authorisations and rights of use where this is objectively justified. Such changes should be duly notified to all interested parties in good time giving them adequate opportunity to express their views on any such amendments.

(18) The objective of transparency requires that service providers, consumers and other interested parties have easy access to any information regarding rights, conditions, procedures, charges, fees and decisions concerning the provision of electronic communications services, rights of use of radio frequencies and numbers, national frequency usage plans and national numbering plans. The national regulatory authorities have an important task in providing such information and keeping it up to date and in centralising all relevant information regarding rights of way where such rights are administered by other levels of government.

(19) The proper functioning of the single market on the basis of the national authorisation regimes under this Directive should be monitored. On the basis of the findings of such monitoring, further harmonisation measures may be necessary where barriers to the single market remain. Directive (on a common regulatory framework for electronic communications networks and services) provides the procedural framework for any such measures.

(20) The replacement of authorisations existing on the date of entry into force of this Directive by the general authorisation and the individual rights of use in accordance with this Directive should not lead to an increase in the obligations for service providers operating under an existing authorisation or to a reduction of their rights, unless this would have a negative effect on the rights and obligations of other undertakings,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Objective and scope**

1. The aim of this Directive is to implement an internal market in electronic communications services through the harmonisation and simplification of authorisation rules and conditions in order to facilitate the provision of electronic communications services and networks throughout the Community.

2. This Directive shall apply to all authorisations relating to the provision of electronic communications services and networks.

*Article 2*

**Definitions**

For the purposes of this Directive, the definitions in Directive (on a common regulatory framework for electronic communications networks and services) shall apply.

*Article 3*

**General authorisation of electronic communications services and networks**

1. Member States shall not prevent an undertaking from providing electronic communications services or networks except where this is necessary to protect public security, safety or health.

2. The provision of electronic communications services or networks may only be subject to a general authorisation. The undertaking concerned may be required to submit a notification, but may not be required to obtain an explicit decision or any other administrative act by the national regulatory authority before exercising the rights stemming from the authorisation. Upon notification, an undertaking may begin commercial activity, where necessary subject to the provisions on rights of use in Articles 5, 6 and 7.

3. The notification referred to in paragraph 2 shall not entail more than a declaration by a legal or natural person to the national regulatory authority of the intention to commence the provision of electronic communication networks or services and the submission of the minimal information which is required to allow the national regulatory authority to keep a register of providers of electronic communications services and networks. This information must be limited to what is necessary for the identification of the provider and the provider's contact persons, the provider's address and a short description of the service to be provided.

*Article 4*

**Minimum list of rights derived from the general authorisation**

Undertakings authorised pursuant to Article 3, shall have the right to:

(a) Provide electronic communications services to the public and negotiate interconnection with other providers of publicly available communications services covered by a general authorisation anywhere in the Community in accordance with Directive . . ./. . ./EC of the European Parliament and of the Council of . . . (on access to, and interconnection of, electronic communications networks and associated facilities).

(b) Establish electronic communications networks and be granted the necessary rights of way in accordance with Directive (on a common regulatory framework for electronic communications networks and services).

(c) Be given an opportunity to be designated to provide elements of a universal service obligation in part or all of the national territory in accordance with Directive . . ./. . ./EC of the European Parliament and of the Council of . . . (on universal service and users' rights relating to electronic communications networks and services).

*Article 5*

**Rights to use radio frequencies and numbers**

1. Member States shall, where possible, in particular where the risk of harmful interference is negligible, not make the use of radio frequencies subject to the grant of individual rights of use but shall include the conditions for usage of such radio frequencies in the general authorisation.

2. Where it is necessary to grant individual rights to use radio frequencies and numbers, Member States shall grant such rights, upon request, to any undertaking providing services under the general authorisation, subject to the provisions of Articles 6 and 7 and any other rules ensuring the efficient use of those resources in accordance with Directive (on a common regulatory framework for electronic communications networks and services).

Such rights of use shall be granted through open, non-discriminatory and transparent procedures. When granting rights of use, Member States shall specify whether those rights can be transferred and under which conditions, in accordance with Article 8 of Directive (on a common regulatory framework for electronic communications networks and services). Where Member States grant rights of use for a limited period of time, the duration shall be appropriate for the service concerned.

3. Decisions on rights of use shall be taken, communicated and published as soon as possible and within two weeks after receipt of the application by the competent authority in the case of numbers, and within six weeks in the case of radio frequencies.

4. Member States shall not limit the granting of rights of use except where this is necessary to ensure the efficient use of radio frequencies and in accordance with Article 7. Member States shall grant rights to use frequency where it is available.

*Article 6*

**Conditions attached to the general authorisation and to the rights of use for radio frequencies and rights of use for numbers**

1. The general authorisation for the provision of electronic communications services or networks and the rights of use for radio frequencies and rights of use for numbers shall be subject only to the conditions listed respectively in Parts A, B and C of the Annex. Such conditions shall be objectively justified in relation to the service concerned, non-discriminatory, proportionate and transparent.

2. Specific obligations which may be imposed on providers of electronic communications services and networks with significant market power under Article 8 of Directive (on access to, and interconnection of, electronic communications networks and associated facilities) or on those designated to provide universal service under Directive (on universal service and users' rights relating to electronic communications networks and services), shall be legally separate from the general rights and obligations under the general authorisation. In order to achieve transparency for undertakings, the criteria and procedures for imposing such specific obligations on individual undertakings, shall be referred to in the general authorisation.

3. The general authorisation shall only contain conditions which are specific for that sector as set out in Part A of the Annex and shall not duplicate conditions which are applicable to undertakings by virtue of other national legislation.

4. Member States shall not duplicate the terms of the general authorisation where they grant the right to use radio frequencies or numbers.

*Article 7*

**Procedure for limited granting of rights to use radio frequencies**

1. Where a Member State is considering to limit the granting of rights of use for radio frequencies, it shall:

(a) give due weight to the need to maximise benefits for users and to facilitate the development of competition;

(b) allow sufficient opportunity and a period of at least 30 days to enable all interested parties, including users and consumers, to express their views on any limitation;

(c) publish its decision to limit the granting of rights of use, stating the reasons therefor;

(d) review the limitation at reasonable intervals or at the request of undertakings; and

(e) invite applications for rights of use.

2. Where a Member State finds that further rights to use radio frequencies can be granted, it shall publish that finding and invite applications for such rights.

3. Where the granting of rights of use for radio frequencies needs to be limited, Member States shall grant such rights on the basis of selection criteria which must be objective, non-discriminatory, detailed, transparent and proportionate. Any such selection must give due weight to the need to facilitate the development of competition and of innovative services and to maximise benefits for users.

4. Where comparative bidding procedures are to be used, Member States may extend the maximum period of six weeks referred to in Article 5(3) for as long as necessary to ensure that such procedures are fair, reasonable, open and transparent to all interested parties, but by no longer than six months.

These time-limits shall be without prejudice to any applicable international agreements relating to the use of radio frequencies and of orbital positions.

*Article 8*

**Harmonised assignment of radio frequencies**

Where the usage of radio frequencies has been harmonised and access conditions and procedures have been agreed, in accordance with Decision (on a regulatory framework for radio spectrum policy in the Community) and other Community rules, Member States shall grant the right of use for radio frequencies in accordance therewith. They shall not impose any conditions, additional criteria or procedures which would restrict, alter or delay the correct implementation of the harmonised assignment of radio frequencies.

*Article 9*

**Declarations to facilitate the exercise of rights of way and rights of interconnection**

At the request of an undertaking Member States shall, within one week, issue declarations confirming that that undertaking is authorised to apply for rights of way and/or to negotiate interconnection under the general authorisation in order to facilitate the exercise of those rights at other levels of government or in relation to other undertakings. Where appropriate such declarations may also be issued as an automatic reply following notification referred to in Article 3(2).

*Article 10*

**Compliance with the conditions of the general authorisation or for rights of use**

1. National regulatory authorities may require undertakings providing electronic communications services or networks covered by the general authorisation or enjoying rights of use for radio frequencies or numbers to provide information necessary to verify compliance with the conditions of the general authorisation or the rights of use, in accordance with Article 11.

2. Where a national regulatory authority finds that an undertaking does not comply with one or more of the conditions of the general authorisation or the rights of use, it shall notify the undertaking of those findings and give the undertaking a reasonable opportunity to state its views or remedy any breaches within one month after notification or within any other period agreed between the undertaking concerned and the national regulatory authority.

3. If the undertaking concerned does not remedy the breaches within the period as referred to in paragraph 2, the national regulatory authority shall take appropriate and proportionate measures aimed at ensuring compliance. The measures and the reasons on which they are based, shall be communicated to the undertaking concerned within one week of their adoption and at least one week before they take effect.

4. Where a breach of the conditions of the general authorisation or rights of use represents an immediate and serious threat to public safety, security or health or creates serious economic or operational problems for other providers or users of electronic communications services or networks, Member States may take urgent interim measures to remedy the situation. The undertaking concerned shall thereafter be given a reasonable opportunity to state its view and to propose any remedies.

5. Undertakings shall have the right to appeal against measures taken by Member States under this Article in accordance with the procedure referred to in Article 4 of Directive (on a common regulatory framework for electronic communications networks and services).

*Article 11*

**Information required under the general authorisation and for rights of use**

1. Without prejudice to information and reporting obligations under national legislation other than the general authorisation, Member States shall not require undertakings to provide more information under the general authorisation than is proportionate and objectively justified for:

(a) systematic verification of compliance with conditions 1 and 2 of Part A, condition 6 of Part B and condition 5 of Part C of the Annex and of compliance with obligations as referred to in Article 6(2);

(b) case-by-case verification of compliance with conditions as set out in the Annex where a complaint has been received or where the national regulatory authority has other reasons to believe that a condition is not complied with;

(c) comparative bidding procedures for radio frequencies;

(d) publication of comparative overviews of quality and price of services for the benefit of consumers;

(e) clearly defined statistical purposes;

(f) market analysis for the purposes of Directive (on access to, and interconnection of, electronic communications networks and associated facilities) or Directive (on universal service and users' rights relating to electronic communications networks and services).

The information referred to in points (a), (b), (d), (e) and (f) of the first subparagraph may not be required prior to or as a condition for market access.

2. Where Member States require undertakings to provide information as referred to in paragraph 1, they shall inform them of the specific purpose for which this information is to be used.

*Article 12*

**Administrative charges**

1. Any administrative charges imposed on undertakings providing a service under the general authorisation shall:

(a) in total, cover only the administrative costs incurred in the management, control and enforcement of the applicable general authorisation scheme and of the granting of rights of use; and

(b) be apportioned between the individual undertakings in proportion to the turnover of each undertaking within the last accounting year on the services covered by the general authorisation, or for which the rights of use are granted, and provided within the national market of the Member State imposing the charges.

2. Undertakings with an annual turnover for the relevant services referred to in paragraph 1(b) of less than EUR 10 million shall be exempt from paying administrative charges.

3. Where Member States impose administrative charges, they shall publish a yearly overview of their administrative costs and of the total sum of the charges collected. If the total sum of the charges exceeds the administrative costs, appropriate adjustments shall be made in the following year.

*Article 13*

**Fees for rights of use and rights of way**

Member States may allow the assigning authority to impose fees for the rights to use radio frequencies, numbers or rights of way which reflect the need to ensure the optimal use of these resources. Such fees shall be non-discriminatory, transparent, objectively justified and proportionate in relation to their intended purpose and take into particular account the need to foster the development of innovative services and competition.

*Article 14*

**Amendment of rights and obligations**

Member States may amend the rights, conditions, procedures, charges and fees concerning general authorisations and rights of use or rights of way in objectively justified cases and in a proportionate manner. Member States shall give appropriate notice of their intention to make such amendments and allow interested parties, including users and consumers, a sufficient period of no less than four weeks to express their views on the proposed amendments.

*Article 15*

**Publication of information**

1. Member States shall ensure that all relevant information on rights, conditions, procedures, charges, fees and decisions concerning general authorisations and rights of use is published and kept up to date in an appropriate manner so as to provide easy access to that information for all interested parties.

2. Where charges, fees, procedures and conditions concerning rights of way are determined at different levels of government, Member States shall publish and keep up to date a register of all such charges, fees, procedures and conditions in an appropriate manner so as to provide easy access to that information for all interested parties.

*Article 16*

**Functioning of the internal market**

Where divergences between national charges, fees, procedures or conditions concerning general authorisation or the grant of rights of use create barriers to the internal market, the Commission may adopt measures to harmonise such charges, fees, procedures or conditions in accordance with the procedure referred to in Article 19(3) of Directive (on a common regulatory framework for electronic communications networks and services).

In order to identify any such barriers to the single market, the Commission shall periodically review the functioning of the national authorisation systems and the development of cross-border service provision within the Community and report to the European Parliament and to the Council.

*Article 17*

**Existing authorisations**

1. Member States shall bring authorisations already in existence on the date of entry into force of this Directive into line with the provisions of this Directive by 31 December 2001 at the latest.

2. Where application of paragraph 1 results in a reduction of the rights or an extension of the obligations under authorisations already in existence, Member States may extend the validity of those rights and obligations until 30 June 2002 at the latest, provided that the rights of other undertakings under Community law are not effected thereby. Member States shall notify such extensions to the Commission and state the reasons therefor.

*Article 18*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive and of any subsequent amendments to those provisions.

*Article 19*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 20*

**Addressees**

This Directive is addressed to the Member States.

*ANNEX*

The conditions listed in this Annex provide the maximum list of conditions which may be attached to general authorisations (Part A), rights to use radio frequencies (Part B) and rights to use numbers (Part C) as referred to in Article 6(1) and Article 11(a).

A. **Conditions which may be imposed by general authorisation**

1. Financial contributions to the funding of universal service in conformity with Directive (on universal service and users' rights relating to electronic communications networks and services).

2. Administrative charges in conformity with Article 12 of this Directive.

3. Interoperability of services and interconnection of networks in conformity with Directive (on access to, and interconnection of, electronic communications networks and associated facilities).

4. Accessibility of numbers from the national numbering plan to end-users in conformity with Directive (on universal service and users' rights relating to electronic communications networks and services).

5. Environmental and town and country planning requirements, including conditions linked to the granting of access to public or private land and conditions linked to collocation and facility sharing in conformity with Directive (on a common regulatory framework for electronic communications networks and services).

6. Mandatory transmission of specified radio and TV broadcasts in conformity with Directive (on universal service and users' rights relating to electronic communications networks and services).

7. Personal data and privacy protection specific to the electronic communications sector in conformity with Directive (on the processing of personal data and the protection of privacy in the electronic communications sector).

8. Consumer protection rules specific to the electronic communications sector including conditions in conformity with Directive (on universal service and users' rights relating to electronic communications networks and services).

9. Obligations in relation to broadcasting content, in particular those concerning the protection of minors in accordance with Article 2(a)(2) of Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities, as amended by Directive 97/36/EC of the European Parliament and of the Council.

10. Information to be provided under a notification procedure in accordance with Article 3(3) of this Directive and for other purposes as included in Article 11 of this Directive.

11. Enabling of legal interception by competent national authorities in conformity with Directive (on the processing of personal data and the protection of privacy in the electronic communications sector and Directive 95/46/EC).

12. Terms of use during major disasters to ensure communications between emergency services and authorities and broadcasts to the general public.

13. Measures regarding the limitation of exposure of the general public to electromagnetic fields caused by electronic communications networks in accordance with Community law.

B. **Conditions which may be attached to rights of use for radio frequencies**

1. Designation of service for which the frequency shall be used, including conditions in relation to the content to be provided.

2. Efficient use of frequencies in conformity with Directive (on a common regulatory framework for electronic communications networks and services).

3. Avoidance of harmful interference.

4. Maximum duration in conformity with Article 5 of this Directive.

5. Transfer of rights and conditions for such transfer in conformity with Directive (on a common regulatory framework for electronic communications networks and services).

6. Usage fees in accordance with Article 13 of this Directive.

7. Any commitments which the undertaking obtaining the usage right has made in the course of a comparative bidding procedure.

C. **Conditions which may be attached to rights of use for numbers**

1. Designation of service for which the number shall be used.

2. Efficient use of numbers in conformity with Directive (on a common regulatory framework for electronic communications networks and services).

3. Number portability requirements in conformity with Directive (on universal service and users' rights relating to electronic communications networks and services).

4. Maximum duration in conformity with Article 5 of this Directive.

5. Transfer of rights and conditions for such transfer in conformity with Directive (on a common regulatory framework for electronic communications networks and services).

6. Usage fees in accordance with Article 13 of this Directive.

# Proposal for a Directive of the European Parliament and of the Council on universal service and users' rights relating to electronic communications networks and services

(2000/C 365 E/19)

**(Text with EEA relevance)**

*COM(2000) 392 final — 2000/0183(COD)*

*(Submitted by the Commission on 28 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The liberalisation of the telecommunications sector and increasing competition and choice for communications services go hand in hand with parallel action to create a harmonised regulatory framework which secures the delivery of universal service. The concept of universal service must evolve to reflect advances in technology, market developments and changes in user demand. The regulatory framework established for the full liberalisation of the telecommunications market in 1998 in the Community defined the minimum scope of universal service obligations and established rules for its costing and financing.

(2) Under Article 153 of the Treaty, the Community is to contribute to the protection of consumers.

(3) The Community and its Member States have taken commitments on the regulatory framework of telecommunications networks and services in the context of the World Trade Organisation (WTO) agreement on basic telecommunications. Any member of the WTO has the right to define the kind of universal service obligation it wishes to maintain. Such obligations will not be regarded as anti-competitive per se, provided they are administered in a transparent, non-discriminatory and competitively neutral manner and are not more burdensome than necessary for the kind of universal service defined by the member.

(4) In a competitive market, certain obligations should apply to all undertakings providing publicly available telephone services at fixed locations and others should apply only to undertakings enjoying significant market power or which have been designated as a universal service operator.

(5) A fundamental requirement of universal service is to provide users on request with a connection to the public telephone network at a fixed location, at an affordable price. The requirement is limited to a single network connection, and does not extend to the Integrated Services Digital Network (ISDN) which provides two or more connections capable of being used simultaneously. There should be no constraints on the technical means by which the connection is provided, allowing for wired or wireless technologies, nor any constraints on which operators provide part or all of universal service obligations. Connections to the public telephone network at a fixed location should be capable of supporting speech and data communications at rates sufficient for access to online services such as those provided via the public Internet. The data rate that can be supported by a single connection to the public telephone network depends on the capabilities of the subscriber's terminal equipment as well as the connection. For this reason it is not appropriate to mandate a specific data or bit rate at Community level. Currently available voice band modems typically offer a data rate of 56 kbit/s and employ automatic data rate adaptation to cater for variable line quality, with the result that the achieved data rate may be lower than 56 kbit/s. In specific cases where the connection to the public telephony network at a fixed location is clearly insufficient to support satisfactory Internet access, Member States should be able to require the connection to be brought up to the level enjoyed by the majority of subscribers so that it supports data rates sufficient for access to the Internet. Where such specific measures produce a net cost burden for those consumers concerned, the net effect may be included in any net cost calculation of universal service obligations.

(6) Affordable price means a price defined by Member States at national level in the light of specific national conditions, and may involve setting common tariffs irrespective of location or special tariff options to deal with the needs of low income users. Affordability for individual consumers is related to their ability to monitor and control their expenditure.

(7) Directory information and a directory enquiry service constitutes an essential access tool for publicly available telephone services and is part of the universal service obligation. Users and consumers desire comprehensive directories and a directory enquiry service covering all listed telephone subscribers and their numbers (including fixed, mobile and personal telephone numbers) and want this information to be presented in a non-preferential fashion. Under Directive .../.../EC of the European Parliament and of the Council (concerning the processing of personal data and the protection of privacy in the electronic communications sector), subscribers have the right to determine which, if any, of their personal information is included in a public directory.

(8) For the citizen, it is important for there to be adequate provision of public pay telephones, and for users to be able to call emergency telephone numbers and, in particular, the single European emergency call number ('112') free of charge from any telephone, including public pay telephones, without the use of coins or cards. Insufficient information about the existence of '112' deprives citizens of the additional safety ensured by the existence of this number at European level especially during their travel in other Member States.

(9) Member States should take suitable measures in order to guarantee access to and affordability of all publicly available telephone services at a fixed location for disabled users and users with special social needs. Specific measures for disabled users could include, as appropriate, making available public text telephones or equivalent measures for deaf or speech-impaired people, providing services such as directory enquiry services or equivalent measures free of charge for blind or partially sighted people, and providing itemised bills in alternative format on request for blind or partially sighted people. Specific measures may also need to be taken to enable disabled users and users with special needs to access emergency services (112) and to give them a similar possibility to choose between different operators or service providers as other consumers. The provider of universal service should not take measures to prevent users from benefiting fully from services offered by different operators or service providers, in combination with its own services offered as part of universal service.

(10) The importance of access to and use of the public telephone network at a fixed location is such that it should be available to anyone reasonably requesting it. In accordance with the principle of subsidiarity, it is for Member States to decide on the basis of objective criteria which undertakings have universal service obligations for the purposes of this Directive, taking into account the ability and, where appropriate, the willingness of undertakings to accept all or part of the universal service obligations. It is important that universal service obligations are fulfilled in the most efficient fashion so that users generally pay prices that correspond to efficient cost provision. It is likewise important that universal service operators maintain the integrity of the network as well as service continuity and quality. The development of greater competition and choice provide more possibilities for all or part of the universal service obligations to be provided by undertakings other than those with significant market power. Therefore, universal service obligations could in some cases be allocated to operators demonstrating the most cost effective means of delivering access and services. Corresponding obligations could be included as conditions in authorisations to provide publicly available services.

(11) Member States should monitor the situation of consumers with respect to their use of publicly available telephone services and in particular with respect to affordability. The affordability of telephone service is related to the information which users receive regarding telephone usage expenses as well as the relative cost of telephone usage compared to other services, and is also related to their ability to control expenditure. Affordability therefore means giving power to consumers through obligations imposed on undertakings designated as having universal service obligations. These obligations include a specified level of itemised billing, the possibility for consumers selectively to block certain calls (such as high-priced calls to premium services), the possibility for consumers to control expenditure via pre-payment means and the possibility for consumers to offset or defray up-front connection fees. Such measures may need to be reviewed and changed in the light of market developments. Current conditions do not warrant a requirement for operators with universal service obligations to alert subscribers where a predetermined limit of expenditure is exceeded or an abnormal calling pattern occurs. Review of the relevant legislative provisions in future should consider whether there is a possible need to alert subscribers for these reasons.

(12) Except in cases of persistent late payment or non-payment of bills, consumers should be protected from immediate disconnection from the network on the grounds of an unpaid bill and, particularly in the case of disputes over high bills for premium rate services, should continue to have access to essential telephone services pending resolution of the dispute. In some Member States such access may continue to be provided only if the subscriber continues to pay line rental charges.

(13) Quality and price are key factors in a competitive market and national regulatory authorities should be able to monitor achieved quality of service for undertakings with significant market power or which have been designated as having universal service obligations. National regulatory authorities should also be able to monitor the achieved quality of services of other undertakings providing public telephone networks and/or publicly available telephone services to users at fixed locations. In relation to the quality of service attained by both types of undertakings, national regulatory authorities should be able to take appropriate corrective measures where they deem it necessary.

(14) Member States may establish mechanisms for covering or financing the net cost of universal service obligations in cases where it is demonstrated that the obligations can only be provided at a loss or at a net cost which falls outside normal commercial standards. It is important to ensure that the net cost of universal service obligations is properly calculated and that any financing is undertaken with minimum distortion to the market and to undertakings, and is compatible with the provisions of Articles 87 and 88 of the Treaty.

(15) Any calculation of the net cost of universal service should take due account of costs and revenues, as well as the intangible benefits resulting from providing universal service but should not hinder the general aim of ensuring that pricing structures reflect costs. Any net costs of universal service obligations should be calculated on the basis of transparent procedures.

(16) When a universal service obligation represents an unfair burden on an undertaking, it is appropriate to allow Member States to establish mechanisms for efficiently recovering net costs. Recovery via general government budgets constitutes one method of recovering the net costs of universal service obligations. It is also reasonable for established net costs to be recovered from all users in a transparent fashion by means of levies on undertakings. In the case of cost recovery by means of levies on undertakings, Member States should ensure that the method of allocation amongst them is based on objective and non-discriminatory criteria and is in accordance with the principle of proportionality. This principle does not prevent Member States from exempting new entrants, which have not yet achieved any significant market presence. Any funding mechanism should ensure that market participants only contribute to the financing of universal service obligations, and not to other activities which are not directly linked to the provision of the universal service obligations. Recovery mechanisms should in all cases respect the principles of Community law, and in the case of fund sharing mechanisms those of non-discrimination and proportionality. Any funding mechanism should ensure that users in one Member State do not contribute to universal service costs in another Member State, for example when making calls from one Member State to another.

(17) National regulatory authorities should satisfy themselves that those undertakings benefiting from universal service funding provide a sufficient level of detail of the specific elements requiring such funding in order to justify their request. Member States' schemes for the costing and financing of universal service obligations will be communicated to the Commission for verification of compatibility with the Treaty. There are incentives for designated operators to raise the assessed net cost of universal service obligations. Therefore Member States should ensure effective transparency and control of amounts charged to finance universal service obligations. In addition, the mechanism should be closely monitored and provision made for efficient procedures for timely appeal to an independent body for the settlement of disputes as to the amount to be paid, without prejudice to other available remedies under national law or Community law.

(18) Communications markets continue to evolve in terms of the services used and the technical means used to deliver them to users. The universal service obligations at a Community level should be periodically reviewed with a view to proposing that the scope be changed or re-defined. Such a review should take account of evolving social, commercial and technological conditions and the fact that any change of scope should be subject to the twin test of services that become available to a substantial majority of the population, with a consequent risk of social exclusion for those who can not afford them. Care should be taken in any change of the scope of universal service obligations to ensure that certain technological choices are not artificially promoted above others, that a disproportionate financial burden is not imposed on sector undertakings (thereby endangering market developments and innovation) and that any financing burden does not fall unfairly on consumers with lower incomes. Any change of scope automatically means that any net cost can be financed via the methods permitted in this Directive. Member States are not permitted to impose on market players financial contributions which relate to measures which are not part of universal service obligations. Individual Member States remain free to impose special measures (outside the scope of universal service obligations) and finance them in conformity with Community law but not by means of contributions from market players.

(19) More effective competition across all access and service markets will give greater choice for users. The extent of effective competition and choice varies across the Community and varies within Member States between geographical areas and between access and service markets. Nevertheless an undertaking that previously had exclusive rights may retain significant market power in access markets and in some service markets. Some users may be entirely dependent on the provision of access and services by an undertaking with significant market power. In general for reasons of efficiency and to encourage effective competition, it is important that the services provided by an undertaking with significant market power reflect costs. For reasons of efficiency and social reasons, end user tariffs should reflect demand conditions as well as cost conditions, provided that this does not result in distortions of competition. There is a risk that an undertaking with significant market power may act in various ways to inhibit entry or distort competition, for example by charging excessive prices, setting predatory prices, compulsory bundling of retail services or showing undue preference to certain customers. Universal service obligations and the public interest imply that for some consumers, tariffs and tariff structures may need to depart from normal commercial conditions. Nevertheless, undertakings which have been found to have significant market power should be free of unnecessary regulation in markets where effective competition exists. Therefore, national regulatory authorities should have powers to establish, maintain and withdraw retail tariff regulations on an undertaking with significant market power. Price cap regulation, geographical averaging or similar instruments may be used to achieve the twin objectives of promoting effective competition whilst pursuing public interest needs, such as maintaining the affordability of publicly available telephone services for some consumers. Access to appropriate cost accounting information is necessary in order for national regulatory authorities to fulfil their regulatory duties in this area, including the imposition of any tariff controls.

(20) Contracts are an important tool for users and consumers to ensure a minimum level of transparency of information and legal security. Most service providers in a competitive environment will conclude contracts with their customers for reasons of commercial desirability. In addition to the provisions of this Directive, the requirements of existing Community consumer protection legislation relating to contracts, in particular Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts [1] and Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts [2], apply to consumer transactions relating to electronic networks and services. Specifically, consumers should enjoy a minimum level of legal certainty in respect of their contractual relations with their direct telephone service provider, such that the contractual terms, conditions, quality of service, condition for termination of the contract and the service, compensation measures and dispute resolution are specified in their contracts. Where service providers other than direct telephone service providers conclude contracts with consumers, the same information should be included in those contracts as well. The measures to ensure transparency on prices, tariffs, terms and conditions will increase the ability of consumers to optimise their choices and thus to benefit fully from competition.

(21) Users and consumers should have access to publicly available information on communications services. Member States should be able to monitor the quality of services which are offered in their territories. National regulatory authorities should be able systematically to collect information on the quality of services offered in their territories on the basis of criteria which allow comparability between service providers and between Member States. Undertakings providing communications services, operating in a competitive environment, are likely to make adequate and up-to-date information on their services publicly available for reasons of commercial advantage. National regulatory authorities should nonetheless be able to require publication of such information where it is demonstrated that such information is not effectively available to the public.

(22) Users and consumers should be able to enjoy a guarantee of interoperability in respect of all equipment sold in the Community for the reception of digital television. Member States should be able to require minimum harmonised standards in respect of such equipment. Such standards should be adapted from time to time in the light of technological and market developments.

(23) All users and consumers should continue to enjoy access to operator assistance services whatever organisation provides access to the public telephone network.

[1] OJ L 95, 21.4.1993, p. 29.

[2] OJ L 144, 4.6.1997, p. 19.

(24) The provision of directory services is already open to competition. The provisions of this Directive complement the provisions of Directive (concerning the processing of personal data and protection of privacy in the electronic communications sector), by giving subscribers a right to have their personal data included in a printed or electronic directory. All service providers which assign telephone numbers to their subscribers are obliged to make relevant information available in a fair, cost-oriented, non-discriminatory manner.

(25) It is important that users should be able to call the single European emergency number '112', and any other national emergency telephone numbers, free of charge, from any telephone, including public pay telephones, without the use of coins or cards. Member States should have already made the necessary organisational arrangements best suited to the national organisation of the emergency systems, in order to ensure that calls to this number are adequately answered and handled. Caller location information, to be made available to the emergency services, will improve the level of protection and the security of users of '112' services and assist the emergency services in the discharge of their duties, provided that the transfer of calls and associated data to the emergency services concerned is guaranteed. Steady information technology improvements will progressively support the simultaneous handling of several languages over the networks at a reasonable cost. This in turn will ensure additional safety for European citizens using the '112' emergency call number.

(26) Easy access to international telephone services is vital for European citizens and European businesses. '00' has already been established as the standard international telephone access code for the Community. Special arrangements for making calls between adjacent locations across borders between Member States may be established or continued. All operators should be obliged to complete calls that use not only the European regional code '3883' but also any other regional codes that may be used in Europe.

(27) Tone dialling and calling line identification facilities are normally available on modern telephone exchanges and can therefore increasingly be provided at little or no expense. Tone dialling is increasingly being used for user interaction with special services and facilities, including value added services, and the absence of this facility can prevent the user from making use of these services. Member States are not required to impose obligations to provide these facilities when they are already available. Directive [on the protection of personal data and privacy in the electronic communications sector] safeguards the privacy of users with regard to itemised billing, by giving them the means to protect their right to privacy when calling-line identification is implemented.

(28) Number portability is a key facilitator of consumer choice and effective competition in a competitive telecommunications environment such that end users who so request should be able to retain their number(s) on the public telephone network independently of the organisation providing service. The provision of this facility between connections to the public telephone network at fixed and non-fixed locations is not appropriate at present, in particular due to the loss of tariff information to the consumer that would result. This provision could be subject to review.

(29) Currently, Member States impose certain 'must-carry' obligations on networks established for the distribution of radio or television broadcasts to the public. Member States should be able to lay down proportionate obligations on undertakings under their jurisdiction, in the interest of legitimate public policy considerations, but such obligations should only be imposed where they are necessary to meet clearly defined general interest objectives and should be proportionate, transparent and limited in time. It would not be proportionate to extend such obligations to new networks such as the Internet. The undertakings on which such obligations fall should be appropriately compensated for the use of their network capacity on reasonable, transparent and non-discriminatory terms.

(30) It is considered necessary to ensure the continued application of the existing provisions relating to leased line services in Community telecommunications legislation, in particular in Council Directive 92/44/EEC of 5 June 1992 on the application of open network provision to leased lines [1], as last amended by Commission Decision 98/80/EC of 7 January 1998 [2], until such time as national regulatory authorities determine, in accordance with the market analysis procedures laid down in Directive .../.../EC (on a common regulatory framework for electronic communications networks and services), that such provisions are no longer needed because a sufficiently competitive market has developed in their territory. For the time being these services constitute mandatory services to be provided without recourse to any compensation mechanisms.

[1] OJ L 165, 19.6.1992, p. 27.

[2] OJ L 14, 20.1.1998, p. 27.

(31) Where a Member State seeks to ensure the provision of other specific services throughout its national territory, such obligations should be implemented on a cost-efficient basis and outside the scope of universal service obligations. As a reaction to the Commission's *e*Europe initiative, the Lisbon European Council called on Member States to ensure that all schools have access to the Internet and to multimedia resources by the end of 2001.

(32) In the context of a competitive environment, the views of interested parties, including users and consumers, should be taken into account by national regulatory authorities when dealing with issues related to users' and consumers' rights. Effective procedures should be available to deal with disputes between users and consumers, on the one hand, and undertakings providing publicly available communications services, on the other. Member States should take full account of Commission Recommendation 98/257/EC of 30 March 1998 on the principles applicable to the bodies responsible for out-of-court settlement of consumer disputes [1].

(33) The provisions of this Directive do not prevent a Member State from taking measures justified on grounds set out in Articles 30 and 46 of the Treaty, and in particular on grounds of public security, public policy and public morality.

(34) In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, the objectives of setting a common level of universal service for telecommunications for all European users and of harmonising conditions for access to and use of public telephone networks at a fixed location and related publicly available telephone services cannot be realised satisfactorily at Member State level. The objective of achieving a harmonised framework for the regulation of electronic communications services, electronic communications networks and associated facilities cannot be sufficiently achieved by the Member States and can therefore be better achieved by the Community. This Directive confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose.

(35) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

[1] OJ L 115, 17.4.1998, p. 31.

[2] OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

**SCOPE, AIMS AND DEFINITIONS**

*Article 1*

**Scope and aims**

1. Within the framework of Directive (on a common regulatory framework for electronic communications networks and services), this Directive concerns the provision of electronic communications networks and services to users and consumers.

2. The aim of this Directive is to ensure the availability throughout the Community of good quality electronic communications services at an affordable price by means of effective competition and choice and to deal with circumstances in which users' and consumers' needs are not satisfactorily met by commercial means. It also aims to ensure interoperability of consumer digital television equipment.

*Article 2*

**Definitions**

The definitions given in Directive (on a common regulatory framework for electronic communications networks and services) shall apply.

The following definitions shall also apply:

(a) 'direct public telephone service provider' means an undertaking that provides publicly available telephone services and that also provides a subscriber with a connection to the public telephone network;

(b) 'subscriber' means any natural or legal person that is party to a contract with undertakings providing publicly available communications services for the supply of such services;

(c) 'public pay telephone' means a telephone available to the general public, for the use of which the means of payment include coins and/or credit/debit cards and/or pre-payment cards, including cards for use with dialling codes;

(d) 'public telephone network' means transmission systems and switching or routing equipment and other resources which are used to provide publicly available telephone services; it supports the transfer between network termination points of speech communications, and also other forms of communication, such as fax and data; connection to the public telephone network at a fixed location may take place via wireless as well as wire-line means;

(e) 'publicly available telephone service' means a service available to the public for originating and receiving national and international calls, and access to emergency services using the code 112 through a number or numbers in a national or international telephone numbering plan; it may include the provision of operator assistance, directory services, provision of public pay phones, provision of service under special terms and/or provision of special facilities for customers with disabilities or with special social needs;

(f) 'network termination point' (NTP) means the physical point at which a subscriber is provided with access to a public communications network; in the case of networks involving switching or routing, the NTP is identified by means of a specific network address, which may be linked to a subscriber number or name; it represents a boundary for regulatory purposes between different systems; defining the location of NTP is the responsibility of the national regulatory authority;

(g) 'geographic number' means a number from the national numbering plan where part of its digit structure contains geographic significance used for routing calls to the physical location of the NTP of the subscriber to whom the number has been assigned.

CHAPTER II

## UNIVERSAL SERVICE OBLIGATIONS

*Article 3*

### Availability of universal service

1. Member States shall ensure that the services set out in this Chapter are made available at the quality specified to all users in their territory, independently of geographical location, and, in the light of specific national conditions, at an affordable price.

2. Member States shall determine the most efficient and appropriate approach for ensuring the implementation of universal service, whilst respecting the principles of transparency, objectivity and non-discrimination. They shall seek to minimise market distortions, in particular the provision of services at prices or subject to other terms and conditions which depart from normal commercial conditions, whilst safeguarding the public interest.

*Article 4*

### Provision of access at fixed locations

1. Member States shall ensure that all reasonable requests for connection to the public telephone network at a fixed location and for access to publicly available telephone services at a fixed location are met by at least one operator.

2. The connection provided shall be capable of allowing users to make and receive local, national and international telephone calls, facsimile communications and data communications, at data rates that are sufficient to permit Internet access.

*Article 5*

### Directory enquiry services and directories

Member States shall ensure that, in respect of subscribers of direct public telephone service providers and in conformity with Article 12 of Directive (on processing of personal data and protection of privacy in the electronic communications sector):

(a) a subscriber directory is available to users in a form approved by the national regulatory authority, whether printed or electronic, or both, and is updated on a regular basis, and at least once a year;

(b) at least one telephone directory enquiry service covering all listed subscribers' numbers is available to all users, including users of public pay telephones;

(c) undertakings that provide the services referred to in paragraphs (a) and (b) apply the principle of non-discrimination to the treatment of information that has been provided to them by other undertakings.

*Article 6*

### Public pay telephones

1. Member States shall ensure that national regulatory authorities can impose obligations on undertakings in order to ensure that public pay telephones are provided to meet the reasonable needs of users in terms of the geographical coverage, the number of telephones and the quality of services.

2. A Member State may decide not to apply paragraph 1 in all or part of its territory on the basis of a consultation of interested parties as referred to in Article 29.

3. Member States shall ensure that it is possible to make emergency calls from public pay telephones using the single European emergency call number '112' and other national emergency numbers, all free of charge and without having to use coins or cards.

*Article 7*

### Special measures for disabled users and users with special needs

1. Member States shall, where appropriate, take specific measures to ensure equivalent access to and affordability of publicly available telephone services, including access to emergency and directory services, for disabled users and users with special social needs.

2. Member States may take specific measures, in the light of national conditions, to ensure that disabled users and users with special needs can also take advantage of the choice of undertakings and service providers available to the majority of users.

*Article 8*

**Designation of undertakings**

1. Member States may, if necessary, designate one or more undertakings to guarantee the provision of universal service as identified in Articles 4 to 7, so that the whole of the national territory is covered. Member States may designate different undertakings or sets of undertakings to provide different elements of universal service.

2. In order to ensure efficient provision of access to and use of the public telephone network, Member States shall ensure that all undertakings have an opportunity to be designated as providing access and services at a fixed location in part or all of the national territory, if necessary by designating different undertakings to provide different elements (geographical or otherwise) of the universal service obligations.

3. When Member States designate undertakings in part or all of the national territory as having universal service obligations, they shall do so using an efficient, objective and transparent allocation mechanism. Such designation methods may include public tenders and public auctions, in order to ensure that universal service is provided in a cost-effective manner and as a means of determining the net cost of the universal service obligation.

*Article 9*

**Level and structure of tariffs**

1. National regulatory authorities shall monitor the evolution of the level and structure of retail tariffs of the publicly available telephone service provided at fixed locations by designated undertakings, in particular in relation to national consumer prices and income. They may, in the light of national conditions, require the designated undertakings to provide tariff options or packages to consumers which depart from those provided under normal commercial conditions, in particular to ensure that those on low incomes or with specific social needs are not prevented from accessing or using the publicly available telephone service.

2. Member States may require undertakings with obligations under Article 4 to apply common tariffs throughout the territory, in the light of national conditions.

3. Member States may, as an alternative to the requirement for designated undertakings to provide special tariff options or for undertakings to apply common tariffs, provide support to consumers identified as having specific economic or social needs, in particular by granting entitlement to the public telephone service at a specified tariff.

4. National regulatory authorities shall ensure that, where an undertaking has an obligation to provide special tariff options 1 or common tariffs, the conditions are fully transparent and are published and applied in accordance with the principle of non-discrimination. National regulatory authorities may require that specific schemes be modified or withdrawn.

*Article 10*

**Specific affordability provisions and control of expenditure**

1. Member States shall ensure that designated undertakings, in providing facilities and services additional to the provision of a connection to the public telephone network and publicly available telephone services, establish tariffs in such a way that the user is not obliged to pay for facilities or services which are not necessary or not required for the service requested.

2. Member States shall ensure that designated undertakings provide the specific facilities and services set out in Annex I in order that consumers can monitor and control expenditure and avoid unwarranted disconnection of service.

*Article 11*

**Quality of service of designated undertakings**

1. National regulatory authorities shall ensure that all undertakings with obligations as referred to in Article 4 publish adequate and up-to-date information concerning their performance in the provision of access and services, based on parameters, definitions and measurement methods set out in Annex III. The published information shall also be supplied to the national regulatory authority.

2. National regulatory authorities shall be able to set performance targets for undertakings with universal service obligations under Article 4. In so doing, national regulatory authorities shall take account of views of interested parties, in particular as referred to in Article 29.

3. Persistent failure by an undertaking to meet performance targets may result in specific measures being taken in accordance with conditions set out in the general authorisation measures for the operator. National regulatory authorities shall be able to order independent audits of the performance data, paid for by the undertaking concerned, in order to ensure the accuracy and comparability of the data made available by undertakings with universal service obligations.

*Article 12*

**Costing of universal service**

1. Where necessary, national regulatory authorities may assess whether the provision of universal service represents an unfair burden on undertakings designated to provide universal service.

For that purpose, national regulatory authorities may:

(a) calculate the net cost of the obligation in accordance with Annex IV, Part A; or

(b) use an efficient, objective and transparent allocation mechanism such as public tendering or auction.

2. The calculation of the net cost of universal service obligations under paragraph 1(a) shall be audited by an independent body or organisation. The results of the cost calculation and the conclusions of the audit shall be open to the public.

*Article 13*

**Financing of universal service obligations**

1. Where, on the basis of the net cost calculation referred to in Article 12, and taking into account any market benefit which accrues to an undertaking designated to provide universal service, national regulatory authorities find that an undertaking is subject to an unfair burden, Member States may decide:

(a) to introduce a mechanism to compensate that undertaking for the determined net costs from the general government budget; or

(b) to share the net cost of universal service obligations.

2. Where the net cost is shared under paragraph 1(b), Member States shall establish a sharing mechanism administered by a body independent from the beneficiaries under the control of the national regulatory authority. Only the net cost, as determined in Article 12, of the obligations laid down in Articles 3 to 10 may be financed.

3. A sharing mechanism based on a Fund shall respect the principles of transparency, least market distortion, non-discrimination and proportionality, in accordance with the principles of Annex IV.

4. Any charges related to the sharing of the cost of universal service obligations shall be unbundled and identified separately. Such charges shall not be imposed or collected from undertakings that are not providing services in the territory of the Member State that has established the sharing mechanism.

*Article 14*

**Transparency**

1. Where a mechanism for sharing the net cost of universal service obligations as referred to in Article 13 is established, national regulatory authorities shall ensure that the principles for cost sharing, and details of the mechanism used, are publicly available.

2. National regulatory authorities shall ensure that an annual report is published giving the calculated cost of universal service obligations, identifying the contributions made by all the parties involved, and identifying any market benefits, both financial and non-financial, that may have accrued to the undertaking(s) designated to provide universal service, where a Fund is actually in place and working.

3. Member States may require that contributions made by undertakings to finance universal service obligations be shown on users' bills.

*Article 15*

**Review of scope of universal service**

1. The Commission shall periodically review the scope of universal service, on the first occasion not later than two years after entry into force of this Directive, in particular with a view to proposing that the scope be changed or redefined.

2. This review shall be undertaken in the light of social, commercial and technological developments. The review process shall be undertaken in accordance with Annex V.

CHAPTER III

**USER AND CONSUMER INTERESTS AND RIGHTS**

*Article 16*

**Retail tariff regulation**

1. Member States shall maintain all obligations relating to retail tariffs for the provision of access to and use of the public telephone network at fixed locations that were in force prior to the date of entry into force of this Directive under Article 17 of Directive 98/10/EC of the European Parliament and of the Council on the application of open network provision (ONP) to voice telephony and a universal service for telecommunications in a competitive environment [1], until a review has been carried out and a determination made in accordance with paragraph 2 of this Article.

[1] OJ L 101, 1.4.1998, p. 24.

2. Member States shall ensure that, on the entry into force of this Directive, and periodically thereafter, national regulatory authorities undertake a market analysis, in accordance with the procedure set out in Article 14(3) of Directive (on a common regulatory framework for electronic communications networks and services) to determine whether to maintain, amend or withdraw the obligations referred to in paragraph 1 of this Article. Measures taken shall be subject to the procedure set out in Article 6(2) to (5) of Directive (on a common regulatory framework for electronic communications networks and services).

3. Where as a result of a market analysis carried out in accordance with Article 14(3) of the Directive (on a common regulatory framework for electronic communications networks and services), national regulatory authorities determine that a market is not effectively competitive, they shall ensure that undertakings with significant market power in that market orient their tariffs towards costs, so as not to charge excessive prices or inhibit market entry, or restrict competition by setting predatory prices, showing undue preference to specific users or unreasonably bundling services. National regulatory authorities may apply appropriate retail price cap measures to such undertakings in order to protect user and consumer interests whilst promoting effective competition.

4. National regulatory authorities shall notify to the Commission the names of undertakings subject to retail tariff controls and, on request, submit information concerning the retail tariff controls applied and the cost accounting systems used by the undertakings concerned.

5. Member States shall ensure that, where an undertaking is subject to retail tariff regulation, the necessary and appropriate cost accounting systems are implemented and that the suitability of such systems is verified by a competent body which is independent of the organisation. National regulatory authorities shall ensure that a statement concerning compliance is published annually.

6. Without prejudice to Article 9(1) and Article 10, national regulatory authorities shall not apply retail tariff control mechanisms under paragraph 1 of this Article to geographical or user markets where they are satisfied that there is effective competition.

*Article 17*

**Contracts**

1. Member States shall ensure that users and consumers have a right to a contract with their direct public telephone service provider(s) that specifies:

(a) the identity and address of the supplier;

(b) services provided, the service quality levels offered, as well as the time for the initial connection;

(c) the types of maintenance service offered;

(d) the means by which up-to-date information on all applicable tariffs and maintenance charges may be obtained;

(e) the duration of the contract, the conditions for renewal and termination of services and of the contract;

(f) any compensation and the refund arrangements which apply if contracted service quality levels are not met; and

(g) the method of initiating procedures for settlement of disputes in accordance with Article 30.

2. Where contracts are concluded between users or consumers and communications services providers other than direct public telephone service providers, the information in paragraph 1 shall also be included in such contracts.

3. Users and consumers shall be given adequate notice of any intention to modify contractual conditions and shall be free to withdraw from contracts if they do not accept the new conditions.

4. Paragraphs 1, 2 and 3 apply without prejudice to Community rules on consumer protection, in particular Directives 97/7/EC and 93/13/EC.

*Article 18*

**Transparency and publication of information**

Member States shall ensure that transparent information on applicable prices and tariffs, and on standard terms and conditions, in respect of access to and use of publicly available telephone services is available to the public, and particularly to all users and consumers, in accordance with the provisions of Annex II.

*Article 19*

**Quality of service**

1. Member States shall ensure that national regulatory authorities are able to require undertakings that provide publicly available electronic communications services to publish comparable, adequate and up-to-date information for consumers on the quality of their services. The published information shall also be supplied to the national regulatory authority.

2. An obligation to publish quality of service information shall be imposed after taking account of the views of interested parties, including users and consumers, as referred to in Article 29, and after a period of public consultation on the measures proposed.

*Article 20*

**Interoperability of consumer digital television equipment**

1. Member States shall ensure the interoperability of consumer digital television equipment as set out in Annex VI.

2. The Commission may amend Annex VI in the light of market and technological developments in accordance with the procedure referred to in Article 33(2).

*Article 21*

**Operator assistance and directory enquiry services**

1. Member States shall ensure that subscribers to publicly available telephone services have the right to have an entry in publicly available directories.

2. Member States shall ensure that all direct public telephone service providers which assign telephone numbers to subscribers meet all reasonable requests to make available, for the purposes of the provision of directory services, the relevant information in an agreed format on terms which are fair, cost-oriented and non-discriminatory.

3. Member States shall ensure that all users provided with a connection to the public telephone network can access operator assistance services and directory enquiry services in accordance with Article 5(b).

4. Member States shall not maintain any regulatory restrictions which prevent users in one Member State from accessing directly the directory enquiry service in another Member State.

5. Paragraphs 1 to 4 apply subject to the requirements of Community legislation on the protection of personal data and privacy and, in particular, Article 12 of Directive (concerning the processing of personal data and the protection of privacy in the electronic communications sector).

*Article 22*

**European emergency number**

1. Member States shall ensure that, in addition to any other national emergency call numbers specified by the national regulatory authorities, all users of publicly available telephone services, including users of public pay telephones, are able to call the emergency services free of charge, by using the single European emergency call number '112'.

2. Member States shall ensure that calls to the single European emergency call number '112' are appropriately answered and handled in a manner best suited to the national organisation of emergency systems and within the technological possibilities of the networks.

3. Member States shall ensure that undertakings which operate public telephone networks make caller location information available to authorities handling emergencies, where technically feasible, for all calls to the European emergency number '112'.

4. Member States shall ensure that citizens are adequately informed about the existence and use of the European emergency call number '112'.

*Article 23*

**European telephone access codes**

1. Member States shall ensure that the '00' code is the standard international access code. Special arrangements for making calls between adjacent locations across borders between Member States may be established or continued. The subscribers to publicly available telephone services in the locations concerned shall be fully informed of such arrangements.

2. Member States shall ensure that all undertakings that operate public telephone networks handle all calls to and from the European telephone numbering space identified by the regional code '3883' or any other European regional codes that may be used.

*Article 24*

**Provision of additional facilities**

1. Member States shall ensure that national regulatory authorities are able to require all undertakings that operate public telephone networks to make available to users the facilities listed in Annex I, Part B, subject to technical feasibility and economic viability.

2. A Member State may decide not to apply paragraph 1 in all or part of its territory on the basis of a consultation as referred to in Article 29.

*Article 25*

**Number portability, carrier selection and carrier pre-selection**

1. Member States shall ensure that all subscribers of publicly available telephone services, including mobile services, who so request can retain their number(s) independently of the undertaking providing the service:

(a) in the case of geographic numbers, at a specific location; and

(b) in the case of numbers other than geographic numbers, at any location.

2. National regulatory authorities shall require undertakings notified as having significant market power for the provision of connection to and use of the public telephone network at fixed locations to enable their subscribers to access the services of any interconnected provider of publicly available telephone services:

(a) on a call-by-call basis by dialling a short prefix; and

(b) by means of pre-selection, with a facility to override any pre-selected choice on a call-by-call basis by dialling a short prefix.

User requirements for these facilities to be implemented on other networks or in other ways shall be assessed in accordance with the market analysis procedure laid down in Article 14 of Directive (on a common regulatory framework for electronic communications networks and services).

3. National regulatory authorities shall ensure that pricing for interconnection related to the provision of number portability under paragraph 1, and the use of the facility in paragraph 2, are cost oriented.

4. National regulatory authorities shall not impose tariffs for the porting of numbers in a manner that would distort competition, such as by imposing a common tariff across all undertakings.

*Article 26*

**'Must carry' obligations**

1. Member States may impose 'must carry' obligations, for the transmission of specified radio and television broadcasts, on undertakings under their jurisdiction providing electronic communications networks established for the distribution of radio or television broadcasts to the public. Such obligations shall only be imposed where they are necessary to meet clearly defined general interest objectives and shall be proportionate, transparent and limited in time.

2. Member States shall ensure that the undertakings subject to 'must carry' obligations receive appropriate compensation on reasonable, transparent and non-discriminatory terms taking into account the network capacity required.

CHAPTER IV

**MANDATORY SERVICES AND LEASED LINES**

*Article 27*

**Availability of leased lines**

1. Member States shall maintain all obligations on undertakings that were in force prior to the date of entry into force of this Directive under Articles 3, 4, 6, 7, 8 and 10 of Directive 92/44/EEC until a review has been carried out and a determination made in accordance with paragraph 2 of this Article.

2. Within one year after the entry into force of this Directive, and every two years thereafter, national regulatory authorities shall conduct a market analysis, in accordance with the procedure set out in Article 14(3) of Directive (on a common regulatory framework for electronic communications networks and services), to determine whether the provision of part or all of the minimum set of leased lines services in their territory is subject to effective competition and to determine whether to maintain, amend or withdraw obligations referred to in paragraph 1 of this Article. Measures taken shall be subject to the procedure set out in Article 6(2) to (5) of Directive (on a common regulatory framework for electronic communications networks and services).

3. Technical standards for the minimum set of leased lines with harmonised characteristics shall be published in the *Official Journal of the European Communities*, as part of the List of Standards referred to in Article 15 of Directive (on a common regulatory framework for electronic communications networks and services). The Commission may adopt amendments necessary to adapt the minimum set of leased lines to new technical developments and to changes in market demand, including the possible deletion of certain types of leased line from the minimum set, acting in accordance with the procedure referred to in Article 33(2) of this Directive.

*Article 28*

**Additional mandatory services**

Member States may decide to make additional services, apart from universal service obligations as defined in Chapter II, publicly available in its own territory but, in such circumstances, no compensation mechanism involving specific undertakings, operators or service providers may be imposed.

CHAPTER V

**GENERAL AND FINAL PROVISIONS**

*Article 29*

**Consultation with interested parties**

1. Member States shall ensure that national regulatory authorities take into account the views of users, consumers, manufacturers, undertakings providing communications networks and service providers on issues related to all user and consumer rights concerning publicly available communications services.

2. In respect of quality of service issues, and in particular in response to complaints relating to quality of service, national regulatory authorities shall be able to determine whether to require publication of quality of service information of network operators and service providers. National regulatory authorities may specify, *inter alia*, the quality of service parameters to be measured, and the content, form and manner of information to be published, in order to ensure that users and consumers have access to comprehensive, comparable and user-friendly information. For services falling within universal service obligations, the parameters, definitions and measurement methods given in Annex III could be used.

*Article 30*

**Dispute resolution**

1. Member States shall ensure that transparent, simple and inexpensive procedures are available for dealing with users' and consumers' complaints. Member States shall adopt measures to ensure that such procedures enable disputes to be settled fairly and promptly with provision, where warranted, for a system of reimbursement and/or compensation. They should follow, wherever possible, the principles set out in Recommendation 98/257/EC.

2. For disputes involving parties in different Member States, the provisions of Article 18 of the Directive on a common regulatory framework for electronic communications networks and services shall apply.

*Article 31*

**Technical adjustment**

Amendments necessary to adapt Annexes I, II, III and VI to technological developments or to changes in market demand shall be adopted by the Commission, acting in accordance with the procedure referred to in Article 33(2).

*Article 32*

**Notification and monitoring**

1. National regulatory authorities shall notify to the Commission by 31 December 2001 at the latest, and immediately in the event of any change thereafter:

(a) the names of undertakings designated as having universal service obligations under Article 8(1);

(b) the names of undertakings subject to retail tariff regulation under Article 16, and details of the relevant product/service and geographical markets;

(c) the names of undertakings found to have significant market power for the purposes of Article 25(2);

(d) the names of those undertakings which have obligations for provision of the minimum set of leased lines, in accordance with Article 27.

They shall notify the Commission of any changes without delay. The Commission shall make the information available in a readily accessible form, and shall distribute it to the Communications Committee and the High-Level Communications Group as appropriate.

2. The Commission shall periodically review the functioning of this Directive and report to the European Parliament and to the Council, on the first occasion not later than two years after the date of entry into force of this Directive. The Member States and national regulatory authorities shall supply the necessary information to the Commission for this purpose.

*Article 33*

**Committee**

1. The Commission shall be assisted by the Communications Committee, instituted by Article 19 of Directive (on a common regulatory framework for electronic communications networks and services).

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 34*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2001 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive and of any subsequent modifications to those provisions.

*Article 35*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 36*

**Addressees**

This Directive is addressed to the Member States.

*ANNEX I*

**Description of facilities referred to in Article 10 (specific affordability provisions) and Article 24 (additional facilities)**

PART A

Facilities and services referred to in Article 10:

(a) Itemised billing

National regulatory authorities, subject to the requirements of relevant legislation on the protection of personal data and privacy, may lay down the basic level of itemised bills which shall be provided by designated undertakings (as established in Article 8) to consumers free of charge in order that they can (i) allow verification and control of the charges incurred in using the public telephone network at a fixed location and/or related publicly available telephone services, and (ii) adequately monitor their usage and expenditure and thereby exercise a reasonable degree of control over their bills.

Where appropriate, additional levels of detail may be offered to subscribers at reasonable tariffs or at no charge. A Member State may authorise its national regulatory authority not to apply the requirements of this paragraph in all or part of its territory if it is satisfied that this facility is widely available.

(b) Selective call barring for outgoing calls, free of charge

i.e. the facility whereby the subscriber can, on request to the telephone service provider, bar outgoing calls of defined types or to defined types of numbers free of charge.

(c) Pre-payment systems

National regulatory authorities may require designated undertakings to provide means for consumers to pay for access to the public telephone network and use of public telephone services on pre-paid terms.

(d) Phased payment of connection fees

National regulatory authorities may require designated undertakings to allow consumers to pay for connection to the public telephone network on the basis of payments phased over time.

(e) Non-payment of bills

Member States shall authorise specified measures, which shall be proportionate, non-discriminatory and published, to cover non-payment of telephone bills for use of the public telephone network at fixed locations. These measures shall ensure that due warning of any consequent service interruption or disconnection is given to the subscriber beforehand. Except in cases of fraud, persistent late payment or non-payment, these measures shall ensure, as far as is technically feasible, that any service interruption is confined to the service concerned. Disconnection for non-payment of bills should take place only after due warning is given to the subscriber. Member States may allow a period of limited service prior to complete disconnection, during which only calls that do not incur a charge to the subscriber (e.g. '112' calls) are permitted.

PART B

List of facilities referred to in Article 24:

(a) Tone dialling or DTMF (dual-tone multi-frequency operation)

i.e. the public telephone network supports the use of DTMF tones as defined in ETSI ETR 207 for end-to-end signalling throughout the network both within a Member State and between Member States.

(b) Calling-line identification

i.e. the calling party's number is presented to the called party prior to the calls being established.

This facility should be provided in accordance with relevant legislation on protection of personal data and privacy, in particular Directive [. . .] concerning the processing of personal data and the protection of privacy in the electronic communications sector.

*ANNEX II*

**Information to be published in accordance with Article 18**

(Transparency and publication of information)

The national regulatory authority has a responsibility to ensure that the information in this Annex is published in accordance with Article 18. It is for the national regulatory authority to decide which information is to be published by the undertakings providing public telephone networks and/or publicly available telephone services and which information is to be published by the national regulatory authority itself.

1. Name(s) and address(es) of undertaking(s)

   i.e. names and head office addresses of undertakings providing public telephone networks and/or publicly available telephone services.

2. Publicly available telephone services offered

   2.1. Scope of the publicly available telephone service

   Description of the publicly available telephone services offered, indicating what is included in the subscription charge and the periodic rental charge (e.g. operator services, directories, directory services, selective call barring, itemised billing, maintenance, etc.)

   2.2. Standard tariffs covering access, all types of usage charges, maintenance, and including details of standard discounts applied and special and targeted tariff schemes

   2.3. Compensation/refund policy, including specific details of any compensation/refund schemes offered

   2.4. Types of maintenance service offered

   2.5. Standard contract conditions, including any minimum contractual period, if relevant.

3. Dispute settlement mechanisms including those developed by the undertaking.

*ANNEX III*

**Quality of service parameters in the context of universal service**

Supply-time and quality-of-service parameters, definitions and measurement methods referred to Articles 11 and 19

| Parameter (Note 1) | Definition | Measurement method |
|---|---|---|
| Supply time for initial connection | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Fault rate per access line | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Fault repair time | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Unsuccessful call ratio (Note 2) | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Call set up time (Note 2) | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Response times for operator services | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Response times for directory enquiry services | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Proportion of coin and card operated public pay-telephones in working order | ETSI EG 201 769-1 | ETSI EG 201 769-1 |
| Bill correctness complaints | ETSI EG 201 769-1 | ETSI EG 201 769-1 |

Version number of ETSI EG 201 769-1 is 1.1.1 (April 2000).

*Note 1*

Parameters should allow for performance to be analysed at a regional level (i.e. no less than level 2 in the Nomenclature of Territorial Units for Statistics (NUTS) established by Eurostat).

*Note 2*

Member States may decide not to require that up-to-date information concerning the performance for these two parameters be kept, if evidence is available to show that performance in these two areas is satisfactory.

*ANNEX IV*

**Calculating the net cost, if any, of universal service obligations and establishing any recovery or sharing mechanism in accordance with Articles 12 and 13**

PART A: CALCULATION OF NET COST

Universal service obligations refer to those obligations placed upon an undertaking by a Member State which concern the provision of a network and service throughout a specified geographical area, including, where required, averaged prices in that geographical area for the provision of that service or provision of specific tariff options for consumers with low incomes or with specific social needs.

In order to avoid the regulatory burden of calculating any net cost of universal service obligations where this subsequently proves to be unnecessary, national regulatory authorities shall consider all means to ensure appropriate incentives for undertakings (designated or not) to provide universal service obligations cost efficiently. Included is an assessment of the feasibility of assigning universal service obligations by tendering or auction methods.

In undertaking a calculation exercise, the net cost of universal service obligations shall be calculated as the difference between the net cost for an organisation of operating with the universal service obligations and operating without the universal service obligations. This applies whether the network in a particular Member State is fully developed or is still undergoing development and expansion. Due attention shall be given to correctly assess the costs that any universal service operator would have chosen to avoid had there been no universal service obligation. The net cost calculation should assess the benefits, both financial and non-financial, to the universal service operator.

The calculation shall be based upon the costs attributable to:

(i) elements of the identified services which can only be provided at a loss or provided under cost conditions falling outside normal commercial standards.

This category may include service elements such as access to emergency telephone services, provision of certain public pay telephones, provision of certain services or equipment for disabled people, etc.

(ii) specific end-users or groups of end-users who, taking into account the cost of providing the specified network and service, the revenue generated and any geographical averaging of prices imposed by the Member State, can only be served at a loss or under cost conditions falling outside normal commercial standards.

This category includes those end-users or groups of end-users which would not be served by a commercial operator which did not have an obligation to provide universal service.

The calculation of the net costs of specific aspects of universal service obligations shall be made separately and so as to avoid the double counting of any direct or indirect benefits and costs. The overall net cost of universal service obligations to any undertaking shall be calculated as the sum of the net costs arising from the specific components of universal service obligations, taking account of both financial and non-financial benefits. The responsibility for verifying the net cost lies with the national regulatory authority.

PART B: RECOVERY OF ANY NET COSTS OF UNIVERSAL SERVICE OBLIGATIONS

The recovery or financing of any net costs of universal service obligations requires undertakings with universal service obligations to be compensated for the services they provide under non-commercial conditions. Because such a compensation involves financial transfers, Member States shall ensure that these are undertaken in a transparent, objective, non-discriminatory and proportional manner. This means that the transfers result in the least distortion to competition and to user demand. Member States should give due consideration to recovering any net costs via general government budgets.

A sharing mechanism based on a Fund may also be used. A sharing mechanism based on a Fund should respect the principles of transparency, least market distortion, non-discrimination and proportionality. Least market distortion means that the contribution burden should be spread as wide as possible, subject to proportionality. Proportionality means that NRAs may choose not to require contributions from undertakings whose national turnover is less than a set limit.

Member States undertaking cost recovery via a Fund should give due consideration to collecting contributions via a VAT mechanism on operators and service providers so as to provide a transparent and consistent mechanism (to avoid the danger of double imposition of contributions on both outputs and inputs of operators and service providers) for collecting contributions.

The independent body administering the fund shall be responsible for collecting contributions from operators or service providers who are assessed as liable to contribute to the net cost of universal service obligations in the Member State and shall oversee the transfer of sums due and/or administrative out-payments to the persons and/or undertakings entitled to receive payments from the Fund.

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*ANNEX V*

**Process for reviewing the scope of universal service in accordance with Article 15**

In considering whether a review of the scope of universal service obligations should be undertaken, the Commission shall take into consideration the following elements:

— social and market developments in terms of the services used by consumers;

— social and market developments in terms of the availability and choice of services to consumers;

— technological developments in terms of the way services are provided to consumers.

In considering whether the scope of universal service obligations be changed or redefined, the Commission shall take into consideration the following elements:

— are specific services available to and used by a majority of consumers and does the lack of availability or non-use by a minority of consumers result in social exclusion; and

— does the availability and use of specific services convey a general net benefit to all consumers such that public intervention is warranted in circumstances where the specific services are not provided to the public under normal commercial circumstances?

In proposing any change or redefinition of the scope of universal service obligations, the Commission may consider the following options:

— propose a change or redefinition of the scope of universal service obligations but require that any net costs are financed only via general government budgets; or

— propose a change or redefinition of the scope of universal service obligations and permit any net costs to be financed by mechanisms in conformity with this Directive.

Alternatively, the Commission may propose that specific services should become mandatory services to be provided under cost-oriented obligations in line with Chapter IV, and not be included in the scope of universal service obligations as specified in Chapter II.

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*ANNEX VI*

**Interoperability of digital consumer equipment (Article 20)**

1. *The Common Scrambling Algorithm and free-to-air reception*

   All consumer equipment intended for the reception of digital television, for sale or rent or otherwise made available in the Community, capable of de-scrambling digital television signals, shall possess the capability:

   — to allow the de-scrambling of such signals according to the Common European Scrambling Algorithm as administered by a recognised European standardisation body, currently ETSI;

   — to display signals that have been transmitted in clear provided that, in the event that such equipment is rented, the rentee is in compliance with the relevant rental agreement.

2. *Interoperability for analogue and digital television sets*

   Any analogue television set with an integral screen of visible diagonal greater than 42 cm which is put on the market for sale or rent in the Community shall be fitted with at least one open interface socket (as standardised by a recognised European standardisation body) permitting simple connection of peripherals, especially additional decoders and digital receivers.

   Any digital television set with an integral screen of visible diagonal greater than 30 cm which is put on the market for sale or rent in the Community shall be fitted with at least one open interface socket (either standardised by a recognised European standardisation body or conforming to an industry-wide specification) permitting simple connection of peripherals, and able to pass all the elements of a digital television signal. Apart from video and audio streams, this includes conditional access information, the full application programme interface (API) command set of the connected devices, service information and copy protection information.

   The above functionality may be updated from time to time under the procedure referred to in Article 20(2).

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# Proposal for a Decision of the European Parliament and of the Council on a regulatory framework for radio spectrum policy in the European Community

(2000/C 365 E/20)

**(Text with EEA relevance)**

*COM(2000) 407 final — 2000/0187(COD)*

*(Submitted by the Commission on 29 August 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) On 10 November 1999 the Commission presented a communication [1] to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions proposing the next steps in radio spectrum policy on the basis of the results of the Public Consultation on the Green Paper on radio spectrum policy in the context of European Community policies such as telecommunications, broadcasting, transport and R & D [2]. This communication received the support of the European Parliament in a resolution of 18 May 2000 [3]. It underlined the need for action at Community level to achieve a harmonised and balanced approach on the use of radio spectrum in the Community in order to fulfil internal market principles and to protect Community interests at international level.

(2) Where necessary, policy principles on the use of radio spectrum need to be defined at Community level with a view to meeting Community policy objectives, in particular in the areas of communications, broadcasting, transport, research which all require, to various extents, the use of radio spectrum, while maintaining a high standard of citizen's health. On the basis of these principles, the use of radio spectrum should be coordinated and harmonised at Community level, where necessary to fulfill these Community objectives. Community coordination and harmonisation may also help achieving harmonisation and coordination of the use of the spectrum at global level in certain cases. At the same time, appropriate technical support can be provided at national level.

(3) Spectrum policy cannot be based only on technical parameters but also needs to take into account economic, political, cultural, health and social considerations. Moreover, the ever increasing scarcity of available radio spectrum may increase the sources of conflicts between the various groups of radio spectrum users in sectors such as communications, broadcasting, transport, law enforcement, military and the scientific community. Therefore, spectrum policy should take into account all sectors and balance the respective needs. This Decision should not affect the right of Member States to impose restrictions necessary for public order and public security purposes.

(4) In order to define general policy objectives regarding the use of spectrum, an appropriate consultative body should be created which will gather together, under the chairmanship of the Member State holding the Presidency of the Council, senior Member States representatives responsible for the various sectors using or affected by the use of radio spectrum, such as communications, broadcasting, audio-visual, transport, research and development as well as of security policy, military defence and police sectors, which may be indirectly affected. This group should provide guidance to the Commission, both on its own initiative and at the request of the Commission, on the need for harmonisation of the use of radio spectrum in the general context of Community policy and on regulatory and other issues related to the use of radio spectrum which impact on Community policies, including, for example, methods for granting rights to use spectrum, information availability, availability of spectrum, refarming, relocation, valuation and efficient use of radio spectrum as well as protection of human health. For that purpose, each national delegation should have a coordinated view of all policy aspects affecting spectrum use in its Member State in relation with the issues to be discussed in the group.

(5) The group will take into account the views of the industry and of all users involved, both commercial and non-commercial, as well as of other interested parties on technological, market and regulatory developments which may affect the use of radio spectrum. Spectrum users should be free to provide all input they believe is necessary. The group may decide to hear representatives of the spectrum users communities at group meetings where necessary to illustrate the situation in a particular sector.

[1] COM(1999) 538.

[2] COM(1998) 596.

[3] A5-0122/2000.

(6) The Commission should report on a regular basis to the European Parliament and the Council on the results achieved under this Decision, on policy objectives for radio spectrum in the Community as well as on planned future actions. This will allow for the provision of the appropriate political support for the policy objectives.

(7) Radio spectrum technical management includes the harmonisation and allocation of radio spectrum. Such harmonisation should reflect the requirements of general policy principles identified at Community level. Coordinated introduction in the Community of systems using radio spectrum is dependent on the various national approaches to assignment and licensing including with regard to spectrum pricing and license fees. These issues should therefore be discussed and where appropriate be harmonised at Community level.

(8) The Community approach should also benefit from cooperation with radio spectrum experts from national authorities responsible for radio spectrum management. Building on the experience of mandating procedures gained in specific sectors, for example as a result of the application of Decision No 710/97/EC of the European Parliament and of the Council of 24 March 1997 on a coordinated authorisation approach in the field of satellite personal-communication services in the Community [1] (the S-PCS Decision) as amended by Decision No 1215/2000/EC [2] and Decision No 128/1999/EC of the European Parliament and of the Council of 14 December 1998 on the coordinated introduction of a third generation mobile and wireless communications system (UMTS) in the Community [3] (the UMTS Decision), a permanent, stable and uniform framework needs to be created at Community level to ensure harmonised availability of radio spectrum use and to provide adequate legal certainty. Harmonisation measures should be adopted as a result of mandates to national experts acting in appropriate spectrum management bodies including the European Conference of Postal and Telecommunications administration (CEPT). Where necessary, the Commission should be able to make the results of such mandates compulsory for Member States, and where the results of such mandates are not acceptable, to take appropriate alternative action. This will in particular provide for the harmonisation of frequency spectrum necessary for the implementation of Directive .../.../EC of the European Parliament and Council Directive [on the authorisation of electronic communications networks and services].

(9) Appropriate information on present and future planning, allocation and assignment of radio spectrum, as well as conditions for access to and use of the whole radio spectrum are essential elements for investments and policy making. So are technological developments which will give rise to new spectrum allocation and management techniques and frequency assignment methods. Development of long-term strategic aspects require proper understanding of the implications of how technology evolves. Such information should therefore be made accessible in the Community, without prejudice to confidential business and personal information protection under Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector [4]. The implementation of a cross-sectoral spectrum policy makes the availability of information on the whole radio spectrum necessary. In view of the general purpose of harmonising spectrum use in the Community and in Europe, such information needs to be aggregated at a European level in a user-friendly manner.

(10) It is therefore necessary to complement existing Community and international requirements for publication of information on use of radio spectrum. At international level, the Reference Paper on Regulatory Principles negotiated in the context of the World Trade Organisation by the Group on Basic Telecommunications also requires that the existing state of allocated frequency bands be made publicly available. Commission Directive 96/2/EC of 16 January 1996 amending Directive 90/388/EEC with regard to mobile and personal communications [5] ('the Mobile Directive') requires Member States to publish every year or make available on request the allocation scheme of frequencies, including plans for future extension of such frequencies, but only covers mobile and personal communications services. Moreover, Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity [6], as well as Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services [7], as amended by Directive 98/48/EC [8], require Member States to notify to the Commission the interfaces which they have regulated so as to assess their compatibility with Community law.

[1] OJ L 105, 23.4.1997, p. 4.

[2] OJ L 139, 10.6.2000, p. 1.

[3] OJ L 17, 22.1.1999, p. 1.

[4] OJ L 24, 30.1.1998, p. 1.

[5] OJ L 20, 26.1.1996, p. 59.

[6] OJ L 91, 7.4.1999, p. 10.

[7] OJ L 204, 21.7.1998, p. 37.

[8] OJ L 217, 5.8.1998, p. 18.

(11) The Mobile Directive was at the origin of the adoption of a first set of measures by CEPT such as European Radiocommunications Committee Decision (ERC/DEC/(97)01) [1] on the publication of national tables of radio spectrum allocations. It is necessary to ensure that CEPT solutions reflect the needs of Community policy and are given the appropriate legal basis so as to be implemented in the Community. For that purpose, specific measures have to be adopted in the Community both on procedure and substance.

(12) Community undertakings should obtain fair and non-discriminatory treatment on access to spectrum in third countries. As access to radio spectrum is a key factor for business development and public interest activities, it is also necessary to ensure that Community requirements for radio spectrum are reflected in international planning.

(13) Implementation of Community policies may require coordination of radio spectrum use, in particular the provision of communications services including Community-wide roaming facilities. Moreover, certain types of spectrum use entail a geographical coverage which goes beyond the borders of a Member State and allow for transborder services without requiring the movement of persons, such as satellite communications services. It is therefore necessary that the Community be adequately represented in the activities of all relevant international organisations and conferences related to radio spectrum management matters, such as within the International Telecommunications Union and its World Radiocommunications Conferences [2]. In international negotiations, Member States and the Community should develop a common action and closely cooperate during the whole negotiations process so as to safeguard the unity of the international representation of the Community. As a consequence, Member States should support the request by the Community in view of involvement in such negotiations, based in particular on the procedures which had been agreed in the Council conclusions of 3 February 1992 for the World Administrative Radio Conference and as confirmed by the Council conclusions of 22 September 1997 and 2 May 2000. For such international negotiations, the Commission sets out the objectives to be achieved in the context of Community policies, in view of obtaining endorsement by Council on the positions to be taken by Member States at international level. Member States accompany any act of acceptance of any agreement or regulation within international fora in charge of or concerned with spectrum management by a joint declaration stating that they will apply such agreement or regulation in accordance with their obligations under the Treaty.

(14) The inherent international nature of spectrum issues may require the adoption of a number of agreements with third countries which also affect frequency bands usage and sharing plans, in view in particular of trade and market access, including in the World Trade Organisation framework, free circulation and use of equipment, communications systems of regional or global coverage such as satellites, safety and distress operations, transportation systems, broadcasting technologies, and research applications such as radio-astronomy and earth observation.

(15) It is necessary, due to the potential commercial sensitivity of information which may be obtained by national authorities in the course of their action relating to spectrum policy and management, to establish common principles applicable to these national regulatory authorities in the field of confidentiality.

(16) Taking into account international trade obligations of the Community and its Member States, Member States should implement this common framework for spectrum policy, in particular through their national authorities and provide all information required to the Commission to assess the proper implementation throughout the Community.

(17) The existing UMTS and S-PCS Decisions should remain in force until they reach their date of expiry as they provide for a legal basis for ongoing harmonisation measures and specific solutions for UMTS and S-PCS.

(18) In accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], measures for the implementation of this Decision should be adopted by use of the advisory procedure provided for in Article 3 of that Decision or the regulatory procedure provided for in Article 5 of that Decision, as appropriate,

HAVE ADOPTED THIS DECISION:

*Article 1*

**Aim**

The aim of this Decision is to:

(a) create a policy framework to address the strategic planning and harmonisation of the use of radio spectrum in the Community taking into consideration in particular economic, health, public policy, cultural, scientific, social and technical aspects of Community policies as well as the various interests of radio spectrum users communities with the aim of optimising the use of spectrum and of avoiding harmful interference;

[1] www.ero.dk.

[2] The Commission reported on the Community issues at stake in WRC in COM(1997) 304, COM(1998) 298 and COM(2000) 86.

[3] OJ L 184, 17.7.1999, p. 23.

(b) establish a procedural framework to ensure the effective implementation of radio spectrum policy in the Community, and in particular establish a general methodology for harmonisation of the use of radio spectrum;

(c) ensure the coordinated and timely provision of information on radio spectrum use and availability in the Community;

(d) safeguard Community interests in international negotiations where radio spectrum use affects Community policies.

This Decision is without prejudice to the specific rules adopted by Member States or the Community governing the content of audio-visual programmes intended for the general public, to the provisions of Directive 1999/5/EC and to the right of Member States to organise their radio spectrum for public order and public security purposes.

*Article 2*

**Definitions**

For the purposes of this Decision:

(a) 'Radio spectrum' includes at least radio waves in frequencies between 9 KHz and 3 000 GHz; radio waves are electromagnetic waves propagated in space without artificial guide;

(b) 'Allocation of a radio frequency band' means the entry of a radio frequency band in a table of radio frequency allocations for the purpose of its use by one or more types of services under specified conditions;

(c) 'Assignment of a radio frequency' means the authorisation given by an authority to use a radio frequency under specified conditions.

*Article 3*

**Senior Official Radio Spectrum Policy Group**

With a view to the strategic planning and harmonisation of use of radio spectrum in the Community, the Commission shall be assisted by a consultative group to be called the Senior Official Radio Spectrum Policy Group.

The Group shall be composed of senior representatives from the Member States and a representative of the Commission, and shall meet at least twice a year under the chairmanship of the representative of the Member State holding the Council Presidency. The Group's secretariat shall be provided by the Commission.

The Group shall consult, as it may deem appropriate, representatives from the various sectors of activities and citizen representatives affected by or requiring the use of radio spectrum in the Community and in the rest of Europe.

*Article 4*

**Function of the Senior Official Radio Spectrum Policy Group**

The Senior Official Radio Spectrum Policy Group shall contribute to the formulation, preparation and implementation of a radio spectrum policy by delivering opinions to the Commission either at the Commission's request or on its own initiative, and shall contribute to the preparation of the Commission's report referred to in Article 11.

The Group shall in particular:

(a) monitor the evolution of the use of and access to radio spectrum in the Community as well as at national, regional, and global levels;

(b) review current needs and anticipate future needs for radio spectrum for commercial as well as non-commercial applications in the Community, based in particular on strategic, economic, technological, political, health, social and cultural aspects of radio spectrum use, in view of the fulfilment of Community policy objectives; advise the Commission on strategic planning of radio spectrum use, and where necessary, balance the various requirements for radio spectrum of different users;

(c) advise the Commission on regulatory, international, technical, economic and political developments affecting the use of spectrum, as well as on the need for harmonisation measures at Community level for radio spectrum use to implement Community policies;

(d) assess the need for European common proposals to be developed in view of international negotiations;

(e) assist in the preparation of the Commission annual report on the developments impacting on existing and future use of radio spectrum in the Community;

(f) encourage the exchange of information among Member States on the evolution of the use of radio spectrum in the Community.

*Article 5*

**Committee**

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission ('the Radio Spectrum Committee').

2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 6*

**Harmonisation measures**

1. Where appropriate, and taking into account where possible the advice of the Senior Official Radio Spectrum Policy Group, the Commission shall propose measures to harmonise the use of radio spectrum, assignment methods, conditions for such use, as well as the availability of information related to the use of radio spectrum.

2. For these purposes, the Commission shall give mandates to the CEPT, setting out the tasks to be performed and the timetable therefor. The Commission shall act in accordance with the procedure referred to in Article 5(2).

3. On the basis of the work completed pursuant to paragraph 2, the Commission shall decide whether the results of the mandate are acceptable and, if so, may decide to make such results mandatory for the Member States, which shall implement them in a deadline to be determined. These Decisions shall be published in the *Official Journal of the European Communities*. For the purpose of this paragraph, the Commission shall act in accordance with the procedure referred to in Article 5(3).

4. Notwithstanding paragraph 3, if the Commission or any Member State considers that the work done on the basis of a mandate granted pursuant to paragraph 2 is not progressing satisfactorily having regard to the set timetable or if the results of the mandate are not acceptable, the Commission may adopt measures to achieve the objectives of the mandate, acting in accordance with the procedure referred to in Article 5(3).

*Article 7*

**Availability of information on spectrum allocation and assignment**

Member States shall publish without delay the information as defined in the Annex and shall keep this information up to date.

Moreover, Member States shall take measures to develop an appropriate data base in order to make such information available to the public in a harmonised way.

*Article 8*

**Relations with third countries and international organisations**

1. The Commission shall monitor developments regarding radio spectrum in third countries and in international organisations, which may have implications for the implementation of this Decision.

2. The Member States shall inform the Commission of any difficulties created, *de jure* or *de facto*, by third countries or international organisations for the implementation of this Decision.

3. The Commission shall report regularly on the results of the application of paragraphs 1 and 2 to the European Parliament and the Council and may propose measures with the aim of securing the implementation of the principles and objectives of this Decision, where appropriate. Whenever necessary, common positions shall be agreed to ensure Community coordination among Member States.

4. Measures taken pursuant to this Article shall be without prejudice to the Community's and Member States' rights and obligations under relevant international agreements.

*Article 9*

**Notification**

Member States shall give the Commission such information as it may require for the purpose of verifying the implementation of this Decision. In particular, Member States shall immediately inform the Commission about the implementation of the results of the mandates pursuant to Article 6(3).

*Article 10*

**Confidentiality**

1. Member States shall not disclose information covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components.

2. Paragraph 1 shall be without prejudice to the right of national authorities to undertake disclosure where it is essential for the purposes of fulfilling their duties, in which case such disclosure shall be proportionate and shall have regard to the legitimate interests of undertakings in the protection of their business secrets.

3. Paragraph 1 shall not preclude publication of information on conditions linked to the granting of rights to use spectrum which does not include information of a confidential nature.

*Article 11*

**Report**

The Commission shall report on an annual basis to the European Parliament and the Council on the activities developed and the measures adopted pursuant to this Decision, on the results of the work done by the Senior Official Radio Spectrum Policy Group as well as on future actions envisaged pursuant to this Decision.

*Article 12*

**Implementation**

Member States shall take all measures necessary, by law or administrative action, for the implementation of this Decision and all resulting measures.

*Article 13*

**Entry into Force**

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 14*

**Addressees**

This Decision is addressed to the Member States.

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*ANNEX*

Pursuant to Article 7, and without prejudice to notification obligations under Directives 1999/5/EC and 98/34/EC, the following information shall be published:

1. Information regarding frequency allocation and assignment includes the following:

   — existing allocations and assignments of radio spectrum as well as conditions for the use of radio spectrum, including where practicable, operating power, emission and any other technical constraints;

   — plans for changes to existing allocations for the next two years at least, including relocation plans and review date of allocation;

   — locations and geographical coverage linked to allocation plans;

   — service actually operated, if different from allocated, and effective use of spectrum;

   — reserved bands for new services.

2. Without prejudice to the provisions of specific legislation relating to communications networks and services, publication shall include procedures for granting rights to use spectrum, and planned changes to spectrum use conditions. These shall include all types of obligations, charges and financial costs related to the use of radio spectrum, including administrative charges, usage fees and procedures for assignment of spectrum (including auctions).

# Proposal for a Council Regulation extending the programme of incentives and exchanges for legal practitioners in the area of civil law (Grotius-civil)

(2000/C 365 E/21)

*COM(2000) 516 final — 2000/0220(CNS)*

*(Submitted by the Commission on 6 September 2000)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 61(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

(1) On 28 October 1996 the Council adopted the Joint Action on a programme of incentives and exchanges for legal practitioners (Grotius) [1], on the basis of the former Article K.3 of the Treaty on European Union. This programme sets out to facilitate judicial cooperation between Member States by fostering mutual knowledge of legal and judicial systems. It provides funding for training, exchange and work-experience programmes, organisation of meetings, studies and research, and the distribution of information. It is aimed at legal practitioners.

(2) The Grotius programme was set up for the period 1996-2000. The annual programme and the call for applications for the last year of the Grotius programme, as established by the Joint Action of 28 October 1996, were published in January 2000 [2]. The two annual reports from the Commission to the European Parliament and the Council drawn up so far on implementation of the Grotius programme [3] demonstrate its importance in strengthening judicial cooperation. Legal practitioners should be able to continue receiving assistance under this programme.

(3) The Grotius programme is concerned with judicial cooperation in the areas of both civil and criminal law. Judicial cooperation in the area of civil law, which was one of the areas of common interest referred to in the former Article K.1 of the Treaty on European Union, is now covered by Article 61 of the Treaty establishing the European Community. Those aspects of the Grotius programme relating to judicial cooperation in the area of civil law therefore now fall within the scope of Article 61 of the Treaty establishing the European Community. Judicial cooperation in the area of criminal law, which was one of the areas of common interest referred to in the former Article K.1 of the Treaty on European Union, is now covered by Article 29 of the Treaty on European Union. Those aspects of the Grotius programme relating to judicial cooperation in the area of criminal law therefore now fall within the scope of Article 29 of the Treaty on European Union. This Regulation does not cover that area.

(4) The Commission is considering the future of the part of the Grotius programme concerned with judicial cooperation in the area of civil law ('Grotius-civil'). This analysis focuses particularly on relations between this programme and other funding programmes, namely the Robert Schuman project [4], and the programmes connected with the creation of an area of freedom, security and justice, related to Title IV of the Treaty establishing the European Community or Title VI of the Treaty on European Union.

(5) Pending the conclusion of this analysis, legal practitioners should be able to continue receiving financial support from the European Community for initiatives designed to facilitate judicial cooperation between Member States by fostering mutual knowledge of legal and judicial systems. The Grotius-civil programme should therefore be extended to cover the year 2001.

(6) This Regulation establishes a financial framework for the duration of the programme, which constitutes the prime reference for the budgetary authority within the meaning of point 33 of the Interinstitutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure [5],

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[1] OJ L 287, 8.11.1996, p. 3.

[2] OJ C 12, 15.1.2000, p. 17.

[3] Reports on the implementation of the Grotius, Sherlock, Stop and Oisin programmes (SEC(98) 1048 and SEC(99) 1955)

[4] The Robert Schuman project is a financial support instrument created in 1998 (Decision of the European Parliament and of the Council of 22 June 1998 establishing an action programme to improve awareness of Community law within the legal professions, OJ L 196, 14.7.1998, p. 24) for a period of three years, with the aim of encouraging and supporting initiatives in the area of training and information designed to raise awareness of Community law among members of the legal professions involved in the administration of justice, namely judges, prosecutors and lawyers in the Member States.

[5] OJ C 172, 18.6.1999, p. 1.

HAS ADOPTED THIS DECISION:

*Article 1*

Those aspects of the Grotius programme which relate to judicial cooperation in the area of civil law shall be extended to cover the year 2001. The programme was established by the Joint Action 96/636/JHA, adopted by the Council on 28 October 1996 on the basis of the former Article K.3 of the Treaty on European Union, establishing a programme of incentives and exchanges for legal practitioners (Grotius).

The provisions of the Joint Action in question relating in particular to procedural matters shall continue to apply to the implementation of this programme in 2001.

*Article 2*

The financial framework for the implementation of the programme in 2001 shall be EUR 650 000.

This appropriation shall be established by the budgetary authority within the limit of the financial perspective.

*Article 3*

The Commission shall report to the European Parliament and the Council on the implementation of the programme at the end of the 2001 budgetary year.

*Article 4*

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

# Proposal for a Council Regulation amending for the sixth time Regulation (EC) No 850/98 for the conservation of fishery resources through technical measures for the protection of juveniles of marine organisms

(2000/C 365 E/22)

*COM(2000) 501 final — 2000/0215(CNS)*

*(Submitted by the Commission on 6 September 2000)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

(1) For the effective performance of various types of fishing activity and for the conservation of fishery resources, clarification or correction is required of conditions established in Council Regulation (EC) No 850/98 [1] for:

(i) the calculation of the proportion by live weight of marine organisms on board after sorting or on landing with respect to catches taken by nets of mesh sizes less than 16 mm;

(ii) the installation of square-meshed panels into towed nets of mesh size range 70 to 79 mm and the installation of sorting grids into towed nets of mesh size range 32 to 54 mm;

(iii) fishing with dredges;

(iv) landing of parts of crabs or damaged crabs;

(v) ensuring that area-specific minimum sizes of crabs are duly observed;

(vi) informing competent control authorities of required information relating to fishing in an area established for the protection of mackerel;

(vii) the establishment of areas and time periods closed to defined methods of fishing for the protection of hake;

(viii) the mesh size of fixed gears to be used when fishing for a variety of species in the North Sea and adjacent geographical areas;

(ix) the use of combinations of nets with mesh sizes 16 to 31 mm and greater than or equal to 100 mm or of 80 to 99 mm and greater than or equal to 100 mm in Regions 1 and 2 except the Skagerrak and Kattegat;

(x) minimum sizes of crawfish, plaice, surf clams and a species of horse mackerel;

(xi) the measurement of the size of crawfish.

(2) Regulation (EC) No 850/98 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 850/98 is hereby amended as follows:

1. Article 5(5) is deleted.

2. In Article 7,

(a) paragraph 4 is replaced by the following:

'4. Notwithstanding paragraph 1(a), any demersal trawl, Danish seine or similar towed net of which the mesh size lies in the range 70 to 79 millimetres shall be equipped with a square-meshed panel having a mesh size equal to, or greater than, 80 millimetres.'

(b) the following text is added to the end of paragraph 5:

'or with a sorting grid whose use is established under the conditions laid down in Article 46.'

3. Article 10 is replaced by the following:

'*Article 10*

Notwithstanding Article 4; it shall be prohibited,

(a) during any fishing voyage when dredges are carried on board to transship marine organisms other than bivalve molluscs and

(b) to retain on board or land more than 5 % by weight of marine organisms other than bivalve molluscs.'

4. Article 18(4) is replaced by the following:

'4. — Edible crabs may only be retained and landed whole.

[1] OJ L 125, 27.4.1998, p. 1.

However, a maximum of 10 % by weight of the total catch of edible crabs or parts thereof retained on board or landed may consist of crabs which are not whole and/or of detached claws.'

5. The following paragraph 4 is added to Article 19:

'4. It shall be prohibited to retain on board or land edible crabs caught during any voyage in which fishing has not been conducted entirely within

— Region 1 and 2 north of longitude 56 °N or

— Region 2 south of longitude 56 °N except ICES Divisions IVb, c and ICES Divisions VIId, e, f or

— ICES Divisions IVb, c south of longitude 56 °N or

— ICES Divisions VIId, e, f or

— Region 3'

6. In Article 22, paragraph 3, last subparagraph, the reference to the competent control authority for France and the United Kingdom shall be changed to:

— for France:

'CROSS Etel
Service Surpeche
Télécopie: 33 (0) 2 97 55 23 75
Télex: CRAPECH 951.892'

— for the United Kingdom:

'Ministry of Agriculture Fisheries and Food:
Fax: + 44 (0) 207 270 8125
E-mail: s.h.dutyroom-wpe@egd.maff.gov.uk
Telex: London 21274'

7. In Article 28:

(a) paragraph 1(a) is replaced by the following:

'(a) from 1 October to 31 January of the following year, within the geographical area bounded by a line sequentially joining the following coordinates:

— latitude 43° 46.5' N, longitude 7° 54.4' W

— latitude 44° 01.5' N, longitude 7° 54.4' W

— latitude 43° 25' N, longitude 9° 12' W

— latitude 43° 10' N longitude, 9° 12' W.'

(b) paragraph 1(b) is deleted

8. Annex VI is replaced by the text in Annex 1 to this Regulation.

9. In Annex X:

(a) point 1 is replaced by:

'1. **Mesh size combination: 16 to 31 mm + > = 100 mm**

The catch retained on board shall consist of at least 20 % of any mixture of shrimps and common prawns (*Pandalus montagui, Crangon* spp. and *Palaemon* spp.).'

(b) point 4 is replaced by:

'4. **Mesh size combination: 80 to 99 mm + > = 100 mm**

The catch retained on board shall consist of at least 40 % of any mixture of those marine organisms indicated in Annex I as the target species for mesh sizes between 80 and 99 mm.'

10. In Annex XII:

— the minimum size of plaice (*Pleuronectes platessa*) in Regions 1 to 5 except the Skagerrak and Kattegat shall be 27 cm;

— a footnote shall be associated with the reference to minimum size of 15 cm for horse mackerel (*Trachurus* spp) in Regions 1 to 5, except Skagerrak and Kattegat, which shall read:

'No minimum size will apply to horse mackerel (*Trachurus picturatus*) caught in waters adjacent to the Azores islands and under the sovereignty or jurisdiction of Portugal';

— the entry 'Surf clams (*Spisula solidissima*)' shall be replaced by 'Surf clams (*Spisula solida*)', and

— the minimum size of crawfish (*Palinurus spp.*) in Regions 1 to 5 except the Skagerrak and Kattegat shall be 95 mm.

11. In Annex XIII

— in point 3, the words 'or crawfish' shall be deleted;

— a new point 8 shall be added and shall read:

'8. The size of a crawfish shall be measured as shown in Figure 7 as the length of the carapace from the tip of the rostrum to the midpoint of the distal edge of the carapace.';

— The figure in Annex 2 to this Regulation shall be inserted as Figure 7.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

*ANNEX 1*

*'ANNEX VI*

**FIXED GEARS: Regions 1 and 2**

| Species/mesh | 10—30 mm | 50—70 mm | 90—99 mm | 100—119 mm | 120—219 mm | ≥ 220 mm |
|---|---|---|---|---|---|---|
| Sardine (*Sardina pilchardus*) | * | * | * | * | * | * |
| Eel (*Anguilla anguilla*) | * | * | * | * | * | * |
| Sprat (*Sprattus sprattus*) | * | * | * | * | * | * |
| Horse mackerel (*Trachurus spp.*) | | * | * | * | * | * |
| Herring (*Clupea harengus*) | | * | * | * | * | * |
| Makerel (*Scomber spp.*) | | * | * | * | * | * |
| Red mullets (*Mullidae*) | | * | * | * | * | * |
| Garfish (*Belone spp.*) | | * | * | * | * | * |
| Sea bass (*Dicentrarchus labrax*) | | | * | * | * | * |
| Grey mullets (*Mugilidae*) | | | * | * | * | * |
| Lesser spotted dogfish (*Scyliorhinus canicula*) | | | * | * | * | * |
| Dab (*Limanda limanda*) | | | * (4) | * | * | * |
| Haddock (*Melanogrammus aeglefinus*) | | | * (4) | * | * | * |
| Withing (*Merlangius merlangus*) (2) | | | * (4) | * | * | * |
| Flounder (*Platichthys flesus*) | | | * (4) | * | * | * |
| Sole (*Solea vulgaris*) | | | * (4) | * | * | * |
| Plaice (*Pleuronectes platessa*) | | | * (4) | * | * | * |
| Cutlefish (*Sepia officinalis*) | | | * (4) | * | * | * |
| Cod (*Gadus morhua*) | | | | | * | * |
| Pollack (*Pollachius pollachius*) (3) | | | | | * | * |
| Ling (*Molva molva*) | | | | | * | * |
| Saithe (*Pollachius virens*) | | | | | * | * |
| Hake (*Merluccius merluccius*) (3) | | | | | * | * |
| Picked dogfish (*Squalus acanthias*) | | | | | * | * |
| Greater spotted dogfish (*Scyliorhinus stellaris*) | | | | | * | * |
| Megrim (*Lepidorhombus spp.*) | | | | | * | * |
| Lumpsucker (*Cyclopterus lumpus*) | | | | | * | * |
| All other marine organisms | | | | | | * (1) |

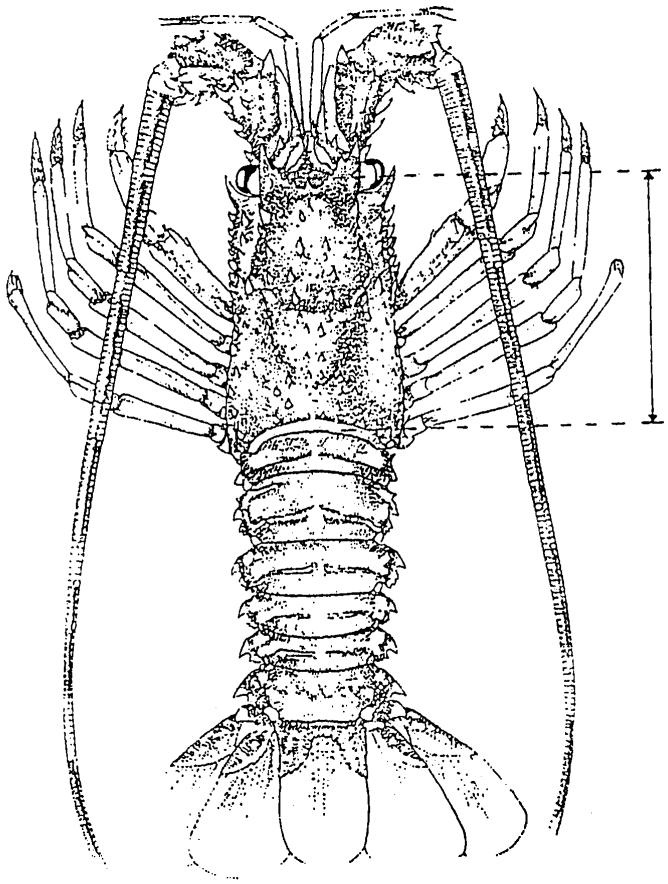
(1) Catches of anglerfish (*Lophius spp.*) taken from ICES Sub-areas VI and VII and retained on board in excess of 30 % of the total catch on board from those areas must be taken with a minimum mesh size of 250 mm or greater.

(2) In ICES divisions VIIe and VIId, with effect from 31 December 1999, the minimum size will be 90 mm.

(3) In ICES divisions VIIe and VIId, with effect from 31 December 1999, the minimum size will be 110 mm.

(4) Applicable only in ICES Divisions VIId and IIIa and in the North Sea'

*ANNEX 2*



# Proposal for a Directive of the European Parliament and of the Council amending Council Directive 70/220/EEC concerning measures to be taken against air pollution by emissions from motor vehicles

(2000/C 365 E/23)

**(Text with EEA relevance)**

*COM(2000) 487 final — 2000/0211(COD)*

*(Submitted by the Commission on 6 September 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States on measures to be taken against air pollution by emissions from vehicles [1], as last amended by Commission Directive 1999/102/EC [2] is one of the separate directives under the type-approval procedure laid down by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers [3], as last amended by Directive 98/91/EC of the European Parliament and of the Council [4].

(2) Directive 70/220/EEC, as amended by Directive 98/69/EC [5], introduced specific emission limits for carbon monoxide and hydrocarbons in combination with a new test to measure those emissions at low temperatures in order to adapt the behaviour of the emission control system of vehicles of category $M_1$ and category $N_1$ class I with positive-ignition engines to the ambient conditions experienced in practice.

(3) The Commission have determined appropriate low temperature emission limits for vehicles of category $N_1$ class II and III with positive-ignition engines. It is now also appropriate to include within the scope of the low temperature test vehicles of category $M_1$ with positive-ignition engines designed to carry more than six occupants and vehicles of category $M_1$ with positive-ignition engines whose maximum mass exceeds 2 500 kg, which were previously excluded.

(4) Due to their emission characteristics, it is appropriate to exempt vehicles with positive-ignition engines that run only on gas fuel (LPG or NG) from the low temperature test. Vehicles where the petrol system is fitted for emergency purposes or starting only and where the petrol tank cannot contain more than 15 litres of petrol, should be regarded as vehicles that can only run on a gaseous fuel.

(5) It is appropriate to align the test for low temperature emissions with the test for emissions at a normal ambient temperature. The test at low temperature is therefore restricted to vehicles of category M and N with a maximum mass not exceeding 3 500 kg.

(6) Directive 70/220/EEC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

Annexes I and VII to Directive 70/220/EEC are amended in accordance with the Annex to this Directive.

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2001. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the main provisions of the national law that they adopt in the field governed by this Directive.

*Article 3*

This Directive shall enter into force on the (third) day following its publication in the *Official Journal of the European Communities*.

*Article 4*

This Directive is addressed to the Member States.

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[1] OJ L 76, 6.4.1970, p. 1.

[2] OJ L 334, 28.12.1999, p. 43.

[3] OJ L 42, 23.2.1970, p. 1.

[4] OJ L 11, 16.1.1999, p. 25.

[5] OJ L 350, 28.12.1998, p. 1.

*ANNEX*

**AMENDMENTS TO ANNEX I TO DIRECTIVE 70/220/EEC**

1. Section 5.3.5. is modified as follows:

   Footnote ([1]) is deleted.

2. Section 5.3.5.1. is replaced by the following:

   '5.3.5.1. This test must be carried out on all vehicles of category $M_1$ and $N_1$ equipped with a positive-ignition engine except such vehicles that only run on a gaseous fuel (LPG or NG). Vehicles that can be fuelled with both petrol and a gaseous fuel, but where the petrol system is fitted for emergency purposes or starting only and of which the petrol tank cannot contain more than 15 litres of petrol will be regarded for the Type VI test as vehicles that can only run on a gaseous fuel.

   Vehicles which can be fuelled with petrol and either LPG or NG shall be tested in the test Type VI on petrol only.

   From 1 January 2002, this section is applicable to new types of vehicles of category $M_1$ and $N_1$ class I, except vehicles designed to carry more than six occupants and vehicles whose maximum mass exceeds 2 500 kg.

   From 1 January 2003, this section is applicable to new types of vehicles of category $M_1$ class II and III and vehicles designed to carry more than six occupants and vehicles whose maximum mass exceeds 2 500 kg.'

3. The table in section 5.3.5.2. is replaced by the following table:

| Test temperature 266 K (–7 °C) | | | |
|---|---|---|---|
| Category | Class | Mass of carbon monoxide (CO) $L_1$ (g/km) | Mass of hydrocarbons (HC) $L_2$ (g/km) |
| $M_1$ ([1]) | — | 15 | 1,8 |
| $N_1$ | I | 15 | 1,8 |
| $N_1$ ([2]) | II | 27 | 3,2 |
| | III | 34 | 4,0 |

([1]) Except vehicles designed to carry more than six occupants and vehicles whose maximum mass exceeds 2 500 kg.
([2]) And those category $M_1$ vehicles which are specified in note 1.

**AMENDMENTS TO ANNEX VII TO DIRECTIVE 70/220/EEC**

4. The first sentence of section 1 is modified as follows:

   '1. This Annex applies only to vehicles with positive-ignition engines as defined in section 5.3.5. of Annex I.'

5. The first sentence of section 2.1.1 is modified as follows:

   '2.1.1. This chapter deals with the equipment needed for low ambient temperature exhaust emission tests on vehicles equipped with positive-ignition engines, as defined in section 5.3.5. of Annex I.'

6. Footnote (1) in section 4.3.3. is deleted.

# Proposal for a Council Regulation on information provision and promotion for agricultural products on the internal market

(2000/C 365 E/24)

**(Text with EEA relevance)**

*COM(2000) 538 final — 2000/0226(CNS)*

*(Submitted by the Commission on 8 September 2000)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Whereas:

(1) Under the sectoral provisions in force the Community can carry out promotional work on the internal market for a number of agricultural products.

(2) Given the outlook for the markets and the experience acquired, and in order to provide full information to consumers, a comprehensive and consistent information and promotion policy should be followed for agricultural products and in a subsidiary way for food products, on the same lines as provided for in regard to countries outside the Union, but with no encouragement to consumption of any product by reason of its specific origins.

(3) Such a policy will usefully supplement and reinforce the schemes run by Member States by boosting product image in consumers' eyes, in particular as regards the quality, nutritional value and safety of foodstuffs.

(4) Criteria should be set for selecting products and sectors concerned and the themes of the Community campaign.

(5) To ensure the consistency and effectiveness of programmes the essential elements of these should be defined for each product or sector by means of guidelines, supplemented by specifications to be drawn up by the Member States.

(6) Given the technical nature of the tasks to be performed the Commission should be able to haverecourse to a committee of communication experts or to technical assistants.

(7) Financing rules must be set. As a general rule, so that proposing organisations and Member States assume their responsibilities, the Community should meet only part of the cost of measures. However, in exceptional cases it may be more suitable not to require any financial contribution from the relevant Member States. In the case of information on some Community schemes (product origin, organic production, labelling) financing shared between the Community and Member States is justified by the need to provide information to the public on these relatively recent schemes.

(8) To ensure the greatest cost-effectiveness, the implementation of measures should be entrusted, through appropriate procedures, to bodies with the necessary structure and expertise.

(9) Programme execution should be carefully monitored by Member States and the impact of measures assessed by an independent body.

(10) The necessary implementing measures for this Regulation will be adopted in accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1]. These measures should be adopted using the management committee procedure provided for in Article 4 of that Decision. The management committees concerned will act jointly.

(11) Expenditure on the financing of measures and technical assistance should be classed as intervention expenditure under Article 1(2)(e) of Council Regulation (EC) No 1258/1999 [2].

(12) The promotional measures contained in the sectoral regulatory provisions, differing in their rules of execution and variously amended, were difficult to apply. They should be standardised, simplified and incorporated in a single text. The sectoral provisions on promotion should therefore be repealed.

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[1] OJ L 184, 17.7.1999, p. 23.

[2] OJ L 160, 26.6.1999, p. 103.

(13) Measures should be laid down for transition between the sectoral provisions and the new arrangements provided for in this Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

1. The Community may finance, wholly or in part, information provision and promotion for agricultural and food products carried out in its territory.

2. Measures as referred to in paragraph 1 must not be brand-oriented or incite to consumption of a product on grounds of its specific origin. This does not exclude the possibility of indicating the origin of a product covered by measures as referred to in Article 2 in the case of designations conferred under Community provisions.

*Article 2*

Measures as referred to in Article 1 shall comprise:

(a) public relations work, promotion and advertising that draws attention to intrinsic features and advantages of Community products, notably quality, hygiene, safety, specific production methods, nutritional value, labelling, high animal welfare standards and respect for the environment;

(b) participation in events, fairs and exhibitions of national or European importance, in particular with stands aimed at upgrading the image of Community products;

(c) information provision notably on the Community protected designation of origin (PDO), protected geographical indication (PGI), traditional speciality guaranteed (TSG), organic production and labelling provided for in agricultural legislation;

(d) information provision on the Community system covering quality wines produced in specified regions (quality wines psr), table wines and spirit drinks with geographical indication;

(e) impact assessment of the measures carried out.

*Article 3*

The sectors and products to be covered by measures as referred to in Article 1 shall be determined with regard to:

(a) the desirability of drawing attention to the quality, typical features, specific production method, nutritional value, hygiene, safety or environment-friendliness of the products in question, by means of thematic or target-specific campaigns;

(b) the implementation of a consumer information labelling system and of product traceability and control systems;

(c) the need to tackle short-term difficulties in individual sectors;

(d) the desirability of providing information on the Community PDO/PDI, TSG and organic production schemes;

(e) the desirability of providing information on the Community system covering quality wines psr, table wines and spirit drinks with geographical indication.

*Article 4*

1. Every three years the Commission shall, in accordance with the procedures laid down in Article 13, draw up a list of the themes and products referred to in Article 3. If necessary this can be modified in the interval through the same procedure.

2. Before drawing up the list referred to in paragraph 1 the Commission may consult the Standing Group on Agricultural Product Promotion of the Advisory Committee on Quality and Health in Agricultural Production.

*Article 5*

1. For each sector or product selected the Commission shall, in accordance with the procedure laid down in Article 13, adopt guidelines to which proposals for information and promotion programmes must conform.

2. These guidelines shall specify:

(a) objectives and targets,

(b) one or more themes to be the subject of the measures selected,

(c) the types of action to be undertaken,

(d) the duration of programmes,

(e) the distribution, by market and type of measure, of the amount available for the Community's contribution to programmes.

*Article 6*

1. For measures as referred to in Article 2(a), (b) and (d) interested Member States shall, on the basis of the Commission's guidelines, draw up a specification and issue a call for proposals open to trade and inter-trade organisations in the Community.

2. In response to such calls for proposals, organisations as referred to in paragraph 1 that are representative of the sector(s) in question shall, in collaboration with an implementing body that they have selected by means of an invitation to tender, draw up an information and promotion programme of a maximum duration of 36 months. A programme may cover one or more Member States and may be from a European-level organisation or an organisation spanning one or more Member States. Programmes in the last category shall have priority.

3. Member States shall examine the suitability of each programme and its conformity and that of the proposed implementing body with the provisions of this Regulation, the guidelines and the relevant specification. They shall also verify that the programme offers value for money. They shall then draw up a provisional list of programmes and bodies selected (within the limit of available funds) and undertake to contribute to financing these programmes.

4. Member States shall send the Commission a provisional list of programmes and bodies selected and copies of the programmes.

If the Commission finds that a programme is not in line with Community rules or the guidelines, it shall within a time limit to be determined notify the Member State(s) concerned of the ineligibility of all or part of that programme.

Member States shall take account of any observations made by the Commission within the set time limit. On its expiry they shall draw up and immediately send the Commission a final list of selected programmes.

*Article 7*

1. For measures as referred to in Article 2(c) each interested Member State shall, on the basis of the Commission guidelines, draw up its specification and select through a public call for tenders the implementing body for the programme it undertakes to part-finance.

2. It shall send the Commission the chosen programme accompanied by a reasoned opinion on its suitability, its conformity and that of the proposed body with the provisions of this Regulation and the guidelines, and its value for money.

3. For the purposes of the Commission's examination of programmes and their final approval by Member States the second and third subparagraphs of Article 6(4) shall apply.

*Article 8*

1. For drawing up the guidelines referred to in Article 5 the Commission may call on the assistance of a committee of independent communication experts or on technical assistants.

2. The Commission shall use an open or restricted call for tenders to select:

— technical assistants as referred to in paragraph 1,

— the body(ies) charged with assessing the impact of measures implemented pursuant to Articles 6 and 7.

*Article 9*

1. The Community shall finance:

(a) in full, measures as referred to in Article 2(e);

(b) in part, the other information and promotion measures referred to in Article 2.

2. The Community's contribution to measures as referred to in paragraph 1(b) may not exceed 50 % of their actual cost.

3. Without prejudice to paragraph 4, Member States shall for 20 % of the actual cost of measures as referred to in paragraph 2, the rest of the financing falling to the proposing organisations. The payments made by Member States and trade or inter-trade organisations may come from parafiscal charges.

However, where justified and provided that the programme is of manifest Community interest, it may be decided, in accordance with the procedure laid down in Article 13, that the proposing organisation will be responsible for all the financing not supplied by the Community.

4. For measures as referred to in Article 2(c) Member States shall be responsible for the financing not supplied by the Community.

Member States' payments may come from parafiscal charges.

*Article 10*

1. The body or bodies entrusted with implementing the measures referred to in Article 6(1) and 7(1) must have expertise in the products and markets concerned and have the necessary resources for highly effective implementation, having due regard to the programme's European dimension.

2. Member States will be responsible for surveillance and payments in the case of all measures other than those referred to in Article 9(1)(a).

*Article 11*

Community financing of measures as referred to in Article 1 shall be held to fall under Article 1(2)(e) of Council Regulation (EC) No 1258/1999 of 17 May 1999 on the financing of the common agricultural policy.

*Article 12*

Detailed rules for the application of this Regulation shall be adopted in accordance with the procedure laid down in Article 13.

*Article 13*

1. For the implementation of this Regulation the Commission shall be assisted by the Management Committee for Oils and Fats set up under Article 37 of Regulation No 136/66/EEC [1] and by the management committees set up under the corresponding articles of the other regulations on the common organisation of agricultural markets (hereinafter called 'the Committee').

2. In cases where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC shall apply.

3. The period mentioned in Article 4(3) of Decision 1999/468/EC shall be one month.

4. Matters shall be referred to the Committee by its Chairman on his own initiative or at the request of a Member State.

*Article 14*

Every three years, for the first time before 31 December 2004, the Commission shall send the Council and the European Parliament a report on the application of this Regulation accompanied by any appropriate proposals.

*Article 15*

1. The following provisions are withdrawn:

— Article 11 of Regulation No 136/66/EEC on the establishment of a common organisation of the market in oils and fats [2],

— Article 2 of Regulation (EEC) No 1308/70 on the common organisation of the market in flax and hemp [3],

— Article 20(4) of Regulation (EEC) No 3763/91 introducing specific measures in respect of certain agricultural products for the benefit of the French overseas departments [4],

— Articles 1 and 2 of Regulation (EEC) No 1332/92 introducing specific measures for table olives [5],

— Article 31(4) of Regulation (EEC) No 1600/92 concerning specific measures for the Azores and Madeira relating to certain agricultural products [6],

— Article 26(4) of Regulation (EEC) No 1601/92 concerning specific measures for the Canary Islands with regard to certain agricultural products [7],

— the second indent of the second paragraph of Article 1 and the second subparagraph of Article 2(1) of Regulation (EC) No 399/94 concerning specific measures for dried grapes [8],

— Article 54 of Regulation (EC) No 2200/96 on the common organisation of the market in fruit and vegetables [9],

— Article 35(5) of Regulation (EC) No 1493/1999 on the common organisation of the market in wine [10].

The words 'and the promotion' and '(d) and (e)' are deleted from the first paragraph of Article 1 and Article 2(2) respectively of Regulation (EC) No 399/94.

2. Regulations (EEC) No 1195/90 on measures to increase the consumption and utilisation of apples [11], (EEC) No 1201/90 on measures to increase the consumption of citrus fruit [12], (EEC) No 2067/92 on measures to promote and market quality beef and veal [13], (EEC) No 2073/92 on promoting consumption in the Community and expanding the markets for milk and milk products [14], (EC) No 2275/96 introducing specific measures for live plants and floricultural products [15] and (EC) No 2071/98 on publicity measures on the labelling of beef and veal [16] are repealed.

3. The provisions, terms and regulations specified in paragraphs 1 and 2 shall remain applicable to promotion and information programmes begun before 1 January 2001.

*Article 16*

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Communities*.

It shall apply from 1 January 2001.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[1] OJ 172, 30.9.1966, p. 3025/66.
[2] OJ 172, 30.9.1966, p. 3025/66.
[3] OJ L 146, 4.7.1970, p. 1.
[4] OJ L 356, 24.12.1991, p. 1.
[5] OJ L 145, 27.5.1992, p. 1.
[6] OJ L 173, 27.6.1992, p. 1.
[7] OJ L 173, 27.6.1992, p. 13.
[8] OJ L 54, 25.2.1994, p. 3.
[9] OJ L 297, 21.11.1996, p. 1.
[10] OJ L 179, 14.7.1999, p. 1.
[11] OJ L 119, 11.5.1990, p. 53.
[12] OJ L 119, 11.5.1990, p. 65.
[13] OJ L 215, 30.7.1992, p. 57.
[14] OJ L 215, 30.7.1992, p. 67.
[15] OJ L 308, 29.11.1996, p. 7.
[16] OJ L 265, 30.9.1998, p. 2.

# Proposal for a Directive of the European Parliament and of the Council amending Directive 80/232/EEC as regards the range of nominal weights for coffee extracts and chicory extracts

(2000/C 365 E/25)

*COM(2000) 568 final — 2000/0235(COD)*

*(Submitted by the Commission on 13 September 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) In order to promote transparency of the body of Community legislation, all ranges of nominal quantities for pre-packaged products should be included in a single legislative text, namely Council Directive 80/232/EEC [1].

(2) For this reason, the range of nominal weights for pre-packaged products, which have been laid down in Article 4 of Council Directive 77/436/EEC of 27 June 1977 on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts [2], as last amended by Council Directive 85/573/EEC of 19 December 1985 [3], should no longer be located in the product-specific Directive.

(3) Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts [4] repeals Directive 77/436/EEC as of 13 September 2000 and contains a recital noting the intention to include in Directive 80/232/EEC a range of nominal weights for pre-packaged products for the products under its scope.

(4) The mandatory Community range for nominal quantities for coffee extracts and chicory extracts continues to be necessary to protect consumers and to enable these pre-packaged products to circulate throughout the Community.

(5) Directive 80/232/EEC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 80/232/EEC is hereby amended as follows:

1. The following paragraph is added to Article 5:

   'Pre-packages containing the products listed in point 12 of Annex I may be marketed only in the nominal quantities given in point 12.'

2. Annex I is amended as shown in the Annex I hereto.

*Article 2*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by . . . at the latest [5] They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 4*

This Directive is addressed to the Member States.

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[1] OJ L 51, 25.2.1980, p. 1.

[2] OJ L 172, 12.7.1977, p. 20.

[3] OJ L 372, 31.12.1985, p. 22.

[4] OJ L 66, 13.3.1999, p. 26.

[5] The date of entry into force of this Directive.

*ANNEX I*

The following point is added to Annex I of Directive 80/232/EEC:

12. **Coffee extracts and chicory extracts (g)**

50 — 100 — 200 — 250 (for mixtures of coffee extracts and chicory extracts only and for coffee extracts intended exclusively for use in automatic vending machines) — 300 (for coffee extracts only) — 500 — 750 — 1 000 — 2 000 — 2 500 — 3 000 — 4 000 — 5 000 — 6 000 — 7 000 — 8 000 — 9 000 — 10 000

# Proposal for a Regulation of the European Parliament and of the Council concerning the Committee on Safe Seas and amending the Regulations on maritime safety and the prevention of pollution from ships

(2000/C 365 E/26)

**(Text with EEA relevance)**

*COM(2000) 489 final — 2000/0236(COD)*

*(Submitted by the Commission on 15 September 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure referred to in Article 251 of the Treaty,

Whereas:

(1) The measures implementing the existing Regulations and Directives in the field of maritime safety were adopted by a regulatory procedure involving the committee set up by Council Directive 93/75/EEC [1] and, in certain cases, an *ad hoc* committee. These committees are governed by the rules set out in Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission [2].

(2) By its resolution of 8 June 1993 on a common policy on safe seas, the Council approved in principle the establishment of a Committee on Safe Seas and called on the Commission to present a proposal to set up such a committee.

(3) The role of the Committee on Safe Seas is to centralise the tasks of the committees set up under the Community legislation on maritime safety, and to assist and advise the Commission on all matters of maritime safety and prevention or reduction of pollution of the environment by shipping activities.

(4) In keeping with the Council Resolution of 8 June 1993, a Committee on Safe Seas should be set up and assigned the tasks previously devolved to the committees established under the existing Community legislation on maritime safety. All new Community legislation adopted in the field of maritime safety should stipulate recourse to the Committee on Safe Seas.

(5) Decision 87/373/EEC has been replaced by Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3]. The purpose of the latter decision is to define the committee procedures applicable and ensure more comprehensive information to the European Parliament and the public on the work of the committees.

(6) The pertinent provisions of Decision 1999/468/EC should therefore be applied to the Committee on Safe Seas. As the measures required to implement the legislation in the field of maritime safety are measures of general scope within the meaning of Article 2 of Decision 1999/468/EC, they should be adopted by the regulatory procedure laid down in Article 5 of the Decision.

(7) The existing maritime safety legislation should also be amended to substitute the Committee on Safe Seas for the committee set up by Directive 93/75/EEC or, where appropriate, for the *ad hoc* committee established under the particular piece of legislation. This Regulation should in particular amend the relevant provisions of Council Regulation (EEC) No 613/91 [4], (EC) No 2978/94 [5] and (EC) No 3051/95 [6], in order to insert a reference to the Committee on Safe Seas and to stipulate the regulatory procedure laid down in Article 5 of Decision 1999/468/EC.

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[1] OJ L 247, 5.10.1993, p. 19. Last amended by Directive 98/74/EC (OJ L 276, 13.10.1998, p. 7).

[2] OJ L 197, 18.7.1987, p. 3.

[3] OJ L 184, 17.7.1999, p. 23.

[4] OJ L 68, 15.3.1991, p. 1

[5] OJ L 319, 12.12.1994, p. 1.

[6] OJ L 320, 30.12.1995, p. 14. Amended by Regulation (EC) No 179/98, 23.1.1998, p. 35.

(8) Moreover, the existing Community legislation on maritime safety is based on the application of rules resulting from international conventions, codes and resolutions in force at the date of adoption of the Community act in question, or at the date specified by the latter. As a consequence, Member States cannot apply the subsequent amendments to these international instruments until the Community directives or regulations have been amended. This has major disadvantages owing to the difficulty of getting the date of entry into force of the amendment at the international level to coincide with that of the regulation integrating this amendment into Community law, not least the delayed application within the Community of the most recent and most stringent international safety standards.

(9) However, it is necessary to make a distinction between the provisions of a Community act making reference, for the purposes of their application, to an international instrument and Community provisions reproducing an international instrument in full or in part. In the latter case, the most recent amendments to the international instruments cannot in any case be rendered applicable until the Community provisions concerned have been amended.

(10) Member States should therefore be permitted to apply the most recent provisions of international conventions, with the exception of those explicitly incorporated in a Community act. This can be done by stating that the version of the international convention applicable for the purposes of the directive or regulation concerned is that 'in force', without mentioning the date.

(11) A specific conformity checking procedure should, however, be set up to enable the Commission, after consulting the Committee on Safe Seas, to take whatever measures may be necessary to exclude the risk of amendments to the international instruments being incompatible with the Community legislation or Community policy on safe seas in force. Such a procedure must also prevent international amendments from lowering the standard of maritime safety achieved in the Community.

(12) The conformity checking procedure will only be fully effective if the planned measures are adopted as speedily as possible, but at all events before the expiry of the deadline for the effective entry into force of the international amendment. Consequently, the time available to the Council to act on the proposed measures in accordance with Article 5(6) of Decision 99/468/EC should be reduced to one month,

HAVE ADOPTED THIS REGULATION:

*Article 1*

**Objective**

The objective of this Regulation is to improve the implementation of the pertinent Community legislation on maritime safety, protection of the marine environment and shipboard living and working conditions:

(a) by centralising the tasks of the committees set up under the pertinent Community legislation by creating a single committee, to be known as the Committee on Safe Seas;

(b) by facilitating the process of amending the pertinent Community legislation in the light of developments in the international instruments applicable to maritime safety, protection of the marine environment and shipboard living and working conditions.

*Article 2*

**Definitions**

For the purposes of this Regulation, the following definitions apply:

1. 'international instruments': the conventions, protocols, resolutions, codes, compendia of rules, circulars, standards and provisions adopted by an international conference, the International Maritime Organisation (IMO), the International Labour Organisation (ILO), the parties to a memorandum of understanding or an international standards body, in the field of maritime safety, prevention of pollution from ships and shipboard living and working conditions.

2. 'Community maritime legislation': the Community acts in force listed below:

   (a) Council Regulation (EEC) No 613/91 of 4 March 1991 on the transfer of ships from one register to another within the Community,

   (b) Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods,

   (c) Council Regulation (EC) No 2978/94 of 21 November 1994 on the implementation of IMO Resolution A.747(18) on the application of tonnage measurement of ballast spaces in segregated ballast oil tankers,

(d) Council Directive 94/57/EC of 22 November 1994 on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations ([1]),

(e) Council Directive 94/58/EC of 22 November 1994 on the minimum level of training of seafarers ([2]),

(f) Council Directive 95/21/EC of 19 June 1995 concerning the enforcement, in respect of shipping using Community ports and sailing in the waters under the jurisdiction of the Member States, of international standards for ship safety, pollution prevention and shipboard living and working conditions (port State control) ([3]),

(g) Council Regulation (EC) No 3051/95 of 8 December 1995 on the safety management of roll-on/roll-off passenger ferries,

(h) Council Directive 96/98/EC of 20 December 1996 on marine equipment ([4]),

(i) Council Directive 97/70/EC of 11 December 1997 setting up a harmonised safety regime for fishing vessels of 24 metres in length and over ([5]),

(j) Council Directive 98/18/EC of 17 March 1998 on safety rules and standards for passenger ships ([6]),

(k) Council Directive 98/41/EC of 18 June 1998 on the registration of persons sailing on board passenger ships operating to or from ports of the Member States of the Community ([7]),

(l) Council Directive 1999/35/EC of 29 April 1999 on a system of mandatory surveys for the safe operation of regular ro-ro ferry and high speed passenger craft services ([8]).

*Article 3*

**Establishment of the Committee on Safe Seas**

1. The Commission shall be assisted by a regulatory committee, hereinafter called the Committee on Safe Seas, composed of representatives of the Member States and chaired by the representative of the Commission.

2. Whenever reference is made to this Article, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, subject to the provisions of Article 7(3) and of Article 8 of the Decision.

3. For the purposes of this Regulation, the period referred to in Article 5(6) of Decision 1999/468/EC shall be one month.

*Article 4*

**Conformity checking procedure**

1. The Community Regulations and Directives listed in Article 2(2) may be amended, in accordance with the procedure laid down in Article 3, in order to exclude from the scope of the Regulation or the Directive concerned any amendment to the international instruments defined in Article 2(1) and to which reference is made in the Regulation or Directive.

Such amendment to the Community legislation shall be possible only if there is a manifest risk that the international amendment will lower the standard of maritime safety or protection of the marine environment established by the Community legislation on maritime safety, or be incompatible with the latter, or if it is likely to compromise the achievement of the Community's objectives in the field of maritime safety.

2. For a period of six months from the adoption at international level of an amendment to an international instrument referred to in Article 2(1), Member States party to this instrument shall refrain from any initiative intended to accept or apply the amendment, in order to enable the Commission to consult the Committee referred to in Article 3(1) on a draft Commission regulation or directive designed, in application of the first paragraph, to exclude the amendment in question from a Community text. If the Committee is consulted within the six months' period, the above standstill period shall continue until the adoption of appropriate measures.

3. Where the amendment to the international instrument is subject to a tacit acceptance procedure, the Commission regulation or directive excluding the new amendment from being incorporated into Community law for the reasons set out in the first paragraph shall be adopted in good time to enable the Member States concerned to lodge an objection to the amendment in question at the international level.

*Article 5*

**Powers of the Committee on Safe Seas**

The Committee on Safe Seas shall exercise the powers conferred on it by virtue of the Community legislation in force.

([1]) OJ L 319, 12.12.1994, p. 20. Amended by Directive 97/58/EC (OJ L 274, 7.10.1997, p. 8).

([2]) OJ L 319, 12.12.1994, p. 28. Amended by Directive 98/35/EC (OJ L 172, 17.6.1998, p. 1).

([3]) OJ L 157, 7.7.1995, p. 1. Last amended by Directive 1999/97/EC (OJ L 331, 23.12.1999, p. 67).

([4]) OJ L 46, 17.2.1997, p. 25. Amended by Directive 98/85/EC (OJ L 315, 11.11.1998, p. 14).

([5]) OJ L 34, 9.2.1998, p. 1. Amended by Directive 1999/19/EC (OJ L 83, 27.3.1999, p. 48).

([6]) OJ L 144, 15.5.1998, p. 1.

([7]) OJ L 188, 2.7.1998, p. 35.

([8]) OJ L 138, 1.6.1999, p. 1.

Article 2(2) of this Regulation may be amended by the procedure set out in Article 3 in order to include a reference to the Community acts that have entered into force following the adoption of this Regulation.

*Article 6*

**Amendment of Regulation (EEC) No 613/91**

Regulation (EEC) No 613/91 is amended as follows:

1. Article 1(a) is amended as follows:

   (a) In the first subparagraph, the words 'at the date of adoption of this Regulation' are deleted and the following words added 'without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council'.

   (b) The final subparagraph is deleted.

2. Articles 6 and 7 are replaced by the following:

   '*Article 6*

   The Commission shall be assisted by the Committee on Safe Seas created by Article 3 of Regulation (EC) No . . ./2000.

   *Article 7*

   Where reference is made to this Article, the regulatory procedure laid down in Article 3 of Regulation (EC) No. . ./2000 shall apply.'.

*Article 7*

**Amendment of Regulation (EC) No 2978/94**

Regulation (EC) No 2978/94 is amended as follows:

1. Article 3(g) is replaced by the following:

   (g) ' "Marpol 73/78": International Convention for the Prevention of Pollution from Ships, 1973, as amended by the Protocol of 1978 relating thereto, and the amendments thereof in force, without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

2. Article 7 is replaced by the following:

   '*Article 7*

   The Commission shall be assisted by the Committee on Safe Seas in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'.

*Article 8*

**Amendment of Regulation (EC) No 3051/95**

Regulation (EC) No 3051/95 is amended as follows:

1. In Article 9, the words 'Article 10(2)' are replaced by the words 'Article 10'.

2. Article 10 is replaced by the following:

   '*Article 10*

   The Commission shall be assisted by the Committee on Safe Seas in accordance with the procedure laid down in Article 3 of Regulation (EC) No. . ./2000 of the European Parliament and of the Council.'.

*Article 9*

**Entry into force**

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

# Proposal for a Directive of the European Parliament and of the Council amending the Directives on maritime safety and the prevention of pollution from ships

(2000/C 365 E/27)

**(Text with EEA relevance)**

*COM(2000) 489 final — 2000/0237(COD)*

*(Submitted by the Commission on 15 September 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The Directives in force in the field of maritime safety make reference to the committee set up by Council Directive 93/75/EEC [1] and, in certain cases, to an *ad hoc* committee set up by the pertinent directive. The existing directives provide that the committees thereby established are governed by the rules of Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission [2].

(2) Decision 87/373/EEC was replaced by Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3]. As the measures necessary to implement the Directives in force in the field of maritime safety are measures of a general scope within the meaning of Article 2 of Decision 1999/468/EC, they should be adopted by the regulatory procedure laid down in Article 5 of the Decision.

(3) Regulation (EC) No . . ./2000 of the European Parliament and of the Council has set up a committee, the Committee on Safe Seas, to centralise the tasks of the committees established under the pertinent Community legislation on maritime safety, and stipulates the use of the regulatory procedure described in Article 5 of Decision 1999/468/EC for the purposes of implementing this legislation.

(4) The Directives in force in the field of maritime safety should therefore be amended in order to replace the existing committees by the Committee on Safe Seas.

(5) These Directives should also be amended in order to apply to them the amendment procedures laid down by Regulation (EC) No . . ./2000 and the relevant provisions of that Regulation designed to facilitate their adaptation to take account of changes to the international instruments applicable in the field of maritime safety,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Objective**

The objective of this Directive is to amend the Council Directives in force governing maritime safety, protection of the marine environment and shipboard living and working conditions:

(a) by making reference to the Committee on Safe Seas set up by Regulation (EC) No . . ./2000;

(b) by facilitating their adaptation to take account of changes to the international instruments applicable in the field of maritime safety, prevention of pollution from ships and shipboard living and working conditions, in the manner laid down by Regulation (EC) No . . ./2000.

*Article 2*

**Amendment of Directive 93/75/EEC**

Directive 93/75/EEC is amended as follows:

1. Article 2 is amended as follows:

(a) in points (e) and (i), the words 'on 1 January 1998' are deleted,

(b) in point (f), the words 'on 1 January 1997' are deleted,

[1] OJ L 247, 5.10.1993, p. 19. Last amended by Directive 98/74/EC (OJ L 276, 13.10.1998, p. 7).

[2] OJ L 197, 18.7.1987, p. 3.

[3] OJ L 184, 17.7.1999, p. 23.

(c) in point (g), the words 'on 10 July 1998' are deleted,

(d) in point (h), the words 'on 1 July 1998' are deleted,

(e) the following subparagraph is added:

'The convention, codes, compendia and resolution referred to in points (e), (f), (g), (h) and (i) of the first subparagraph shall be understood without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

2. Article 12 is replaced by the following:

'*Article 12*

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

*Article 3*

**Amendment of Directive 94/57/EC**

Council Directive 94/57/EC is amended as follows ([1]):

1. In Article 2(d), the words 'at the date of adoption of this Directive' are replaced by the words 'without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

2. In Article 7, the first sentence is replaced by the sentence 'The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

3. In Article 8(1), first indent, the words 'to the international codes' are replaced by the words 'to the international conventions, protocols and codes'.

4. Article 13 is replaced by the following:

'*Article 13*

The regulatory procedure laid down in Article 3 of Regulation (EC) No . . ./2000 shall apply to the matters covered by Article 4(3) and (4), Article 5(1), Articles 8, 9 and 10 and Article 14(2).'

*Article 4*

**Amendment of Directive 94/58/EC**

Council Directive 94/58/EC is amended as follows ([2]):

1. Article 4 is amended as follows:

(a) In points (p), (q) and (x), the words 'as in force at the time of the adoption of this Directive' are replaced by the words 'in force'.

(b) In points (r) and (v), the words 'as in force at the time of the adoption of this Directive' are replaced by the words 'in force'.

(c) Point (w) is replaced by the following:

'(w) "ro-ro passenger ship": a passenger ship with ro-ro cargo spaces or special category spaces as defined in the SOLAS convention in force.'

(d) In point (u), the words 'all being applied as in force at the time of the adoption of this Directive' are replaced by the words 'in force'.

(e) The following subparagraph is added:

'The conventions, code, compendia and regulation mentioned in points (p), (q), (r), (u), (v) (w) and (x) shall be understood without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

2. Article 13 is replaced by the following:

'*Article 13*

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

*Article 5*

**Amendment of Directive 95/21/EC**

Council Directive 95/21/EC is amended as follows ([3]):

1. Article 2 is amended as follows:

(a) In point (1), the words 'on 1 July 1999' are replaced by the words 'without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council'.

(b) In point (2), the words 'as it stands on 1 July 1999' are replaced by the words 'as it is in force, without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000'.

([1]) OJ L 319, 12.12.1994, p. 20. Amended by Directive 97/58/EC (OJ L 274, 7.10.1997, p. 8).

([2]) OJ L 319, 12.12.1994, p. 28. Amended by Directive 98/35/EC (OJ L 172, 17.6.1998, p. 1).

([3]) OJ L 157, 7.7.1995, p. 1. Last amended by Directive 1999/97/EC (OJ L 331, 23.12.1999, p. 67).

2. Article 18 is replaced by the following:

'*Article 18*

**Committee on Safe Seas**

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

3. In Article 19, point (c) is deleted.

*Article 6*

**Amendment of Directive 96/98/EC**

Council Directive 96/98/EC is amended as follows [1]:

1. Article 2 is amended as follows:

(a) In points (c), (d) and (n), the words 'on 1 January 1999' are deleted.

(b) The following subparagraph is added:

'The conventions and testing standards referred to in points (c), (d) and (n) shall be understood without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

2. Article 18 is replaced by the following:

'*Article 18*

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

*Article 7*

**Amendment of Directive 97/70/EC**

Article 9 of Council Directive 97/70/EC is replaced by the following [2]:

'*Article 9*

**Committee on Safe Seas**

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

*Article 8*

**Amendment of Directive 98/18/EC**

Council Directive 98/18/EC is amended as follows [3]:

1. Article 2 is amended as follows:

(a) In point (a), the words 'on the date of adoption of this Directive' are deleted.

(b) In points (b) and (c), the words 'as amended at the date of adoption of this Directive' are replaced by the words 'in force'.

(c) In points (d) and (f), the words 'as amended at the date of adoption of this Directive' are replaced by the words 'in force'.

(d) The following subparagraph is added:

'The conventions and compendia referred to in points (a), (b), (c), (d) and (f) shall be understood without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

2. In Article 6(1), points (b) and (c), 6(2), point (a)(i) and 6(3) point (a), the words 'as amended at the date of adoption of this Directive' are deleted.

3. In Article 8, point (b) is replaced by the following:

'(b) Annex I may be amended in order to:

(i) apply, for the purpose of this Directive, amendments made to international conventions;

(ii) improve the technical specifications thereof, in the light of experience.'

4. Article 9 is replaced by the following:

'*Article 9*

**Committee on Safe Seas**

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

*Article 9*

**Amendment of Directive 98/41/EC**

Council Directive 98/41/EC is amended as follows [4]:

1. In Article 2, third indent, the words 'as in force at the time of the adoption of this Directive' are replaced by the words 'in force, without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'

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[1] OJ L 46, 17.2.1997, p. 25. Amended by Directive 98/85/EC (OJ L 315, 11.11.1998, p. 14).

[2] OJ L 34, 9.2.1998, p. 1. Amended by Directive 1999/19/EC (OJ L 83, 27.3.1999, p. 48).

[3] OJ L 144, 15.5.1998, p. 1.

[4] OJ L 188, 2.7.1998, p. 35.

2. Article 13 is replaced by the following:

'*Article 13*

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

*Article 10*

**Amendment of Directive 1999/35/EC**

Council Directive 1999/35/EC is amended as follows [1]:

1. Article 2 is amended as follows:

(a) In points (b) and (o), the words 'as amended on the date of the adoption of this Directive' are replaced by the words 'in force'.

(b) In point (d), the words 'on the date of adoption of this Directive' are deleted.

(c) In point (e), the words 'as amended on the date of the adoption of this Directive' are replaced by the words 'in force'.

(d) The following subparagraph is added:

'The conventions and compendia referred to in points (b), (d), (e) and (o) shall be understood without prejudice to any measures taken in application of Article 4 of Regulation (EC) No . . ./2000 of the European Parliament and of the Council.'.

2. Article 16 is replaced by the following:

'*Article 16*

**Committee on Safe Seas**

The Commission shall be assisted by the Committee on Safe Seas, in accordance with the procedure laid down in Article 3 of Regulation (EC) No . . ./2000.'

*Article 11*

**Application**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than . . . They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. The Member States shall notify to the Commission the text of the main provisions of domestic law which they adopt in the field governed by this Directive.

*Article 12*

**Entry into force**

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Communities*.

*Article 13*

**Addressees**

This Directive is addressed to the Member States.

[1] OJ L 138, 1.6.1999, p. 1.

# Proposal for a Council Regulation on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty and amending Regulations (EEC) No 1017/68, (EEC) No 2988/74, (EEC) No 4056/86 and (EEC) No 3975/87 ('Regulation implementing Articles 81 and 82 of the Treaty')

(2000/C 365 E/28)

**(Text with EEA relevance)**

*COM(2000) 582 final — 2000/0243(CNS)*

*(Submitted by the Commission on 28 September 2000)*

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 83 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

(1) If a system is to be established which ensures that competition in the common market is not distorted, Articles 81 and 82 must be applied effectively and uniformly in the Community. Council Regulation No 17 of 6 February 1962, First Regulation implementing Articles 85 and 86 of the Treaty [1], has allowed a Community competition policy to develop that has helped to disseminate a competition culture within the Community. In the light of experience, however, that Regulation should now be replaced by legislation designed to meet the challenges of an integrated market and a future enlargement of the Community.

(2) In particular, there is a need to rethink the arrangements for applying the exception from the prohibition on agreements, which restrict competition, laid down in Article 81(3). Under Article 83(2)(b), account must be taken in this regard of the need to ensure effective supervision, on the one hand, and to simplify administration to the greatest possible extent, on the other.

(3) The centralised scheme set up by Regulation No 17 no longer secures a balance between those two objectives. It hampers application of the Community competition rules by the courts and competition authorities of the Member States, and the system of notification it involves prevents the Commission from concentrating its resources on curbing the most serious infringements. It also imposes considerable costs on undertakings.

(4) The present system should therefore be replaced by a directly applicable exception system in which the competition authorities and courts of the Member States have the power to apply not only Articles 81(1) and 82, which have direct applicability by virtue of the case-law of the Court of Justice of the European Communities, but also Article 81(3).

(5) It should be specified here that, in line with the case-law developed in the framework of Regulation No 17, the burden of proving that the conditions of Article 81(3) are fulfilled rests on the party seeking to rely on that provision. That party is usually best placed to prove that the conditions of that paragraph are fulfilled.

(6) In order to ensure that the Community competition rules are applied effectively, the competition authorities of the Member States must be associated more closely with their application. To this end, they must be empowered to apply Community law.

(7) National courts have an essential part to play in applying the Community competition rules. When deciding disputes between private individuals, they protect the subjective rights under Community law, for example by awarding damages to the victims of infringements. The role of the national courts here complements that of the competition authorities of the Member States. They must therefore be allowed to apply Articles 81 and 82 of the Treaty in full.

(8) In order to ensure that the same competition rules apply to businesses throughout the Community, provision must be made pursuant to Article 83(2)(e) to regulate the relationship between Articles 81 and 82 and national competition law by excluding the application of national law to agreements, decisions and practices within the scope of Articles 81 and 82.

[1] OJ 13, 21.2.1962, p. 204/62; Regulation as last amended by Regulation (EC) No 1216/1999 (OJ L 148, 15.6.1999, p. 5).

(9) Although, in the new system, application of the rules will be decentralised, the uniformity of Community law requires that the rules be laid down centrally. To this end, the Commission must be given a general power to adopt block exemption regulations in order to enable it to adapt and clarify the legislative framework. This power must be exercised in close cooperation with the competition authorities of the Member States. It must be without prejudice to the existing rules in Council Regulations (EEC) No 1017/68 [1], (EEC) No 4056/86 [2] and (EEC) No 3975/87 [3].

(10) As the system of notification will now come to an end, it may be expedient, in order to improve transparency, to require registration of certain types of agreement. The Commission should accordingly be empowered to require registration of certain types of agreement. If any such requirement is introduced, it must not confer any entitlement to a decision on the compatibility with the Treaty of the agreement registered, and must not be prejudicial to effective action against infringements.

(11) For it to ensure that the provisions of the Treaty are applied, the Commission must be able to address decisions to undertakings or associations of undertakings for the purpose of bringing to an end infringements of Articles 81 and 82. Provided there is a legitimate interest in doing so, the Commission must also be able to adopt decisions which find that an infringement has been committed in the past even if it does not impose a fine. This Regulation should also make explicit provision for the Commission's power to adopt decisions ordering interim measures, which has been acknowledged by the Court of Justice.

(12) Where, in the course of proceedings which might lead to an agreement being prohibited, undertakings offer the Commission commitments such as to meet its objections, the Commission should be able to adopt decisions which make those commitments binding on the undertakings concerned, without settling the question of the applicability of Article 81 or Article 82, so that the commitments can be relied upon by third parties before national courts and failure to comply with them can be punished by the imposition of fines and periodic penalty payments.

(13) In exceptional cases where the public interest of the Community so requires, it may also be expedient for the Commission to adopt a decision of a declaratory nature finding that the prohibition in Article 81 or Article 82 does not apply, with a view to clarifying the law and ensuring its consistent application throughout the Community.

(14) If the Commission and the competition authorities of the Member States are to form together a network of public authorities applying the Community competition rules in close cooperation, arrangements for information and consultation must be set up and the exchange of information must be allowed between the members of the network even where the information is confidential, subject to appropriate guarantees for undertakings.

(15) If the competition rules are to be applied consistently and, at the same time, the network is to be managed in the best possible way, it is essential to retain the rule that the competition authorities of the Member States are automatically relieved of their competence if the Commission initiates its own proceedings.

(16) To ensure that cases are dealt with by the most appropriate authorities within the network, a general provision should be laid down allowing a competition authority to suspend or close a case on the ground that another authority is dealing with it or has already dealt with it, the objective being that each case should be handled by a single authority. This provision must not prevent the Commission from rejecting a complaint for lack of Community interest, as the case-law of the Court of Justice has acknowledged it may do, even if no other competition authority has indicated its intention of dealing with the case.

(17) The Advisory Committee on Restrictive Practices and Dominant Positions set up by Regulation No 17 has functioned in a very satisfactory manner. It will fit perfectly into the new system of decentralised application. It is necessary, therefore, to build upon the rules laid down by Regulation No 17, while improving the effectiveness of the organisational arrangements. To this end, it would be expedient to allow opinions to be delivered by written procedure. The Advisory Committee should also be able to act as a forum for discussing cases handled by the competition authorities of the Member States, so as to help safeguard the consistent application of the Community competition rules.

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[1] OJ L 175, 23.7.1968, p. 1; Regulation as last amended by the Act of Accession of Austria, Finland and Sweden.

[2] OJ L 378, 31.12.1986, p. 4; Regulation as amended by the Act of Accession of Austria, Finland and Sweden.

[3] OJ L 374, 31.12.1987, p. 1; Regulation as last amended by Regulation (EC) No 2410/92 (OJ L 240, 24.8.1992, p. 18).

(18) Consistency in the application of the competition rules also requires that arrangements be established for cooperation between the courts of the Member States and the Commission. In particular, it will be useful to allow national courts to ask the Commission for information or for its opinion on points concerning the application of Community competition law. The Commission and the competition authorities of the Member States must also be able to submit written or oral observations to courts called upon to apply Article 81 or Article 82. Steps must therefore be taken to ensure that the Commission and the competition authorities of the Member States are kept sufficiently well informed of proceedings before national courts.

(19) In order to ensure compliance with the principles of legal certainty and the uniform application of the Community competition rules in a system of parallel powers, conflicting decisions must be avoided. When the Commission has adopted a decision, therefore, the competition authorities and courts of the Member States must use every effort to avoid contradicting it. In this context, it should be recalled that the courts may refer questions to the Court of Justice for a preliminary ruling.

(20) The Commission must be empowered throughout the Community to require such information to be supplied and to undertake such inspections as are necessary to detect any agreement, decision or concerted practice prohibited by Article 81 or any abuse of a dominant position prohibited by Article 82. The competition authorities of the Member States must cooperate actively in the exercise of these powers.

(21) The detection of infringements of the competition rules is growing ever more difficult, and, in order to protect competition effectively, the Commission's powers of investigation need to be supplemented. The Commission must in particular be empowered to interview any persons who may be in possession of useful information and to record the statements made. In the course of an inspection, authorised Commission officials must be empowered to affix seals and to ask for any information relevant to the subject matter and purpose of the inspection.

(22) It is expedient to clarify, in keeping with the case-law of the Court of Justice, the limits to the power of review that the national courts may exercise when asked, under national law, to order measures allowing assistance from law enforcement authorities in order to overcome opposition on the part of an undertaking to an inspection ordered by decision.

(23) Experience has shown that business records are often kept in the homes of directors or other people working for an undertaking. In order to safeguard the effectiveness of inspections, therefore, authorised Commission officials should be empowered to enter any premises where business records may be kept, including private homes. However, the exercise of this latter power must be subject to the authorisation of the judicial authority.

(24) In order to help the competition authorities of the Member States to apply Articles 81 and 82 effectively, it is expedient to enable them to assist one another by carrying out fact-finding measures.

(25) Compliance with Articles 81 and 82 and the fulfilment of the obligations imposed on undertakings and associations of undertakings under this Regulation must be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fine should also be laid down for infringements of the procedural rules.

(26) The rules on periods of limitation for the imposition of fines and periodic penalty payments were laid down in Council Regulation (EEC) No 2988/74 [1], which also concerns penalties in the field of transport. In a system of parallel powers, the acts, which may interrupt a limitation period, should include procedural steps taken independently by the competition authority of a Member State. To clarify the legal framework, Regulation (EEC) No 2988/74 should therefore be amended to prevent it applying to matters covered by this Regulation, and this Regulation should include provisions on periods of limitation.

(27) The undertakings concerned must be accorded the right to be heard by the Commission, third parties whose interests may be affected by a decision must be given the opportunity of submitting their observations beforehand, and the decisions taken must be widely publicised. While ensuring the rights of defence of the undertakings concerned, in particular, the right of access to the file, it is essential that business secrets be protected. The confidentiality of information exchanged in the network must likewise be safeguarded.

(28) Since all decisions taken by the Commission under this Regulation are subject to review by the Court of Justice in accordance with the Treaty, the Court of Justice should, in accordance with Article 229 thereof be given unlimited jurisdiction in respect of decisions by which the Commission imposes fines or periodic penalty payments.

[1] OJ L 319, 29.11.1974, p. 1.

(29) The principles laid down in Articles 81 and 82 of the Treaty, as they have been applied by Regulation No 17, have given a central role to the Community bodies.

This central role should be retained, whilst associating the Member States more closely with the application of the Community competition rules. In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty, this Regulation confines itself to the minimum required in order to achieve its objective, which is to allow the Community competition rules to be applied effectively, and does not go beyond what is necessary for that purpose.

(30) As the case-law has made it clear that the competition rules apply to transport, that sector should be made subject to the procedural provisions of this Regulation. Regulations (EEC) No 1017/68, (EEC) No 4056/86 and (EEC) No 3975/87 should therefore be amended in order to delete the specific procedural provisions they contain.

(31) In order to take account of the new arrangements established by this Regulation, the following Regulations should be repealed: Council Regulation No 141 of 26 November 1962 exempting transport from the application of Regulation No 17 [1], Council Regulation No 19/65/EEC of 2 March 1965 on application of Article 85(3) of the Treaty to certain categories of agreements and concerted practices [2], Council Regulation (EEC) No 2821/71 of 20 December 1971 on application of Article 85(3) of the Treaty to categories of agreements, decisions and concerted practices [3], Council Regulation (EEC) No 3976/87 of 14 December 1987 on the application of Article 85(3) of the Treaty to certain categories of agreements and concerted practices in the air transport sector [4], Council Regulation (EEC) No 1534/91 of 31 May 1991 on the application of Article 85(3) of the Treaty to certain categories of agreements, decisions and concerted practices in the insurance sector [5], and Council Regulation (EEC) No 479/92 of 25 February 1992 on the application of Article 85(3) of the Treaty to certain categories of agreements, decisions and concerted practices between liner shipping companies (consortia) [6],

HAS ADOPTED THIS REGULATION:

CHAPTER I

**PRINCIPLES**

*Article 1*

**Direct applicability**

Agreements, decisions and concerted practices caught by Article 81(1) of the Treaty which do not satisfy the conditions of Article 81(3), and the abuse of a dominant position referred to in Article 82, shall be prohibited, no prior decision to that effect being required.

*Article 2*

**Burden of proof**

In any national or Community proceedings for the application of Article 81 and Article 82 of the Treaty, the burden of proving an infringement of Article 81(1) or of Article 82 shall rest on the party alleging the infringement. A party claiming the benefit of Article 81(3) shall bear the burden of proving that the conditions of that paragraph are fulfilled.

*Article 3*

**Relationship between Articles 81 and 82 and national competition laws**

Where an agreement, a decision by an association of undertakings or a concerted practice within the meaning of Article 81 of the Treaty or the abuse of a dominant position within the meaning of Article 82 may affect trade between Member States, Community competition law shall apply to the exclusion of national competition laws.

CHAPTER II

**POWERS**

*Article 4*

**Powers of the Commission**

1. For the purpose of applying Articles 81 and 82 of the Treaty, the Commission shall have the powers provided for by this Regulation.

2. The Commission may, by regulation, determine types of agreements, decisions of associations of undertakings and concerted practices caught by Article 81(1) of the Treaty which must be registered by undertakings. In that event, it shall also determine the procedures for such registration and the penalties applicable in the event of failure to comply with the obligation. Registration of an agreement, a decision of an association or a concerted practice shall confer no entitlement

[1] OJ 124, 28.11.1962, p. 2751/62; Regulation as last amended by Regulation No 1002/67/EEC (OJ 306, 16.12.1967, p. 1).

[2] OJ 36, 6.3.1965, p. 533/65; Regulation as last amended by Regulation (EC) No 1215/1999 (OJ L 148, 15.6.1999, p. 1).

[3] OJ L 285, 29.12.1971, p. 46; Regulation as last amended by the Act of Accession of Austria, Finland and Sweden.

[4] OJ L 374, 31.12.1987, p. 9; Regulation as last amended by the Act of Accession of Austria, Finland and Sweden.

[5] OJ L 143, 7.6.1991, p. 1.

[6] OJ L 55, 29.2.1992, p. 3; Regulation as amended by the Act of Accession of Austria, Finland and Sweden.

on the registering undertakings or associations of undertakings and shall not form an obstacle to the application of this Regulation.

*Article 5*

**Powers of the competition authorities of the Member States**

The competition authorities of the Member States shall have the power in individual cases to apply the prohibition in Article 81(1) of the Treaty where the conditions of Article 81(3) are not fulfilled, and the prohibition in Article 82. For this purpose, acting on their own initiative or on a complaint, they may take any decision requiring that an infringement be brought to an end, adopting interim measures, accepting commitments or imposing fines, periodic penalty payments or any other penalty provided for in their national law. Where on the basis of the information in their possession the conditions for prohibition are not met they may likewise decide that there are no grounds for action on their part.

*Article 6*

**Powers of the national courts**

National courts before which the prohibition in Article 81(1) of the Treaty is invoked shall also have jurisdiction to apply Article 81(3).

CHAPTER III

**COMMISSION DECISIONS**

*Article 7*

**Finding and termination of infringement**

1. Where the Commission, acting on a complaint or on its own initiative, finds that there is an infringement of Article 81 or of Article 82 of the Treaty, it may by decision require the undertakings and associations of undertakings concerned to bring such infringement to an end. For this purpose, it may impose on them any obligations necessary, including remedies of a structural nature. If it has a legitimate interest in doing so, it may also find that an infringement has been committed in the past.

2. Those entitled to lodge a complaint for the purposes of paragraph 1 are Member States and natural or legal persons who can show a legitimate interest.

*Article 8*

**Interim measures**

1. In cases of urgency due to the risk of serious and irreparable damage to competition, the Commission, acting on its own initiative, may, on the basis of a *prima facie* finding of infringement, by decision order interim measures.

2. A decision under paragraph 1 shall apply for a maximum of one year but shall be renewable.

*Article 9*

**Commitments**

1. Where the Commission intends to adopt a decision requiring that an infringement be brought to an end and the undertakings concerned offer commitments such as to meet the Commission's objections, the Commission may by decision make those commitments binding on the undertakings. Such a decision shall be adopted for a specified period.

2. Irrespective of whether or not there has been or still is an infringement of Article 81 or Article 82 of the Treaty, such a decision shall terminate the proceedings.

3. The Commission may reopen the proceedings:

(a) where there has been a material change in any of the facts on which the decision was based;

(b) where the undertakings concerned act contrary to their commitments; or

(c) where the decision was based on incomplete, incorrect or misleading information.

*Article 10*

**Finding of inapplicability**

For reasons of the Community public interest, the Commission, acting on its own initiative, may by decision find that, on the basis of the information in its possession, Article 81 of the Treaty is not applicable to an agreement, a decision of an association of undertakings or a concerted practice, either because the conditions of Article 81(1) are not fulfilled, or because the conditions of Article 81(3) are satisfied.

The Commission may likewise make such a finding with reference to Article 82 of the Treaty.

CHAPTER IV

**COOPERATION WITH NATIONAL AUTHORITIES AND COURTS**

*Article 11*

**Cooperation between the Commission and the competition authorities of the Member States**

1. The Commission and the competition authorities of the Member States shall apply the Community competition rules in close cooperation.

2. The Commission shall forthwith transmit to the competition authorities of the Member States copies of the most important documents it has collected with a view to applying Articles 7 to 10.

3. Where a matter involving the application of Article 81 or Article 82 of the Treaty is referred to the competition authorities of the Member States or where they act on their own initiative to apply those Articles, they shall inform the Commission accordingly at the outset of their own proceedings.

4. Where competition authorities of Member States intend to adopt a decision under Article 81 or Article 82 of the Treaty requiring that an infringement be brought to an end, accepting commitments or withdrawing the benefit of a block exemption regulation, they shall first consult the Commission. For that purpose, they shall no later than one month before adopting the decision provide the Commission with a summary of the case and with copies of the most important documents drawn up in the course of their own proceedings. At the Commission's request, they shall provide it with a copy of any other document relating to the case.

5. The competition authorities of the Member States may consult the Commission on any other case involving the application of Community law.

6. The initiation by the Commission of proceedings for the adoption of a decision under this Regulation shall relieve the competition authorities of the Member States of their competence to apply Articles 81 and 82 of the Treaty.

*Article 12*

**Exchange of information**

1. Notwithstanding any national provision to the contrary, the Commission and the competition authorities of the Member States may provide one another with and use in evidence any matter of fact or of law, including confidential information.

2. Information provided under paragraph 1 may be used only for the purpose of applying Community competition law. Only financial penalties may be imposed on the basis of information provided.

*Article 13*

**Suspension or termination of proceedings**

1. Where competition authorities of two or more Member States have received a complaint or are acting on their own initiative under Article 81 or Article 82 of the Treaty against the same agreement, decision of an association or practice, the fact that one authority is dealing with the case shall be sufficient grounds for the others to suspend the proceedings before them or to reject the complaint. The Commission may likewise reject a complaint on the ground that the competition authority of a Member State is dealing with the case.

2. Where the competition authority of a Member State or the Commission has received a complaint against an agreement, decision of an association or practice which has already been dealt with by another competition authority, it may reject it.

*Article 14*

**Advisory Committee**

1. An Advisory Committee on Restrictive Practices and Dominant Positions shall be consulted prior to the taking of any decision under Articles 7, 9, 10, 22 and 23(2).

2. The Advisory Committee shall be composed of representatives of the competition authorities of the Member States. Each Member State shall appoint a representative who, if prevented from attending, may be replaced by another representative.

3. The consultation may take place at a meeting convened by the Commission, which shall supply the chairman, not earlier than fourteen days after dispatch of the notice convening it. The Member States may accept a period of notice of less than fourteen days. The Commission shall attach to the notice convening the meeting a summary of the case, together with an indication of the most important documents, and a preliminary draft decision. The Advisory Committee shall deliver an opinion on the Commission's preliminary draft decision. It may deliver an opinion even if some members are absent and are not represented.

4. Consultation may also take place by written procedure. In that case, the Commission shall determine a date by which the Member States are to put forward their observations. However, if any Member State so requests, the Commission shall convene a meeting.

5. The opinion of the Advisory Committee shall be delivered in writing and appended to the draft decision. The Advisory Committee may recommend publication of the opinion. The Commission may carry out such publication. The decision to publish shall take account of the legitimate interest of undertakings in the protection of their business secrets.

6. Acting on its own initiative or at the request of a Member State, the Commission may include a case being dealt with by the competition authority of a Member State on the agenda of the Advisory Committee for discussion before the final decision is adopted.

*Article 15*

**Cooperation with national courts**

1. In proceedings for the application of Article 81 or Article 82 of the Treaty, courts of the Member States may ask the Commission for information in its possession or for its opinion on questions concerning the application of the Community competition rules.

2. Courts of the Member States shall send the Commission copies of any judgments applying Article 81 or Article 82 of the Treaty within one month of the date on which the judgment is delivered.

3. For reasons of the Community public interest, the Commission may, on its own initiative, submit written or oral observations to courts of the Member States on the subject of proceedings in which questions concerning the application of Article 81 or Article 82 of the Treaty arise. It may have itself represented by competition authorities of Member States. Acting on their own initiative, competition authorities of Member States may likewise submit written or oral observations to the national courts of their Member State.

To this end, the Commission and the competition authorities of the Member States may request the national courts to transmit to them any documents necessary.

*Article 16*

**Uniform application of Community competition law**

In accordance with Article 10 of the Treaty and the principle of the uniform application of Community law, national courts and the competition authorities of the Member States shall use every effort to avoid any decision that conflicts with decisions adopted by the Commission.

CHAPTER V

**POWERS OF INVESTIGATION**

*Article 17*

**Inquiries into sectors of the economy**

1. If, in any sector of the economy, the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition is being restricted or distorted within the common market, the Commission may conduct a general inquiry into that sector and, in the course of that inquiry, may request undertakings in the sector concerned to supply the information necessary for giving effect to Articles 81 and 82 of the Treaty and may carry out any inspections necessary for that purpose.

The Commission may in particular request any undertaking or association of undertakings in the sector concerned to communicate to it all agreements, decisions and concerted practices.

2. Articles 18 to 23 shall apply by analogy.

*Article 18*

**Requests for information**

1. In order to carry out the duties assigned to it by this Regulation, the Commission may request all necessary information from the governments and competition authorities of the Member States and from undertakings and associations of undertakings.

2. In its request for information the Commission shall state the legal bases of the request, the time-limit within which the information is to be provided, the purpose of the request, and the penalties provided for in Articles 22 and 23 for supplying incorrect, incomplete or misleading information.

3. The owners of the undertakings or their representatives and, in the case of legal persons, companies or firms, or associations having no legal personality, the persons authorised to represent them by law or by their constitution shall supply the information requested. Lawyers duly authorised to act may supply the information on behalf of their clients. The latter shall remain fully responsible if the information supplied is incomplete, incorrect or misleading.

4. Where an undertaking or association of undertakings does not supply the information requested within the time-limit fixed or supplies incomplete information, the Commission shall by decision require the information to be supplied. The decision shall specify what information is required and fix an appropriate time-limit within which it is to be supplied. It shall indicate the penalties provided for in Article 22(1)(a), and indicate or impose the penalties provided for in Article 23(1)(d). It shall also indicate the right to have the decision reviewed by the Court of Justice of the European Communities.

*Article 19*

**Power to take statements**

In order to carry out the duties assigned to it by this Regulation, the Commission may interview any natural or legal person that may be in possession of useful information, in order to ask questions relating to the subject matter of an investigation and recording the answers.

*Article 20*

**The Commission's powers of inspection**

1. In order to carry out the duties assigned to it by this Regulation, the Commission may conduct all necessary inspections of undertakings and associations of undertakings.

2. The officials authorised by the Commission to conduct an inspection are empowered:

(a) to enter any premises, land and means of transport of the undertakings and associations of undertakings concerned;

(b) to enter any other premises, including the homes of directors, managers and other members of staff of the undertakings and associations of undertakings concerned, in so far as it may be suspected that business records are being kept there;

(c) to examine the books and other business records, irrespective of the medium on which they are stored;

(d) to take copies of or extracts from the documents examined;

(e) to seal any premises or business records during the inspection;

(f) to ask any representative or member of staff of the undertaking or association of undertakings for information relating to the subject matter and purpose of the inspection and to record the answers.

3. The officials authorised by the Commission to conduct an inspection shall exercise their powers upon production of a written authorisation specifying the subject matter and purpose of the inspection and the penalties provided for in Article 22 in cases where production of the required books or other business records is incomplete or where the answers to questions asked under paragraph 2 of this Article are incorrect, incomplete or misleading. In good time before the inspection, the Commission shall give notice of the inspection to the competition authority of the Member State in whose territory it is to be conducted.

4. Undertakings and associations of undertakings are required to submit to inspections ordered by decision of the Commission. The decision shall specify the subject matter and purpose of the inspection, appoint the date on which it is to begin and indicate the penalties provided for in Articles 22 and 23 and the right to have the decision reviewed by the Court of Justice. The Commission shall take such decisions after consulting the competition authority of the Member State in whose territory the inspection is to be conducted.

5. Officials of the competition authority of the Member State in whose territory the inspection is to be conducted shall, at the request of that authority or of the Commission, actively assist the officials of the Commission. To this end, they shall enjoy the powers specified in paragraph 2.

6. Where the officials authorised by the Commission find that an undertaking opposes an inspection ordered pursuant to this Article, the Member State concerned shall afford them the necessary assistance, requesting where appropriate the assistance of the police, so as to enable them to conduct their inspection.

If national law requires authorisation from the judicial authority before the assistance of the police can be called upon, such authorisation may be applied for as a precautionary measure.

7. Where the officials authorised by the Commission wish to exercise the power provided for by paragraph 2(b), authorisation from the judicial authority must be obtained beforehand.

8. The lawfulness of the Commission decision shall be subject to review only by the Court of Justice. The power of review of the national court shall extend only to establishing that the Commission decision is authentic and that the enforcement measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the inspection. The national court may not review the necessity for the inspection or require information other than that set out in the Commission decision.

*Article 21*

**Investigations by competition authorities of Member States**

1. The competition authority of a Member State may in its own territory carry out any fact-finding measure under its national law on behalf and for the account of the competition authority of another Member State in order to establish whether there has been an infringement of Article 81 or Article 82 of the Treaty. It shall transmit the information collected to the requesting authority in accordance with Article 12 of this Regulation.

2. At the request of the Commission, the competition authorities of the Member States shall undertake the inspections which the Commission considers to be necessary under Article 20(1) or which it has ordered by decision pursuant to Article 20(4). The officials of the competition authorities of the Member States who are responsible for conducting these inspections shall exercise their powers upon production of a written authorisation issued by the competition authority of the Member State in whose territory the inspection is to be conducted. Such authorisation shall specify the subject matter and purpose of the inspection.

If so requested by the Commission or by the competition authority of the Member State in whose territory the inspection is to be conducted, the officials of the Commission may assist the officials of the authority concerned.

CHAPTER VI

**PENALTIES**

*Article 22*

**Fines**

1. The Commission may by decision impose on undertakings and associations of undertakings fines not exceeding 1 % of the total turnover in the preceding business year where, intentionally or negligently:

(a) they supply incorrect, incomplete or misleading information in response to a request made pursuant to Article 17 or Article 18(1) or (4), or do not supply information within the time-limit fixed by a decision adopted pursuant to Article 18(4);

(b) they produce the required books or other business records in incomplete form during inspections under Article 20 or Article 21(2), or refuse to submit to inspections ordered by a decision adopted pursuant to Article 20(4);

(c) they refuse to answer a question asked in accordance with Article 20(2)(f) or give an incorrect, incomplete or misleading answer;

(d) seals affixed by authorised officials of the Commission in accordance with Article 20(2)(e) have been broken.

2. The Commission may by decision impose on undertakings and associations of undertakings fines not exceeding 10 % of the total turnover in the preceding business year of each of the undertakings participating in the infringement where, either intentionally or negligently:

(a) they infringe Article 81 or Article 82 of the Treaty; or

(b) they contravene a decision ordering interim measures under Article 8 of this Regulation; or

(c) they fail to comply with a commitment made binding by a decision pursuant to Article 9 of this Regulation.

3. In fixing the amount of the fine, regard shall be had both to the gravity and to the duration of the infringement.

4. Where a fine is imposed on an association of undertakings under this Regulation and the association is not solvent, the Commission may require payment of the fine by any of the undertakings which were members of the association at the time the infringement was committed. The amount required to be paid by each individual member cannot exceed 10 % of its total turnover in the preceding business year.

5. Decisions taken pursuant to paragraphs 1 and 2 shall not be of a criminal law nature.

*Article 23*

**Periodic penalty payments**

1. The Commission may, by decision, impose on undertakings or associations of undertakings periodic penalty payments not exceeding 5 % of the average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel them:

(a) to put an end to an infringement of Article 81 or Article 82 of the Treaty, in accordance with a decision taken pursuant to Article 7 of this Regulation;

(b) to comply with a decision ordering interim measures taken pursuant to Article 8;

(c) to comply with a commitment made binding by a decision pursuant to Article 9;

(d) to supply complete and correct information which it has requested by decision taken pursuant to Article 18(4);

(e) to submit to an inspection which it has ordered by decision taken pursuant to Article 20.

2. Where the undertakings or associations of undertakings have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision. Article 22(4) shall apply by analogy.

CHAPTER VII

**LIMITATION PERIODS**

*Article 24*

**Limitation periods for the imposition of penalties**

1. The powers conferred on the Commission by Articles 22 and 23 shall be subject to the following limitation periods:

(a) three years in the case of infringements of provisions concerning requests for information or the conduct of inspections;

(b) five years in the case of all other infringements.

2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.

3. Any action taken by the Commission or by the competition authority of a Member State for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments. The limitation period shall be interrupted with effect from the date on which the action is notified to at least one undertaking or association of undertakings which has participated in the infringement. Actions which interrupt the running of the period shall include in particular the following:

(a) written requests for information by the Commission or by the competition authority of a Member State;

(b) written authorisations to conduct inspections issued to its officials by the Commission or by the competition authority of a Member State;

(c) the initiation of proceedings by the Commission or by the competition authority of a Member State;

(d) notification of the statement of objections of the Commission or of the competition authority of a Member State.

4. The interruption of the limitation period shall apply for all the undertakings or associations of undertakings which have participated in the infringement.

5. Each interruption shall start time running afresh. However, the limitation period shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which limitation is suspended pursuant to paragraph 6.

6. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice.

*Article 25*

**Limitation period for the enforcement of penalties**

1. The power of the Commission to enforce decisions taken pursuant to Articles 22 and 23 shall be subject to a limitation period of five years.

2. Time shall begin to run on the day on which the decision becomes final.

3. The limitation period for the enforcement of penalties shall be interrupted:

(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;

(b) by any action of the Commission or of a Member State, acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.

4. Each interruption shall start time running afresh.

5. The limitation period for the enforcement of penalties shall be suspended for so long as:

(a) time to pay is allowed;

(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice.

CHAPTER VIII

**HEARINGS AND PROFESSIONAL SECRECY**

*Article 26*

**Hearing of the parties, complainants and others**

1. Before taking decisions as provided for in Articles 7, 8, 22 and 23(2), the Commission shall give the undertakings or associations of undertakings which are the subject of the proceedings the opportunity of being heard on the matters to which the Commission has taken objection. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment. Complainants shall be associated closely with the proceedings.

2. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the file, subject to the legitimate interest of undertakings in the protection of their business secrets. That legitimate interest may not constitute an obstacle to the disclosure and use by the Commission of information necessary to prove an infringement.

The right of access to the file shall not extend to confidential information and internal documents of the Commission or the competition authorities of the Member States. In particular, any correspondence between the Commission and the Competition Authority of the Member States, or between the latter, inter alia, documents drawn up pursuant to Articles 8 and 11 are excluded.

3. If the Commission or the competition authorities of the Member States consider it necessary, they may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show sufficient interest, be granted.

*Article 27*

**Professional secrecy**

1. Without prejudice to Articles 12 and 15, information collected pursuant to Articles 17 to 21 shall be used only for the purpose for which it was acquired.

2. Without prejudice to Articles 11, 12, 14, 15 and 26, the Commission and the competition authorities of the Member States, their officials and other servants shall not disclose information acquired or exchanged by them pursuant to this Regulation and of the kind covered by the obligation of professional secrecy.

CHAPTER IX

**BLOCK EXEMPTIONS**

*Article 28*

**Adoption of block exemption regulations**

1. In accordance with Article 81(3) of the Treaty, the Commission may, by regulation, declare that Article 81(1) is not applicable to categories of agreements, decisions by associations of undertakings or concerted practices, subject to the conditions in paragraphs 2 to 5 of this Article.

2. Exemption regulations must define the categories of agreements, decisions or concerted practices to which they apply and specify in particular the restrictions, which are not exempted, and any conditions that must be fulfilled.

3. Exemption regulations must be limited in time.

4. Before adopting an exemption regulation, the Commission must publish a draft thereof and invite all interested parties concerned to submit their comments within the time-limit it lays down, which may not be less than one month.

5. Before publishing a draft exemption regulation and before adopting such a regulation, the Commission shall consult the Advisory Committee on Restrictive Practices and Dominant Positions.

*Article 29*

**Withdrawal in individual cases**

1. Where, in any particular case, the Commission, acting on its own initiative or on a complaint, finds that agreements, decisions or concerted practices to which a block exemption regulation applies nevertheless have certain effects which are incompatible with Article 81(3) of the Treaty, it may withdraw the benefit of the regulation.

2. Where in any particular case agreements, decisions or concerted practices to which a block exemption regulation applies have effects which are incompatible with Article 81(3) of the Treaty in the territory of a Member State, or in a part thereof, which has all the characteristics of a distinct geographic market, the competition authority of that Member State may withdraw the benefit of the regulation in question in respect of that territory.

*Article 30*

**Regulations ending the application of a block exemption**

A block exemption regulation adopted pursuant to Article 28 may specify the circumstances which may lead to the exclusion from its scope of certain types of agreement, decision or concerted practice that are applied on a particular market. Where those circumstances obtain, the Commission may establish this by way of regulation, and fix a period on the expiry of which the block exemption regulation will no longer be applicable to the relevant agreements, decisions or concerted practices on that market. That period must not be less than six months. Article 28(4) and (5) shall apply by analogy.

CHAPTER X

**GENERAL PROVISIONS**

*Article 31*

**Publication of decisions**

1. The Commission shall publish the decisions, which it takes pursuant to Articles 7 to 10, 22 and 23.

2. The publication shall state the names of the parties and the main content of the decision, including any penalties imposed. It shall have regard to the legitimate interest of undertakings in the protection of their business secrets.

*Article 32*

**Review by the Court of Justice**

The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has fixed a fine or periodic penalty payment. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

*Article 33*

**Exclusions**

This Regulation shall not apply to agreements, decisions and concerted practices or to the abuse of a dominant position within the meaning of Article 82 of the Treaty in the following areas:

(a) international sea transport of the tramp service type;

(b) sea transport between ports in the same Member State;

(c) air transport between the Community and third countries.

*Article 34*

**Implementing provisions**

The Commission shall be authorised to take such measures as may be appropriate in order to apply this Regulation. The measures may concern *inter alia*:

(a) the introduction of a registration requirement for certain types of agreement;

(b) the form, content and other details of complaints lodged pursuant to Article 7 and the procedure for rejecting complaints;

(c) the practical arrangements for the exchange of information and consultations provided for in Article 11;

(d) the practical arrangements for the hearings provided for in Article 26.

CHAPTER XI

**TRANSITIONAL AND FINAL PROVISIONS**

*Article 35*

**Transitional provisions**

1. Applications made to the Commission under Article 2 of Regulation No 17, notifications made under Articles 4 and 5 of that Regulation and the corresponding applications and notifications made under Regulations (EEC) No 1017/68, (EEC) No 4056/86 and (EEC) No 3975/87 shall lapse as from the date of application of this Regulation.

The validity of decisions applying Article 81(3) of the Treaty adopted by the Commission under those Regulations shall come to an end no later than the date of application of this Regulation.

2. Procedural steps taken under Regulation No 17 and Regulations (EEC) No 1017/68, (EEC) No 4056/86 and (EEC) No 3975/87 shall continue to have effect for the purposes of applying this Regulation.

*Article 36*

**Designation of competition authorities of Member States**

The Member States shall designate the competition authorities responsible for the application of Articles 81 and 82 of the Treaty, and shall take the measures necessary to empower those authorities to apply those Articles before . . ..

*Article 37*

**Amendment of Regulation (EEC) No 1017/68**

Regulation (EEC) No 1017/68 is amended as follows:

1. Article 2 is deleted.

2. In Article 3(1), the words 'The prohibition laid down in Article 2' are replaced by the words 'The prohibition in Article 81(1) of the Treaty'.

3. Articles 5 to 29 are deleted.

4. In Article 30, paragraphs 2 and 3 are deleted.

*Article 38*

**Amendment of Regulation (EEC) No 2988/74**

In Regulation (EEC) No 2988/74, the following Article 7a is inserted:

'*Article 7a*

**Exclusion**

This Regulation shall not apply to measures taken under Council Regulation (EC) No . . . (*)

(*) OJ L . . .'

*Article 39*

**Amendment of Regulation (EEC) No 4056/86**

Regulation (EEC) No 4056/86 is amended as follows:

1. Article 7 is amended as follows:

(a) Paragraph 1 is replaced by the following:

'1. *Breach of an obligation*

Where the persons concerned are in breach of an obligation which, pursuant to Article 5, attaches to the exemption provided for in Article 3, the Commission may, in order to put an end to such breach and under the conditions laid down in Council Regulation (EC) No . . . (*):

— address recommendations to the persons concerned;

— in the event of failure by such persons to observe those recommendations and depending on the gravity of the breach concerned, adopt a decision that either prohibits them from carrying out or requires them to perform certain specific acts, or withdraws the benefit of the block exemption which they enjoyed.

(*) OJ L . . . .'

(b) Paragraph 2 is amended as follows:

(i) In point (a), the words 'under the conditions laid down in Section II' are replaced by the words 'under the conditions laid down in Regulation (EC) No . . ./. . .';

(ii) The second sentence of the second subparagraph of point (c)(i) is replaced by the following:

'At the same time it shall decide, in accordance with Article 9 of Regulation (EC) No. . ./. . ., whether it accepts commitments offered by the undertakings concerned with a view, *inter alia*, to obtaining access to the market for non-conference lines.'

2. In Article 8, paragraph 1 is deleted.

3. Article 9 is amended as follows:

(a) In paragraph 1, the words 'Advisory Committee referred to in Article 15' are replaced by the words 'Advisory Committee referred to in Article 14 of Regulation (EC) No . . ./. . .';

(b) In paragraph 2, the words 'Advisory Committee as referred to in Article 15' are replaced by the words 'the Advisory Committee referred to in Article 14 of Regulation (EC) No . . ./. . .'.

4. Articles 10 to 25 are deleted.

5. In Article 26, the words 'the form, content and other details of complaints pursuant to Article 10, applications pursuant to Article 12 and the hearings provided for in Article 23(1) and (2)' are deleted.

*Article 40*

**Amendment of Regulation (EEC) No 3975/87**

Articles 3 to 19 of Regulation (EEC) No 3975/87 are deleted.

*Article 41*

**Repeals**

Regulations No 17, No 141, No 19/65/EEC, (EEC) No 2821/71, (EEC) No 3976/87, (EEC) No 1534/91 and (EEC) No 479/92 are hereby repealed.

References to the repealed Regulations shall be construed as references to this Regulation.

*Article 42*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from . . .

This Regulation shall be binding in its entirety and directly applicable in all Member States.