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Legislation

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([1]) Text with EEA relevance

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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II *Acts whose publication is not obligatory*

Commission

EN

[1] Text with EEA relevance

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 719/1999

of 6 April 1999

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables [1], as last amended by Regulation (EC) No 1498/98 [2], and in particular Article 4 (1) thereof,

Whereas Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto;

Whereas, in compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 7 April 1999.

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

Done at Brussels, 6 April 1999.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ L 337, 24.12.1994, p. 66.
[2] OJ L 198, 15.7.1998, p. 4.

ANNEX

to the Commission Regulation of 6 April 1999 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	82,9
	204	67,8
	999	75,4
0707 00 05	052	114,3
	068	107,2
	999	110,8
0709 10 00	220	220,2
	999	220,2
0709 90 70	052	83,1
	204	117,8
	999	100,5
0805 10 10, 0805 10 30, 0805 10 50	052	30,0
	204	45,0
	212	47,2
	220	34,4
	600	74,4
	624	47,8
	999	46,5
0805 30 10	052	64,3
	999	64,3
0808 10 20, 0808 10 50, 0808 10 90	039	109,3
	388	85,9
	400	90,4
	404	98,3
	508	87,4
	512	86,3
	524	103,8
	528	79,2
	720	97,3
	999	93,1
0808 20 50	388	64,3
	400	79,1
	512	73,4
	528	80,0
	720	84,3
	999	76,2

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2317/97 (OJ L 321, 22.11.1997, p. 19). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 720/1999

of 6 April 1999

fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [1], as last amended by Regulation (EC) No 1300/97 [2], and in particular Article 5 (2) (a) thereof,

Whereas, pursuant to Article 2 (2) and Article 3 of abovementioned Regulation (EEC) No 4088/87, Community import and producer prices are fixed each fortnight for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses and apply for two-weekly periods; whereas, pursuant to Article 1b of Commission Regulation (EEC) No 700/88 of 17 March 1988 laying down detailed rules for the application of the arrangements for the import into the Community of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [3], as last amended by Regulation (EC) No 2062/97 [4], those prices are determined for fortnightly periods on the basis of weighted prices provided by the Member States; whereas those prices should be fixed immediately so the customs duties applicable can be determined; whereas, to that end, provision should be made for this Regulation to enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

The Community producer and import prices for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses as referred to in Article 1b of Regulation (EEC) No 700/88 for a fortnightly period shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 7 April 1999.

It shall apply from 7 to 20 April 1999.

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

Done at Brussels, 6 April 1999.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 382, 31.12.1987, p. 22.
[2] OJ L 177, 5.7.1997, p. 1.
[3] OJ L 72, 18.3.1988, p. 16.
[4] OJ L 289, 22.10.1997, p. 1.

ANNEX

(EUR/100 pieces)

Period from 7 to 20 April 1999

Community producer price	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
	12,72	10,58	31,58	16,14
Community import prices	**Uniflorous (bloom) carnations**	**Multiflorous (spray) carnations**	**Large-flowered roses**	**Small-flowered roses**
Israel	11,53	6,79	12,81	11,76
Morocco	13,74	14,06	19,94	—
Cyprus	—	—	—	—
Jordan	—	—	—	—
West Bank and Gaza Strip	—	—	—	—

COMMISSION REGULATION (EC) No 721/1999

of 6 April 1999

suspending the preferential customs duties and re-establishing the Common Customs Tariff duty on imports of small-flowered roses originating in Israel

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan and Morocco and the West Bank and the Gaza Strip [1], as last amended by Regulation (EC) No 1300/97 [2], and in particular Article 5 (2) (b) thereof,

Whereas Regulation (EEC) No 4088/87 lays down the conditions for applying a preferential duty on large-flowered roses, small-flowered roses, uniflorous (bloom) carnations and multiflorous (spray) carnations within the limit of tariff quotas opened annually for imports into the Community of fresh cut flowers;

Whereas Council Regulation (EC) No 1981/94 [3], as last amended by Commission Regulation (EC) No 650/98 [4], opens and provides for the administration of Community tariff quotas for cut flowers and flower buds, fresh, originating in Cyprus, Egypt, Israel, Malta, Morocco and the West Bank and the Gaza Strip;

Whereas Commission Regulation (EC) No 720/1999 [5] fixes the Community producer and import prices for carnations and roses for the application of the import arrangements;

Whereas Commission Regulation (EEC) No 700/88 [6], as last amended by Regulation (EC) No 2062/97 [7], lays down the detailed rules for the application of the arrangements;

Whereas, on the basis of prices recorded pursuant to Regulations (EEC) No 4088/87 and (EEC) No 700/88, it must be concluded that the conditions laid down in Article 2 (2) of Regulation (EEC) No 4088/87 for suspension of the preferential customs duty are met for small-flowered roses originating in Israel; whereas the Common Customs Tariff duty should be re-established;

Whereas the quota for the products in question covers the period 1 January to 31 December 1998; whereas, as a result, the suspension of the preferential duty and the reintroduction of the Common Customs Tariff duty apply up to the end of that period at the latest;

Whereas, in between meetings of the Management Committee, the Commission must adopt such measures,

HAS ADOPTED THIS REGULATION:

Article 1

For imports of small-flowered roses (CN codes ex 0603 10 11 and ex 0603 10 51) originating in Israel, the preferential customs duty fixed by Regulation (EC) No 1981/94 is hereby suspended and the Common Customs Tariff duty is hereby re-established.

Article 2

This Regulation shall enter into force on 8 April 1999.

(1) OJ L 382, 31.12.1987, p. 22.
(2) OJ L 177, 5.7.1997, p. 1.
(3) OJ L 199, 2.8.1994, p. 1.
(4) OJ L 88, 24.3.1998, p. 8.
(5) See page 3 of this Official Journal
(6) OJ L 72, 18.3.1988, p. 16.
(7) OJ L 289, 22.10.1997, p. 1.

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

Done at Brussels, 6 April 1999.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION REGULATION (EC) No 722/1999
of 6 April 1999
amending the import duties in the cereals sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organization of the market in cereals [1], as last amended by Commission Regulation (EC) No 923/96 [2],

Having regard to Commission Regulation (EC) No 1249/96 of 28 June 1996 laying down detailed rules for the application of Council Regulation (EEC) No 1766/92 as regards import duties in the cereals sector [3], as last amended by Regulation (EC) No 2519/98 [4], and in particular Article 2 (1) thereof,

Whereas the import duties in the cereals sector are fixed by Commission Regulation (EC) No 694/1999 [5];

Whereas Article 2, (1) of Regulation (EC) No 1249/96 provides that if during the period of application, the average import duty calculated differs by EUR 5 per tonne from the duty fixed, a corresponding adjustment is to be made; whereas such a difference has arisen; whereas it is therefore necessary to adjust the import duties fixed in Regulation (EC) No 694/1999,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Regulation (EC) No 694/1999 are hereby replaced by Annexes I and II to this Regulation.

Article 2

This Regulation shall enter into force on 7 April 1999.

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

Done at Brussels, 6 April 1999.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ L 181, 1.7.1992, p. 21.
[2] OJ L 126, 24.5.1996, p. 37.
[3] OJ L 161, 29.6.1996, p. 125.
[4] OJ L 315, 25.11.1998, p. 7.
[5] OJ L 89, 1.4.1999, p. 5.

ANNEX I

Import duties for the products covered by Article 10(2) of Regulation (EEC) No 1766/92

CN code	Description	Import duty by land inland waterway or sea from Mediterranean, the Black Sea or Baltic Sea ports (EUR/tonne)	Import duty by air or by sea from other ports (2) (EUR/tonne)
1001 10 00	Durum wheat high quality	58,87	48,87
	medium quality (1)	68,87	58,87
1001 90 91	Common wheat seed	55,84	45,84
1001 90 99	Common high quality wheat other than for sowing (3)	55,84	45,84
	medium quality	80,29	70,29
	low quality	96,34	86,34
1002 00 00	Rye	101,86	91,86
1003 00 10	Barley, seed	101,86	91,86
1003 00 90	Barley, other (3)	101,86	91,86
1005 10 90	Maize seed other than hybrid	103,25	93,25
1005 90 00	Maize other than seed (3)	103,25	93,25
1007 00 90	Grain sorghum other than hybrids for sowing	101,86	91,86

(1) In the case of durum wheat not meeting the minimum quality requirements for durum wheat of medium quality, referred to in Annex I to Regulation (EC) No 1249/96, the duty applicable is that fixed for low-quality common wheat.

(2) For goods arriving in the Community via the Atlantic Ocean or via the Suez Canal (Article 2(4) of Regulation (EC) No 1249/96), the importer may benefit from a reduction in the duty of:

— EUR 3 per tonne, where the port of unloading is on the Mediterranean Sea, or

— EUR 2 per tonne, where the port of unloading is in Ireland, the United Kingdom, Denmark, Sweden, Finland or the Atlantic Coasts of the Iberian Peninsula.

(3) The importer may benefit from a flat-rate reduction of EUR 14 or 8 per tonne, where the conditions laid down in Article 2(5) of Regulation (EC) No 1249/96 are met.

ANNEX II

Factors for calculating duties

(period from 31 March 1999 to 05 April 1999)

1. Averages over the two-week period preceding the day of fixing:

Exchange quotations	Minneapolis	Kansas-City	Chicago	Chicago	Minneapolis	Minneapolis	Minneapolis
Product (% proteins at 12 % humidity)	HRS2. 14 %	HRW2. 11,5 %	SRW2	YC3	HAD2	Medium quality (*)	US barley 2
Quotation (EUR/tonne)	115,41	104,06	94,87	81,29	133,44 (**)	123,44 (**)	90,45 (**)
Gulf premium (EUR/tonne)	21,86	7,96	1,11	8,57	—	—	—
Great Lakes premium (EUR/tonne)	—	—	—	—	—	—	—

(*) A discount of EUR 10 per tonne (Article 4(1) of Regulation (EC) No 1249/96).
(**) Fob Gulf.

2. Freight/cost: Gulf of Mexico — Rotterdam: EUR 10,92 per tonne; Great Lakes — Rotterdam: EUR 22,77 per tonne.

3. Subsidy within the meaning of the third paragraph of Article 4 (2) of Regulation (EC) No 1249/96 : EUR 0,00 per tonne (HRW2)
: EUR 0,00 per tonne (SRW2).

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty [3], in the light of the joint text approved by the Conciliation Committee on 8 December 1998,

(1) Whereas the radio equipment and telecommunications terminal equipment sector is an essential part of the telecommunications market, which is a key element of the economy in the Community; whereas the directives applicable to the telecommunications terminal equipment sector are no longer capable of accommodating the expected changes in the sector caused by new technology, market developments and network legislation;

(2) Whereas in accordance with the principles of subsidiarity and proportionality referred to in Article 3b of the Treaty, the objective of creating an open competitive single market for telecommunications equipment cannot be sufficiently achieved by the Member States and can therefore be better achieved by the Community; whereas this Directive does not go beyond what is necessary to achieve this aim;

(3) Whereas Member States may rely upon Article 36 of the Treaty to exclude certain classes of equipment from this Directive;

(4) Whereas Directive 98/13/EC [4] consolidated the provisions relating to telecommunications terminal equipment and satellite earth station equipment, including measures for the mutual recognition of their conformity;

(5) Whereas that Directive does not cover a substantial proportion of the radio equipment market;

(6) Whereas dual-use goods are subject to the Community regime of export controls introduced by Council Regulation (EC) No 3381/94 [5];

(7) Whereas the broad scope of this Directive requires new definitions of the expressions 'radio equipment' and 'telecommunications terminal equipment'; whereas a regulatory regime aimed at the development of a single market for radio equipment and telecommunications terminal equipment should permit investment, manufacture and sale to take place at the pace of technology and market developments;

(8) Whereas, given the increasing importance of telecommunications terminal equipment and networks using radio transmission besides equipment connected through wired links, any rules governing the manufacturing, marketing and use of radio equipment and telecommunications terminal equipment should cover both classes of such equipment;

(9) Whereas 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 [6] calls on national regulatory authorities to ensure the publication of details of technical interface specifications for network access for the purpose of ensuring a competitive market for the supply of terminal equipment;

(10) Whereas the objectives of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits [7] are sufficient to cover radio equipment and telecommunications terminal equipment, but with no lower voltage limit applying;

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[1] OJ C 248, 14.8.1997, p. 4.
[2] OJ C 73, 9.3.1998, p. 10.
[3] Opinion of the European Parliament of 29 January 1998 (OJ C 56, 23.2.1998, p. 27), Council common position of 8 June 1998 (OJ C 227, 20.7.1998, p. 37) and Decision of the European Parliament of 6 October 1998 (OJ C 328, 26.10.1998, p. 32). Decision of the Council of 25 January 1999 and Decision of the European Parliament of 10 February 1999.
[4] OJ L 74, 12.3.1998, p. 1.
[5] OJ L 367, 31.12.1994, p. 1.
[6] OJ L 101, 1.4.1998, p. 24.
[7] OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

(11) Whereas the electromagnetic compatibility related protection requirements laid down by Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility [1] are sufficient to cover radio equipment and telecommunications terminal equipment;

(12) Whereas Community law provides that obstacles to the free movement of goods within the Community, resulting from disparities in national legislation relating to the marketing of products, can only be justified where any national requirements are necessary and proportionate; whereas, therefore, the harmonisation of laws must be limited to those requirements necessary to satisfy the essential requirements relating to radio equipment and telecommunications terminal equipment;

(13) Whereas the essential requirements relevant to a class of radio equipment and telecommunications terminal equipment should depend on the nature and the needs of that class of equipment; whereas these requirements must be applied with discernment in order not to inhibit technological innovation or the meeting of the needs of a free-market economy;

(14) Whereas care should be taken that radio equipment and telecommunications terminal equipment should not represent an avoidable hazard to health;

(15) Whereas telecommunications are important to the well-being and employment of people with disabilities who represent a substantial and growing proportion of the population of Europe; whereas radio equipment and telecommunications terminal equipment should therefore in appropriate cases be designed in such a way that disabled people may use it without or with only minimal adaptation;

(16) Whereas radio equipment and telecommunications terminal equipment can provide certain functions required by emergency services;

(17) Whereas some features may have to be introduced on the radio equipment and telecommunications terminal equipment in order to prevent the infringement of personal data and privacy of the user and of the subscriber and/or the avoidance of fraud;

(18) Whereas in some cases interworking via networks with other apparatus within the meaning of this Directive and connection with interfaces of the appropriate type throughout the Community may be necessary;

(19) Whereas it should therefore be possible to identify and add specific essential requirements on user privacy, features for users with a disability, features for emergency services and/or features for avoidance of fraud;

(20) Whereas it is recognised that in a competitive market, voluntary certification and marking schemes developed by consumer organisations, manufacturers, operators and other industry actors contribute to quality and are a useful means of improving consumers' confidence in telecommunications products and services; whereas Member States may support such schemes; whereas such schemes should be compatible with the competition rules of the Treaty;

(21) Whereas unacceptable degradation of service to persons other than the user of radio equipment and telecommunications terminal equipment should be prevented; whereas manufacturers of terminals should construct equipment in a way which prevents networks from suffering harm which results in such degradation when used under normal operating conditions; whereas network operators should construct their networks in a way that does not oblige manufacturers of terminal equipment to take disproportionate measures to prevent networks from being harmed; whereas the European Telecommunications Standards Institute (ETSI) should take due account of this objective when developing standards concerning access to public networks;

(22) Whereas effective use of the radio spectrum should be ensured so as to avoid harmful interference; whereas the most efficient possible use, according to the state of the art, of limited resources such as the radio frequency spectrum should be encouraged;

(23) Whereas harmonised interfaces between terminal equipment and telecommunications networks contribute to promoting competitive markets both for terminal equipment and network services;

(24) Whereas, however, operators of public telecommunications networks should be able to define the technical characteristics of their interfaces, subject to the competition rules of the Treaty; whereas, accordingly, they should publish accurate and adequate technical specifications of such interfaces so as to enable manufacturers to design telecommunications terminal equipment which satisfies the requirements of this Directive;

[1] OJ L 139, 23.5.1989, p. 19. Directive as last amended by Directive 93/68/EEC.

(25) Whereas, nevertheless, the competition rules of the Treaty and Commission Directive 88/301/EEC of 16 May 1988 on competition in the markets in telecommunications terminal equipment [1] establish the principle of equal, transparent and non-discriminatory treatment of all technical specifications having regulatory implications; whereas therefore it is the task of the Community and the Member States, in consultation with the economic players, to ensure that the regulatory framework created by this Directive is fair;

(26) Whereas it is the task of the European standardisation organisations, notably ETSI, to ensure that harmonised standards are appropriately updated and drafted in a way which allows for unambiguous interpretation; whereas maintenance, interpretation and implementation of harmonised standards constitute very specialised areas of increasing technical complexity; whereas those tasks require the active participation of experts drawn from amongst the economic players; whereas in some circumstances it may be necessary to provide more urgent interpretation of or corrections to harmonised standards than is possible through the normal procedures of the European standardisation organisations operating in conformity with Directive 98/34/EC of 22 June 1998 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services [2];

(27) Whereas it is in the public interest to have harmonised standards at European level in connection with the design and manufacture of radio equipment and telecommunications terminal equipment; whereas compliance with such harmonised standards gives rise to a presumption of conformity to the essential requirements; whereas other means of demonstrating conformity to the essential requirements are permitted;

(28) Whereas the assignment of equipment class identifiers should draw on the expertise of CEPT/ERC and of the relevant European standards bodies in radio matters; whereas other forms of cooperation with those bodies is to be encouraged where possible;

(29) Whereas, in order to enable the Commission to monitor market control effectively, the Member States should provide the relevant information concerning types of interfaces, inadequate or incorrectly applied harmonised standards, notified bodies and surveillance authorities;

(30) Whereas notified bodies and surveillance authorities should exchange information on radio equipment and telecommunications terminal equipment with a view to efficient surveillance of the market; whereas such cooperation should make the utmost use of electronic means; whereas, in particular, such cooperation should enable national authorities to be informed about radio equipment placed on their market operating in frequency bands not harmonised in the Community;

(31) Whereas manufacturers should notify Member States of their intention to place radio equipment on the market using frequency bands whose use is not harmonised throughout the Community; whereas Member States therefore need to put in place procedures for such notification; whereas such procedures should be proportionate and should not constitute a conformity assessment procedure additional to those provided for in Annexes IV or V; whereas it is desirable that those notification procedures should be harmonised and preferably implemented by electronic means and one-stop-shopping;

(32) Whereas radio equipment and telecommunications terminal equipment which complies with the relevant essential requirements should be permitted to circulate freely; whereas such equipment should be permitted to be put into service for its intended purpose; whereas the putting into service may be subject to authorisations on the use of the radio spectrum and the provision of the service concerned;

(33) Whereas, for trade fairs, exhibitions, etc., it must be possible to exhibit radio equipment and telecommunications terminal equipment which does not conform to this Directive; whereas, however, interested parties should be properly informed that such equipment does not conform and cannot be purchased in that condition; whereas Member States may restrict the putting into service, including the switching on, of such exhibited radio equipment for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health;

(34) Whereas radio frequencies are allocated nationally and, to the extent that they have not been harmonised, remain within the exclusive competence of the Member States; whereas it is necessary to include a safeguard provision permitting Member States, in conformity with Article 36 of the Treaty, to prohibit,

[1] OJ L 131, 27.5.1988, p. 73. Directive as amended by Directive 94/46/EC (OJ L 268, 19.10.1994, p. 15).
[2] OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

restrict or require the withdrawal from its market of radio equipment which has caused, or which it reasonably considers will cause, harmful interference; whereas interference with nationally allocated radio frequencies constitutes a valid ground for Member States to take safeguard measures;

(35) Whereas manufacturers are liable for damage caused by defective apparatus according to the provisions of Council Directive 85/374/EEC [1]; whereas without prejudice to any liability on the part of the manufacturer, any person who imports apparatus into the Community for sale in the course of his business is liable according to that Directive; whereas the manufacturer, his authorised representative or the person responsible for placing the apparatus on the Community market is liable according to the rules of the law of contractual or non-contractual liability in the Member States;

(36) Whereas the measures which are appropriate to be taken by the Member States or the Commission where apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network or harmful radio interference shall be determined in accordance with the general principles of Community law, in particular, the principles of objectivity, proportionality and non-discrimination;

(37) Whereas on 22 July 1993 the Council adopted Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and the use of EC conformity marking which are intended to be used in the technical harmonisation directives [2]; whereas the applicable conformity assessment procedures should preferably be chosen from among the available modules laid down by that Decision;

(38) Whereas Member States may request that notified bodies they designate and their surveillance authorities be accredited according to appropriate European standards;

(39) Whereas it is appropriate that compliance of radio equipment and telecommunications terminal equipment with the requirements of Directives 73/23/EEC and 89/336/EEC may be demonstrated using the procedures specified in those Directives where the apparatus is within their scope; whereas, as a result, the procedure provided for in Article 10(1) of Directive 89/336/EEC may be used where the application of harmonised standards gives rise to a presumption of conformity with the protection requirements; whereas the procedure provided for in Article 10 [3] may be used where the manufacturer has not applied harmonised standards or where no such standards exist;

(40) Whereas Community undertakings should have effective and comparable access to third countries' markets and enjoy treatment in third countries similar to that offered in the Community to undertakings owned wholly, controlled through majority ownership or effectively controlled by nationals of the third countries concerned;

(41) Whereas it is desirable to establish a committee bringing together parties directly involved in the implementation of regulation of radio equipment and telecommunications terminal equipment, in particular the national conformity assessment bodies and national bodies responsible for market surveillance, in order to assist the Commission in achieving a harmonised and proportionate application of the provisions so as to meet the needs of the market and the public at large; whereas representatives of telecommunications operators, users, consumers, manufacturers and service providers should be consulted where appropriate;

(42) Whereas a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was concluded on 20 December 1994 [4];

(43) Whereas the Commission should keep under review the implementation and practical application of this and other relevant directives and take steps to ensure coordination of the application of all relevant directives in order to avoid disturbance to telecommunications equipment which affects the health of humans or is harmful to property;

(44) Whereas the functioning of this Directive should be reviewed in due course in the light of the development of the telecommunications sector and of experience gained from application of the essential requirements and the conformity assessment procedures provided for in this Directive;

(45) Whereas it is necessary to ensure that with the introduction of changes to the regulatory regime there is a smooth transition from the previous regime in order to avoid disruption to the market and legal uncertainty;

[1] OJ L 210, 7.8.1985, p. 29.
[2] OJ L 220, 30.8.1993, p. 23.
[3] OJ L 220, 30.8.1993, p. 23.
[4] OJ C 102, 4.4.1996, p. 1.

(46) Whereas this Directive replaces Directive 98/13/EC, which should accordingly be repealed; whereas Directives 73/23/EEC and 89/336/EEC will no longer apply to apparatus within the scope of this Directive, with the exception of protection and safety requirements and certain conformity assessment procedures,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL ASPECTS

Article 1

Scope and aim

1. This Directive establishes a regulatory framework for the placing on the market, free movement and putting into service in the Community of radio equipment and telecommunications terminal equipment.

2. Where apparatus as defined in Article 2(a) incorporates, as an integral part, or as an accessory:

(a) a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([1]), or

(b) an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([2]),

the apparatus shall be governed by this Directive, without prejudice to the application of Directives 93/42/EEC and 90/385/EEC to medical devices and active implantable medical devices, respectively.

3. Where apparatus constitutes a component or a separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC ([3]) relating to the radio interference (electromagnetic compatibility) of vehicles or a component or a separate technical unit of a vehicle within the meaning of Article 1 of Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles, the apparatus shall be governed by this Directive without prejudice to the application of Directive 72/245/EEC or of Directive 92/61/EEC respectively.

4. This Directive shall not apply to equipment listed in Annex I.

5. This Directive shall not apply to apparatus exclusively used for activities concerning public security, defence, State security (including the economic well-being of the State in the case of activities pertaining to State security matters) and the activities of the State in the area of criminal law.

Article 2

Definitions

For the purpose of this Directive the following definitions shall apply:

(a) 'apparatus' means any equipment that is either radio equipment or telecommunications terminal equipment or both;

(b) 'telecommunications terminal equipment' means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);

(c) 'radio equipment' means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radiocommunication;

(d) 'radio waves' means electromagnetic waves of frequencies from 9 kHz to 3 000 GHz, propagated in space without artificial guide;

(e) 'interface' means

(i) a network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network, and/or

(ii) an air interface specifying the radio path between radio equipment

and their technical specifications;

(f) 'equipment class' means a class identifying particular types of apparatus which under this Directive are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;

(g) 'technical construction file' means a file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented;

(h) 'harmonised standard' means a technical specification adopted by a recognised standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement, compliance with which is not compulsory.

([1]) OJ L 169, 12.7.1993, p. 1.
([2]) OJ L 152, 6.7.1972, p. 15. Directive as last amended by Commission Directive 95/54/EC (OJ L 266, 8.11.1995, p. 1).
([3]) OJ L 225, 10.8.1992, p. 72. Directive as amended by the 1994 Act of Accession.

(i) 'harmful interference' means interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Community or national regulations.

Article 3

Essential requirements

1. The following essential requirements are applicable to all apparatus:

(a) the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements contained in Directive 73/23/EEC, but with no voltage limit applying;

(b) the protection requirements with respect to electromagnetic compatibility contained in Directive 89/336/EEC.

2. In addition, radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.

3. In accordance with the procedure laid down in Article 15, the Commission may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that:

(a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that

(b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

(c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that

(d) it supports certain features ensuring avoidance of fraud; and/or that

(e) it supports certain features ensuring access to emergency services; and/or that

(f) it supports certain features in order to facilitate its use by users with a disability.

Article 4

Notification and publication of interface specifications

1. Member States shall notify the interfaces which they have regulated to the Commission insofar as the said interfaces have not been notified under the provisions of Directive 98/34/EC. After consulting the committee in accordance with the procedure set out in Article 15, the Commission shall establish the equivalence between notified interfaces and assign an equipment class identifier, details of which shall be published in the *Official Journal of the European Communities*.

2. Each Member State shall notify to the Commission the types of interface offered in that State by operators of public telecommunications networks. Member States shall ensure that such operators publish accurate and adequate technical specifications of such interfaces before services provided through those interfaces are made publicly available, and regularly publish any updated specifications. The specifications shall be in sufficient detail to permit the design of telecommunications terminal equipment capable of utilising all services provided through the corresponding interface. The specifications shall include, *inter alia,* all the information necessary to allow manufacturers to carry out, at their choice, the relevant tests for the essential requirements applicable to the telecommunications terminal equipment. Member States shall ensure that those specifications are made readily available by the operators.

Article 5

Harmonised standards

1. Where apparatus meets the relevant harmonised standards or parts thereof whose reference numbers have been published in the *Official Journal of the European Communities*, Member States shall presume compliance with those of the essential requirements referred to in Article 3 as are covered by the said harmonised standards or parts thereof.

2. Where a Member State or the Commission considers that conformity with a harmonised standard does not ensure compliance with the essential requirements referred to in Article 3 which the said standard is intended to cover, the Commission or the Member State concerned shall bring the matter before the committee.

3. In the case of shortcomings of harmonised standards with respect to the essential requirements, the Commission may, after consulting the committee and in accordance with the procedure laid down in Article 14, publish in the *Official Journal of the European Communities* guidelines on the interpretation of harmonised standards or the conditions under which compliance with that standard raises a presumption of conformity. After consultation of the committee and in accordance with the procedure laid down in Article 14, the Commission may withdraw harmonised standards by publication of a notice in the *Official Journal of the European Communities*.

Article 6

Placing on the market

1. Member States shall ensure that apparatus is placed on the market only if it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Directive when it is properly installed and maintained and used for its intended purpose. It shall not be subject to further national provisions in respect of placing on the market.

2. In taking a decision regarding the application of essential requirements under Article 3(3), the Commission shall determine the date of application of the requirements. If it is determined that an equipment class needs to comply with particular essential requirements under Article 3(3), any apparatus of the equipment class in question which is first placed on the market before the date of application of the Commission's determination can continue to be placed on the market for a reasonable period. Both the date of application and the period shall be determined by the Commission in accordance with the procedure laid down in Article 14.

3. Member States shall ensure that the manufacturer or the person responsible for placing the apparatus on the market provides information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the apparatus the Member States or the geographical area within a Member State where the equipment is intended to be used and shall alert the user by the marking on the apparatus referred to in Annex VII, paragraph 5, to potential restrictions or requirements for authorisation of use of the radio equipment in certain Member States. Where it concerns telecommunications terminal equipment, such information shall be sufficient to identify interfaces of the public telecommunications networks to which the equipment is intended to be connected. For all apparatus such information shall be prominently displayed.

4. In the case of radio equipment using frequency bands whose use is not harmonised throughout the Community, the manufacturer or his authorised representative established within the Community or the person responsible for placing the equipment on the market shall notify the national authority responsible in the relevant Member State for spectrum management of the intention to place such equipment on its national market.

This notification shall be given no less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment (in particular frequency bands, channel spacing, type of modulation and RF-power) and the identification number of the notified body referred to in Annex IV or V.

Article 7

Putting into service and right to connect

1. Member States shall allow the putting into service of apparatus for its intended purpose where it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Directive.

2. Not withstanding paragraph 1, and without prejudice to conditions attached to authorisations for the provision of the service concerned in conformity with Community law, Member States may restrict the putting into service of radio equipment only for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health.

3. Without prejudice to paragraph 4, Member States shall ensure that operators of public telecommunications networks do not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds where that equipment complies with the applicable requirements of Article 3.

4. Where a Member State considers that apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network or harmful radio interference or harm to the network or its functioning, the operator may be authorized to refuse connection, to disconnect such apparatus or to withdraw it from service. The Member States shall notify each such authorisation to the Commission, which shall convene a meeting of the committee for the purpose of giving its opinion on the matter. After the committee has been consulted, the Commission may initiate the procedures referred to in Article 5(2) and (3). The Commission and the Member States may also take other appropriate measures.

5. In case of emergency, an operator may disconnect apparatus if the protection of the network requires the equipment to be disconnected without delay and if the user can be offered, without delay and without costs for him, an alternative solution. The operator shall immediately inform the national authority responsible for the implementation of paragraph 4 and Article 9.

Article 8

Free movement of apparatus

1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of apparatus bearing the CE marking referred to in Annex VII, which indicates its conformity with all provisions of this Directive, including the conformity assessment procedures set out in Chapter II. This shall be without prejudice to Articles 6(4), 7(2) and 9(5).

2. At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacles to the display of apparatus which does not comply with this Directive, provided that a visible sign clearly indicates that such apparatus may not be marketed or put into service until it has been made to comply.

3. Where the apparatus is subject to other directives which concern other aspects and also provide for the affixing of the CE marking, the latter shall indicate that such apparatus also fulfils the provisions of those other directives. However, should one or more of those directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the apparatus fulfils the provisions only of those directives applied by the manufacturer. In this case, the particulars of those directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by those directives and accompanying such products.

Article 9

Safeguards

1. Where a Member State ascertains that apparatus within the scope of this Directive does not comply with the requirements of this Directive, it shall take all appropriate measures in its territory to withdraw the apparatus from the market or from service, prohibit its placing on the market or putting into service or restrict its free movement.

2. The Member State concerned shall immediately notify the Commission of any such measures indicating the reasons for its decision and whether non-compliance is due to:

(a) incorrect application of the harmonised standards referred to in Article 5(1);

(b) shortcomings in the harmonised standards referred to in Article 5(1);

(c) failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1).

3. If the measures referred to in paragraph 1 are attributed to incorrect application of the harmonised standards referred to in Article 5(1) or to a failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1), the Commission shall consult the parties concerned as soon as possible. The Commission shall forthwith inform the Member States of its findings and of its opinion as to whether the measures are justified, within two months of notification of the said measures to the Commission.

4. Where the decision referred to in paragraph 1 is attributed to shortcomings in the harmonised standards referred to in Article 5(1), the Commission shall bring the matter before the committee within two months. The committee shall deliver an opinion in accordance with the procedure laid down in Article 14. After such consultation, the Commission shall inform the Member States of its findings and of its opinion as to whether the action by the Member State is justified. If it finds that the action is justified it shall forthwith initiate the procedure referred to in Article 5(2).

5. (a) Notwithstanding the provisions of Article 6, a Member State may, acting in conformity with the Treaty, and in particular Articles 30 and 36 thereof, adopt any appropriate measures with a view to:

(i) prohibiting or restricting the placing on its market, and/or

(ii) requiring the withdrawal from its market,

of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands.

(b) Where a Member State takes measures in accordance with subparagraph (a) it shall immediately inform the Commission of the said measures, specifying the reasons for adopting them.

6. When a Member State notifies the Commission of a measure referred to in paragraph 1 or 5 the Commission shall in turn inform other Member States and consult the committee on the matter.

Where, after such consultation, the Commission considers that:

— the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States,

— the measure is unjustified, it shall immediately so inform the Member State and request it to withdraw the measure.

7. The Commission shall maintain a record of the cases notified by Member States, which shall be made available to them on request.

CHAPTER II

CONFORMITY ASSESSMENT

Article 10

Conformity assessment procedures

1. The conformity assessment procedures identified in this Article shall be used to demonstrate the compliance of the apparatus with all the relevant essential requirements identified in Article 3.

2. At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in Article 3(1)(a) and (b) may be demonstrated using the procedures specified in Directive 73/23/EEC and Directive 89/336/EEC respectively, where the apparatus is within the scope of those Directives, as an alternative to the procedures laid out below.

3. Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial/space radio communication and receiving parts of radio equipment shall be subject to the procedures described in any one of Annexes II, IV or V at the choice of the manufacturer.

4. Where a manufacturer has applied the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 shall be subject to the procedures described in any one of Annexes III, IV or V at the choice of the manufacturer.

5. Where a manufacturer has not applied or has only applied in part the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 of this Article shall be subject to the procedures described in either of Annexes IV or V at the choice of the manufacturer.

6. Records and correspondence relating to the conformity assessment procedures referred to in paragraphs 2 to 5 shall be in an official language of the Member State where the procedure will be carried out, or in a language accepted by the notified body involved.

Article 11

Notified bodies and surveillance authorities

1. Member States shall notify the Commission of the bodies which they have designated to carry out the relevant tasks referred to in Article 10. Member States shall apply the criteria laid down in Annex VI in determining the bodies to be designated.

2. Member States shall notify the Commission of the authorities established within their territory which are to carry out the surveillance tasks related to the operation of this Directive.

3. The Commission shall publish a list of the notified bodies, together with their identification numbers and the tasks for which they have been notified, in the *Official Journal of the European Communities*. The Commission shall also publish a list of surveillance authorities in the *Official Journal of the European Communities*. Member States shall provide the Commission with all information necessary to keep these lists up to date.

CHAPTER III

CE CONFORMITY MARKING AND INSCRIPTIONS

Article 12

CE marking

1. Apparatus complying with all relevant essential requirements shall bear the EC conformity marking referred to in Annex VII. It shall be affixed under the responsibility of the manufacturer, his authorized representative within the Community or the person responsible for placing the apparatus on the market.

Where the procedures identified in Annex III, IV or V are used, the marking shall be accompanied by the identification number of the notified body referred to in Article 11(1). Radio equipment shall in addition be accompanied by the equipment class identifier where such indentifier has been assigned. Any other marking may be affixed to the equipment provided that the visibility and legibility of the EC marking is not thereby reduced.

2. No apparatus, whether or not it complies with the relevant essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the EC marking specified in Annex VII.

3. The competent Member State shall take appropriate action against any person who has affixed a marking not in conformity with paragraphs 1 and 2. If the person who affixed the marking is not identifiable, appropriate action may be taken against the holder of the apparatus at the time when non-compliance was discovered.

4. Apparatus shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer or the person responsible for placing the apparatus on the market.

CHAPTER IV

THE COMMITTEE

Article 13

Constitution of the committee

The Commission shall be assisted by a committee, the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), composed of representatives of the Member States and chaired by a representative of the Commission.

Article 14

Advisory committee procedure

1. The committee shall be consulted on the matters covered by Articles 5, 6(2), 7(4), 9(4) and Annex VII(5).

2. The Commission shall consult the committee periodically on the surveillance tasks related to the application of this Directive, and, where appropriate, issue guidelines on this matter.

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 manner in which its opinion has been taken into account and decide within one month after having received the opinion of the committee.

4. The Commission shall periodically consult the representatives of the telecommunications networks providers, the consumers and the manufacturers. It shall keep the committee regularly informed of the outcome of such consultations.

Article 15

Regulatory committee procedure

1. Notwithstanding the provisions of Article 14, the following procedure shall apply in respect of the matters covered by Articles 3(3) and 4(1).

2. 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. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Article 16

Third countries

1. Member States may inform the Commission of any general difficulties encountered, *de jure* or *de facto,* by Community undertakings with respect to placing on the market in third countries, which have been brought to their attention.

2. Whenever the Commission is informed of such difficulties, it may, if necessary, submit proposals to the Council for an appropriate mandate for negotiation of comparable rights for Community undertakings in these third countries. The Council shall decide by qualified majority.

3. Measures taken pursuant to paragraph 2 shall be without prejudice to the obligations of the Community and of the Member States under relevant international agreements.

Article 17

Review and reporting

The Commission shall review the operation of this Directive and report thereon to the European Parliament and to the Council, on the first occasion not later than 7 October 2000 18 months after the entry into force of this Directive and every third year thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the committee, assess progress in achieving an open competitive market for apparatus at Community level and examine how the regulatory framework for the placing on the market and putting into service of apparatus should be developed to:

(a) ensure that a coherent system is achieved at Community level for all apparatus;

(b) allow for convergence of the telecommunications, audiovisual and information technology sectors;

(c) enable harmonisation of regulatory measures at international level.

It shall in particular examine whether essential requirements are still necessary for all categories of apparatus covered and whether the procedures contained in Annex IV, third paragraph, are proportionate to the aim of ensuring that the essential requirements are met for apparatus covered by that Annex. Where necessary, further measures may be proposed in the report for full implementation of the aim of the Directive.

Article 18

Transitional provisions

1. Standards under Directive 73/23/EEC or 89/336/EEC whose references have been published in the *Official Journal of the European Communities* may be used as the basis for a presumption of conformity with the essential requirements referred to in Article 3(1)(a) and Article 3(1)(b). Common technical regulations under Directive 98/13/EC whose references have been published in the *Official Journal of the European Communities* may be used as the basis for a presumption of conformity with the other relevant essential requirements referred to in Article 3. The Commission shall publish a list of references to those standards in the *Official Journal of the European Communities* immediately after this Directive enters into force.

2. Member States shall not impede the placing on the market and putting into service of apparatus which is in accordance with the provisions in Directive 98/13/EC or rules in force in their territory and was placed on the market for the first time before this Directive entered into force or at the latest two years after this Directive entered into force.

3. Apart from the essential requirements referred to in Article 3(1), the Member States may request to continue, for a period of up to 30 months following the date referred to in the first sentence of Article 19(1), and in conformity with the provisions of the Treaty, to require telecommunications terminal equipment not to be capable of causing unacceptable deterioration of a voice telephony service accessible within the framework of the universal service as defined in Directive 98/10/EC.

The Member State shall inform the Commission of the reasons for requesting a continuation of such a requirement, the date by which the service concerned will no longer need the requirement, and the measures envisaged in order to meet this deadline. The Commission shall consider the request taking into account the particular situation in the Member State and the need to ensure a coherent regulatory environment at Community level, and shall inform the Member State whether it deems that the particular situation in that Member State justifies a continuation and, if so, until which date such continuation is justified.

Article 19

Transposition

1. Member States shall not later than 7 April 2000 adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. They shall apply these provisions as from 8 April 2000.

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 Member States.

2. Member States shall inform the Commission of the main provisions of domestic law which they adopt in the field covered by this Directive.

Article 20

Repeal

1. Directive 98/13/EC is hereby repealed as from 8 April 2000.

2. This Directive is not a specific directive within the meaning of Article 2(2) of Directive 89/336/EEC. The provisions of Directive 89/336/EEC shall not apply to apparatus falling within the scope of this Directive, with the exception of the protection requirements in Article 4 and Annex III and the conformity assessment procedure in Article 10(1) and (2) of, and Annex I to, Directive 89/336/EEC, as from 8 April 2000.

3. The provisions of Directive 73/23/EEC shall not apply to apparatus falling within the scope of this Directive, with the exceptions of the objectives with respect to safety requirements in Article 2 and Annex I and the conformity assessment procedure in Annex III, Section B, and Annex IV to Directive 73/23/EEC, as from 8 April 2000.

Article 21

Entry into force

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

Article 22

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 9 March 1999.

For the European Parliament	*For the Council*
The President	*The President*
J. M. GIL-ROBLES	W. RIESTER

ANNEX I

EQUIPMENT NOT COVERED BY THIS DIRECTIVE AS REFERRED TO IN ARTICLE 1(4)

1. Radio equipment used by radio amateurs within Article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially.

   Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.

2. Equipment falling within the scope of Council Directive 96/98/EC of 20 December 1996 on marine equipment [1].

3. Cabling and wiring.

4. Receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services.

5. Products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation [2].

6. Air-traffic-management equipment and systems within the meaning of Article 1 of Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems [3].

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[1] OJ L 46, 17.2.1997, p. 25.
[2] OJ L 373, 31.12.1991, p. 4. Regulation as amended by Commission Regulation (EC) No 2176/96 (OJ L 291, 14.11.1996, p. 15).
[3] OJ L 187, 29.7.1993, p. 52. Directive as last amended by Commission Directive 97/15/EC (OJ L 95, 10.4.1997, p. 16).

ANNEX II

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(3)

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of this Directive that apply to them. The manufacturer or his authorised representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in point 4 and he or his authorised representative established within the Community must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.

3. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

4. The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the design, manufacture and operation of the product, in particular:

   — a general description of the product,

   — conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

   — descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,

   — a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist,

   — results of design calculations made, examinations carried out, etc.,

   — test reports.

5. The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.

6. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

ANNEX III

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(4)

(Internal production control plus specific apparatus tests) [1]

This Annex consists of Annex II, plus the following supplementary requirements:

For each type of apparatus, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of a notified body chosen by the manufacturer except where the test suites are defined in the harmonised standards. The notified body must take due account of previous decisions made by notified bodies acting together.

The manufacturer or his authorised representative established within the Community or the person responsible for placing the apparatus on the market must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the notified body's identification number during the manufacturing process.

ANNEX IV

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(5)

(Technical construction file)

This Annex consists of Annex III plus the following supplementary requirements:

The technical documentation described in point 4 of Annex II and the declaration of conformity to specific radio test suites described in Annex III must form a technical construction file.

The manufacturer, his authorised representative established within the Community or the person responsible for placing the apparatus on the market, must present the file to one or more notified bodies, each of the notified bodies must be informed of others who have received the file.

The notified body must review the file and if it is considered that it has not been properly demonstrated that the requirements of the Directive have been met, the notified body may issue an opinion to the manufacturer, his representative or the person responsible for placing the apparatus on the market and must inform the other notified bodies who have received the file accordingly. Such an opinion must be given within four weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the four-week period, the apparatus may be placed on the market, without prejudice to Articles 6(4) and 9(5).

The manufacturer or his authorised representative established within the Community or the person responsible for placing the apparatus on the market must keep the file for a period ending at least 10 years after the last apparatus has been manufactured at the disposal of the relevant national authorities of any Member States for inspection.

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[1] Annex based on Module A with additional requirements appropriate to the sector.

ANNEX V

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10

Full quality assurance

1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer must affix the marks referred to in Article 12(1) to each product and draw up a written declaration of conformity.

2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.

3. *Quality system*

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

— all relevant information for the products envisaged,

— the quality system's documentation.

3.2. The quality system must ensure compliance of the products with the requirements of the Directive that apply to them. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

— the technical specifications, including the harmonised standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in Article 5(1) will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive that apply to the products will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate,

— the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.

The notified body must assess in particular whether the quality control system ensures conformity of the products with the requirements of the Directive in the light of the relevant documentation supplied in respect of points 3.1 and 3.2 including, where relevant, test results supplied by the manufacturer.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4 and in points 4.3 and 4.4.

6. Each notified body must make available to the other notified bodies the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

ANNEX VI

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN DESIGNATING NOTIFIED BODIES IN ACCORDANCE WITH ARTICLE 11(1)

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorised representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunications terminal equipment, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its staff must carry out the tasks for which the notified body has been designated with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of any inspection, especially from persons or groups of persons with an interest in such results.

3. The notified body must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.

4. The staff responsible for inspections must have:

   — sound technical and professional training,

   — satisfactory knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections,

   — the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.

5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.

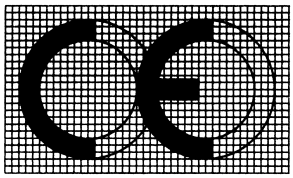
6. The notified body must take out liability insurance unless its liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible.

7. The staff of the notified body is bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except *vis-à-vis* the competent administrative authorities of the Member State in which its activities are carried out) under this Directive or any provision of national law giving effect thereto.

ANNEX VII

MARKING OF EQUIPMENT REFERRED TO IN ARTICLE 12(1)

1. The CE conformity marking must consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.

3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.

4. The CE marking must be affixed visibly, legibly and indelibly.

5. The equipment class identifier must take a form to be decided by the Commission in accordance with the procedure laid down in Article 14.

Where appropriate it must include an element intended to provide information to the user that the apparatus makes use of radio frequency bands where their use is not harmonised throughout the Community.

It must have the same height as the initials 'CE'.

Joint Declaration of the European Parliament, the Council and the Commission

The European Parliament, the Council and the Commission recognise the importance of the requirement relating to the prevention of harm to the network or its functioning which causes an unacceptable degradation of service taking into account in particular the need to safeguard the interests of the consumer.

Therefore, they note that the Commission will carry out a continuous assessment of the situation in order to evaluate whether that risk occurs frequently and, in such a case, to find an appropriate solution in the framework of the Committee acting in accordance with the procedure laid down in Article 15.

Such a solution will, where appropriate, consist of the systematic application of the essential requirement provided for in Article 3(3)(b).

Furthermore, the European Parliament, the Council and the Commission state that the procedure described above applies without prejudice to the possibilities foreseen in Article 7(5) and to the development of voluntary certification and marking schemes to prevent either the degradation of service or any harm to the network.

COMMISSION DIRECTIVE 1999/21/EC

of 25 March 1999

on dietary foods for special medical purposes

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses [1], as amended by Directive 96/84/EC of the European Parliament and of the Council [2], and in particular Article 4(1) thereof,

After consulting the Scientific Committee for food,

(1) Whereas dietary foods for special medical purposes are intended to meet the particular nutritional requirements of persons affected by or malnourished because of a specific disease, disorder or medical condition; whereas for this reason they must be used under medical supervision which may be applied with the assistance of other competent health professionals;

(2) Whereas such foods are numerous and their composition may differ substantially depending on the specific disease, disorder or medical condition of the patients for whom they are intended, the age of the patients and the place in which they receive health care support, on whether the foods are intended to be used as the sole source of nourishment or not, and possibly on other factors;

(3) Whereas, because of the wide diversity of such foods and the rapidly evolving scientific knowledge on which they are based, it is not appropriate to lay down detailed compositional rules;

(4) Whereas, however, some basic rules concerning vitamin and mineral substances content can be laid down for products considered to be nutritionally complete for covering the particular nutritional requirements of the intended user; whereas such rules for nutritionally incomplete foods can be laid down only for the maximum levels of these substances as appropriate;

(5) Whereas this Directive reflects current knowledge about those products; whereas any modification to allow for innovation based on scientific and technical progress will be decided in accordance with the procedure laid down in Article 13 of Directive 89/398/EEC;

(6) Whereas pursuant to Article 4(2) of Directive 89/398/EEC, the provisions relating to the substances with specific nutritional purposes to be used in the manufacture of foods for special medical purposes should be laid down in a separate Commission directive;

(7) Whereas pursuant to Article 7 of Directive 89/398/EEC, the products covered by that Directive are subject to the general rules laid down by Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [3], as last amended by Commission Directive 1999/10/EC [4]; whereas the present Directive adopts and expands upon the additions and exceptions to those general rules, where appropriate;

(8) Whereas, in particular, in view of the nature and destination of dietary foods for special medical purposes, it is necessary to provide information concerning the energy value and principal nutrients contained in such foods;

(9) Whereas, given the particular nature of dietary foods for special medical purposes, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products;

(10) Whereas, in accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of approximating the laws of the Member States relating to foodstuffs intended for particular nutritional uses to lay down rules on foods for special medical purposes; whereas this Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 3b of the Treaty;

(11) Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on foodstuffs,

[1] OJ L 186, 30.6.1989, p. 27.
[2] OJ L 48, 19.2.1997, p. 20.
[3] OJ L 33, 8.2.1979, p. 1.
[4] OJ L 69, 16.3.1999, p. 22.

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 4(1) of Directive 89/398/EEC and lays down compositional and labelling requirements for dietary foods for special medical purposes as defined in paragraph 2 and presented as such.

2. For the purposes of this Directive:

(a) 'infants' means children under the age of 12 months;

(b) 'dietary foods for special medical purposes' means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

3. Dietary foods for special medical purposes are classified in the following three categories:

(a) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(b) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(c) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.

The foods referred to in points (b) and (c) may also be used as a partial replacement or as a supplement to the patient's diet.

Article 2

Member States shall ensure that dietary foods for special medical purposes may be marketed within the Community only if they comply with the rules laid down in this Directive.

Article 3

The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.

They must comply with the compositional criteria specified in the Annex.

Article 4

1. The name under which dietary foods for special medical purposes are sold shall be respectively:

— in Spanish:
'Alimento dietético para usos médicos especiales'
— in Danish:
'Levnedsmiddel/Levnedsmidler til særlige medicinske formål'
— in German:
'Diätetisches/Diätetische Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diäten)'
— in Greek:
'Διαιτητικά τρόφιμα για ειδικούς ιατρικούς σκοπούς'
— in English:
'Food(s) for special medical purposes'
— in French:
'Aliment(s) diététique(s) destiné(s) a des fins médicales spéciales'
— in Italian:
'Alimento dietetico destinato a fini medici speciali'
— in Dutch:
'Dieetvoeding voor medisch gebruik'
— in Portuguese:
'Produto dietético de use clínico'
— in Finnish:
'Kliininen ravintovalmiste/kliinisiä ravintovalmisteita'
— in Swedish:
'Livsmedel för speciella medicinska ändamål'.

2. The labelling shall bear, in addition to the particulars provided for in Article 3 of Directive 79/112/EEC, the following mandatory particulars:

(a) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(b) the average quantity of each mineral substance and each vitamin mentioned in the Annex present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(c) selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components the declaration of which would be necessary for the appropriate intended use of the product, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(d) information on the osmolality or the osmolarity of the product where appropriate;

(e) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

3. The labelling shall in addition bear the following mandatory particulars, preceded by the words 'important notice' or their equivalent:

(a) a statement that the product must be used under medical supervision;

(b) a statement whether the product is suitable for use as the sole source of nourishment;

(c) a statement that the product is intended for a specific age group, as appropriate;

(d) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

4. The labelling shall also include:

(a) the statement 'For the dietary management of.....' where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;

(b) where appropriate a statement concerning adequate precautions and contra-indications;

(c) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;

(d) where appropriate a warning that the product is not for parenteral use.

5. The labelling shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

Article 5

1. To facilitate efficient official monitoring of dietary foods for special medical purposes, when a product is placed on the market, the manufacturer, or where a product is manufactured in a third country, the importer, shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product. Member States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation.

2. The competent authorities within the meaning of this Article are those referred to in Article 9(4) of Directive 89/398/EEC.

Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2000 at the latest. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

— permit trade in products complying with this Directive with effect from 1 May 2000,

— prohibit trade in products which do not comply with this Directive with effect from 1 November 2001.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

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.

Done at Brussels, 25 March 1999.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

ESSENTIAL COMPOSITION OF FOODS FOR SPECIAL MEDICAL PURPOSES

The specifications refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Products referred to in Article 1(3)(a) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1.

2. Products referred to in Article 1(3)(b) intended specifically for infants will contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in products referred to in Article 1(3)(c) intended specifically for infants shall not exceed those specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

4. Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the provisions relating to other nutrients applicable to infant formulae and follow-on formulae, as the case may be, laid down in Directive 91/321/EEC and its subsequent modifications.

5. Products referred to in Article 1(3)(a), other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2.

6. Products referred to in Article 1(3)(b) other than those specifically intended for infants will contain the vitamins and mineral substances as specified in Table 2 without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

7. Maximum levels of vitamins and mineral substances present in products referred to in Article 1(3)(c) other than those intended specifically for infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

TABLE 1

Values for vitamins, mineral and trace elements in nutritionally complete foods intended for use by infants

Vitamins:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (μg ER)	14	43	60	180
Vitamin D (μg)	0,25	0,75	1	3
Vitamin K (μg)	1	5	4	20
Vitamin C (mg)	1,9	6	8	25
Thiamin (mg)	0,01	0,075	0,04	0,3
Riboflavin (mg)	0,014	0,1	0,06	0,45
Vitamin B6 (mg)	0,009	0,075	0,035	0,3

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Niacin (mg NE)	0,2	0,75	0,8	3
Folic acid (μg)	1	6	4	25
Vitamin B_{12} (μg)	0,025	0,12	0,1	0,5
Pantothenic acid (mg)	0,07	0,5	0,3	2
Biotin (μg)	0,4	5	1,5	20
Vitamin E (mg α-TE)	0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	0,75	0,5/g polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	3

Minerals:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Chloride (mg)	12	29	50	125
Potassium (mg)	15	35	60	145
Calcium (mg)	12	60	50	250
Phosphorus (mg) [1]	6	22	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,12	0,5	0,5	2
Zinc (mg)	0,12	0,6	0,5	2,4
Copper Cuivre (μg)	4,8	29	20	120
Iodine (μg)	1,2	8,4	5	35
Selenium (μg)	0,25	0,7	1	3
Manganese (mg)	0,012	0,05	0,05	0,2
Chromium (μg)	—	2,5	—	10
Molybdenum (μg)	—	2,5	—	10
Fluoride (mg)	—	0,05	—	0,2

[1] The calcium/phosphorus ratio shall not be less than 1,2 nor greater than 2,0.

TABLE 2

Values for vitamins, minerals and trace elements in nutritionally complete foods other than those intended for use by infants

Vitamins:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)	8,4	43	35	180
Vitamin D (µg)	0,12	0,65/0,75 (1)	0,5	2,5/3 (1)
Vitamin K (µg)	0,85	5	3,5	20
Vitamin C (mg)	0,54	5,25	2,25	22
Thiamin (mg)	0,015	0,12	0,06	0,5
Riboflavin (mg)	0,02	0,12	0,08	0,5
Vitamin B6 (mg)	0,02	0,12	0,08	0,5
Niacin (mg EN)	0,22	0,75	0,9	3
Folic acid (µg)	2,5	12,5	10	50
Vitamin B_{12} (µg)	0,017	0,17	0,07	0,7
Pantothenic acid (mg)	0,035	0,35	0,15	1,5
Biotin (µg)	0,18	1,8	0,75	7,5
Vitamin E (mg α-TE)	0,5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	0,75	0,5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	3

(1) For products intended for children of 1 to 10 years of age.

Minerals:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	7,2	42	30	175
Chloride (mg)	7,2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8,4/12 (1)	42/60 (1)	35/50 (1)	175/250 (1)
Phosphorus (mg)	7,2	19	30	80
Magnesium (mg)	1,8	6	7,5	25
Iron (mg)	0,12	0,5	0,5	2,0
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	15	125	60	500
Iodine (µg)	1,55	8,4	6,5	35

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Selenium (μg)	0,6	2,5	2,5	10
Manganese (mg)	0,012	0,12	0,05	0,5
Chromium (μg)	0,3	3,6	1,25	15
Molybdenum (μg)	0,72	4,3	3,5	18
Fluoride (mg)	—	0,05	—	0,2

(1) For products intended for children of 1 to 10 years of age.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 26 March 1999

amending Decision 97/296/EC drawing up the list of third countries from which the import of fishery products is authorised for human consumption

(notified under document number C(1999)768)

(Text with EEA relevance)

(1999/244/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs [1], as last amended by Decision 98/603/EC [2], and in particular Article 2(2) and Article 7 thereof,

(1) Whereas Commission Decision 97/296/EC [3], as last amended by Decision 1999/136/EC [4], lists the countries and territories from which importation of fishery products for human consumption is authorised. Part I of the Annex I lists the names of the countries and territories covered by a specific Decision and Part II names those qualifying under Article 2(2) of Decision 95/408/EC. Annex II lists the names of the countries and territories from which importation were authorised until the 31 January 1999, on the conditions of Article 11(7) of Directive 91/493/EEC;

(2) Whereas Commission Decision 1999/245/EC [5], set specific import conditions for fishery and aquaculture products originating in the Seychelles. Whereas the Seychelles should therefore be added to Part I of the list of Annex I of countries and territories from which importation of fishery products for human consumption is authorised;

(3) Whereas French Polynesia, Gabon and Saint Pierre et Miquelon, have provided information that they satisfy the equivalent conditions and are able to guarantee that the fishery products they export to the Community meet the health requirements of the Directive 91/493/EEC, it is therefore necessary to modify the above list to include those countries and territories in the Part II of the list;

(4) Whereas the seriousness of the deficiencies observed during an inspection visit to Kazakhstan the imports of caviar would not be authorised and, therefore, this country shall be deleted from the Part II of the list;

(5) Whereas the imports from third countries listed in the Annex II are no longer authorised, since 1 February 1999;

(6) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

[1] OJ L 243, 11.10.1995, p. 17.
[2] OJ L 289, 28.10.1998, p. 36.
[3] OJ L 122, 14.5.1997, p. 21.
[4] OJ L 44, 18.2.1999, p. 61.

[5] See page 40 of this Official Journal.

HAS ADOPTED THIS DECISION:

Article 1

The Annex of the present Decision replaces the Annex I and the Annex II to Decision 97/296/EC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 26 March 1999.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

List of countries and territories from which importation of fishery products in any form intended for human consumption is authorised

I. *Countries and territories covered by a specific decision under Council Directive 91/493/EC*

AL — Albania
AR — Argentina
AU — Australia
BD — Bangladesh
BR — Brazil
CA — Canada
CI — Côte d'Ivoire
CL — Chile
CO — Colombia
CU — Cuba
EC — Ecuador
EE — Estonia
FK — Falkland Islands
FO — Faroes
GH — Ghana
GM — Gambia
GT — Guatemala
ID — Indonesia
IN — India
JP — Japan
KR — South Korea
MA — Morocco
MG — Madagascar
MR — Mauritania
MV — Maldives
MX — Mexico
MY — Malaysia
NG — Nigeria
NZ — New Zealand
PE — Peru
PH — Philippines
RU — Russia
SC — Seychelles
SG — Singapore
SN — Senegal
TH — Thailand
TN — Tunisia
TW — Taiwan
TZ — Tanzania
UY — Uruguay
ZA — South Africa

II. *Countries and territories meeting the terms of Article 2(2) of Council Decision 95/408/EC*

AG — Antigua and Barbuda [1]
AN — Netherlands Antilles
AO — Angola
AZ — Azerbaijan [2]
BJ — Benin
BS — Bahamas
BZ — Belize
CH — Switzerland
CM — Cameroun
CN — China
CR — Costa Rica
CV — Cape Verde
CY — Cyprus
CZ — Czech Republic
DZ — Algeria
ER — Eritrea
FJ — Fiji
GA — Gabon
GL — Greenland
GN — Guinea Conakri
HK — Hong Kong
HN — Honduras
HR — Croatia
HU — Hungary [3]
IL — Israel
IR — Iran
JM — Jamaica
KE — Kenya
LK — Sri Lanka
LT — Lithuania
LV — Latvia
MM — Myanmar
MT — Malta
MU — Mauritius
MZ — Mozambique
NA — Namibia
NI — Nicaragua
PA — Panama
PF — French Polynesia
PG — Papua New Guinea
PK — Pakistan
PL — Poland
PM — St Pierre and Miquelon
RO — Romania
SB — Solomon Island
SH — St Helena
SI — Slovenia
SR — Suriname
TG — Togo
TR — Turkey
UG — Uganda
US — United States of America
VC — St Vincent and Grenadines [1]
VE — Venezuela
VN — Vietnam
ZW — Zimbabwe

[1] Authorised only for imports of fresh fish.
[2] Authorised only for imports of caviar.
[3] Authorised only for import of live animals intended for human consumption.

COMMISSION DECISION

of 26 March 1999

laying down special conditions governing imports of fishery and aquaculture products originating in the Seychelles

(notified under document number C(1999)770)

(Text with EEA relevance)

(1999/245/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], as last amended by Directive 97/79/EC [2], and in particular Article 11 thereof,

(1) Whereas a Commission expert has conducted an inspection visit to the Seychelles to verify the conditions under which fishery products are produced, stored and dispatched to the Community;

(2) Whereas the provisions of legislation of the Seychelles on health inspection and monitoring of fishery products may be considered equivalent to those laid down in Directive 91/493/EEC;

(3) Whereas, in the Seychelles the 'Fish Inspection Unit (FIU) of the Veterinary Services under the Ministry of Agriculture and Marine Resources' is capable of effectively verifying the application of the laws in force;

(4) Whereas the procedure for obtaining the health certificate referred to in Article 11(4)(a) of Directive 91/493/EEC must also cover the definition of a model certificate, the minimum requirements regarding the languages in which it must be drafted and the grade of the person empowered to sign it;

(5) Whereas, pursuant to Article 11(4)(b) of Directive 91/493/EEC, a mark should be affixed to packages of fishery products giving the name of the third country and the approval/registration number of the establishment, factory vessel, cold store or freezer vessel of origin;

(6) Whereas, pursuant to Article 11(4)(c) of Directive 91/493/EEC, a list of approved/registration establishments, factory vessels, or cold stores must be drawn up; whereas a list of freezer vessels registered in the sense of Council Directive 92/48/EEC [3] must be drawn up; whereas these lists must be drawn up on the basis of a communication from the FIU to the Commission; whereas it is therefore for the FIU to ensure compliance with the provisions laid down to that end in Article 11(4) of Directive 91/493/EEC;

(7) Whereas the FIU has provided official assurances regarding compliance with the rules set out in Chapter V of the Annex to Directive 91/493/EEC, and regarding the fulfilment of requirements equivalent to those laid down by that Directive for the approval or registration of establishments, factory vessels, cold stores or freezer vessels of origin;

(8) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The 'Fish Inspection Unit (FIU) of the Veterinary Services under the Ministry of Agriculture and Marine Resources' shall be the competent authority in the Seychelles for verifying and certifying compliance of fishery and aquaculture products with the requirements of Directive 91/493/EEC.

Article 2

Fishery and aquaculture products originating in the Seychelles must meet the following conditions:

1. each consignment must be accompanied by a numbered original health certificate, duly completed, signed, dated and comprising a single sheet in accordance with the model in Annex A hereto;

2. the products must come from approved establishments, factory vessels, cold stores or registered freezer vessels listed in Annex B hereto;

[1] OJ L 268, 24.9.1991, p. 15.
[2] OJ L 24, 30.1.1998, p. 31.
[3] OJ L 187, 7.7.1992, p. 41.

3. except in the case of frozen fishery products in bulk and intended for the manufacture of preserved foods, all packages must bear the word 'SEYCHELLES' and the approval/registration number of the establishment, factory vessel, cold store or freezer vessel of origin in indelible letters.

Article 3

1. Certificates as referred to in Article 2(1) must be drawn up in at least one official language of the Member State where the checks are carried out.

2. Certificates must bear the name, capacity and signature of the representative of the FIU and the latter's official stamp in a colour different from that of other endorsements.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 26 March 1999.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX A

HEALTH CERTIFICATE

for fishery and aquaculture products originating in the Seychelles and intended for export to the European Community, excluding bivalve molluscs, echinoderms, tunicates and marine gastropods in whatever form

Reference No: .....

Country of dispatch: SEYCHELLES

Competent authority: 'Fish Inspection Unit (FIU) of the Veterinary Services under the Ministry of Agriculture and Marine Resources'

I. **Details identifying the fishery products**

— Description of fishery/aquaculture products ([1]): .....

— species (scientific name): .....

— presentation of product and type of treatment ([2]): .....

— Code number (where available): .....

— Type of packaging: .....

— Number of packages: .....

— Net weight: .....

— Requisite storage and transport temperature: .....

II. **Origin of products**

Name(s) and official approval number(s) of establishment(s), factory vessel(s), or cold store(s) approved or freezer vessel(s) registered by the FIU for export to the European Community: .....
.....
.....

III. **Destination of products**

The products are dispatched .....

from: .....
(place of dispatch)

to: .....
(country and place of destination)

by the following means of transport: .....

Name and address of dispatcher: .....
.....
.....

Name of consignee and address at place of destination: .....
.....
.....

IV. **Health attestation**

— The official inspector hereby certifies that the fishery or aquaculture products specified above:

(1) were caught and handled on board vessels in accordance with the health rules laid down by Directive 92/48/EEC;

([1]) Delete where applicable.
([2]) Live, refrigerated, frozen, salted, smoked, preserved, etc.

(2) were landed, handled and where appropriate packaged, prepared, processed, frozen, thawed and stored hygienically in compliance with the requirements laid down in Chapters II, III and IV of the Annex to Directive 91/493/EEC;

(3) have undergone health controls in accordance with Chapter V of the Annex to Directive 91/493/EEC;

(4) are packaged, marked, stored and transported in accordance with Chapters VI, VII and VIII of the Annex to Directive 91/493/EEC;

(5) do not come from toxic species or species containing biotoxins;

(6) have satisfactorily undergone the organoleptic, parasitological, chemical and microbiological checks laid down for certain categories of fishery products by Directive 91/493/EEC and in the implementing decisions thereto.

— The undersigned official inspector hereby declares that he is aware of the provisions of Directive 91/493/EEC, Directive 92/48/EEC and Decision 1999/245/EC.

Done at ..... , on .....
(Place) (Date)

Official stamp ([3])

.....
Signature of official inspector ([3])

.....
(name in capital letters, capacity and qualifications of person signing)

([3]) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

ANNEX B

I. **LIST OF APPROVED ESTABLISHMENTS**

Number	Name	Address
P.P.01	SMB Trading Prawn Project	Victoria-Mahe
F.C.01	Indian Ocean Tuna Ltd	Victoria-Mahe
F.F.07	Oceana Fisheries Co. Ltd	Victoria-Mahe
F.F.10	Sea Harvest (Pty) Ltd	Victoria-Mahe

II. **LIST OF FACTORY VESSELS**

Number	Name	Port
F.V.01	Via Gwalarn (Saupiquet, Concarneau)	Mahe