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(Information)

COUNCIL

COMMON POSITION (EC) No 1/2005

adopted by the Council on 19 July 2004

with a view to the adoption of Regulation (EC) No.../2005 of the European Parliament and of the Council of... on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

(Text with EEA relevance)

(2005/C 25E/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables ([3]), Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ([4]), Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ([5]), and Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on products of plant origin, including fruit and vegetables ([6]), have been substantially amended several times. In the interests of clarity and simplicity, those Directives should be repealed and replaced by a single act.

(2) Differences in national maximum residue levels for pesticides can pose barriers to trade in products included in Annex I to the Treaty and products derived therefrom between Member States and trade between third countries and the Community. Accordingly, in the interest of free movement of goods and equal competition conditions among the Member States, as well as consumer protection, it is appropriate that maximum residue levels (MRLs) for products of plant and animal origin be set at Community level.

(3) A Regulation establishing MRLs does not require transposition into national law in the Member States. It is therefore the most appropriate legal instrument with which to set MRLs for pesticides in products of plant and animal origin, as its precise requirements are to be applied at the same time and in the same manner throughout the Community and accordingly permit a more efficient use of national resources.

([1]) OJ C 234, 30.9.2003, p. 33.

([2]) Opinion of the European Parliament of 20 April 2004 (OJ C 104 E, 30.4.2004), Council Common Position of 19 July 2004 and position of the European Parliament of ……. (not yet published in the Official Journal).

([3]) OJ L 340, 9.12.1976, p. 26. Directive as last amended by Regulation (EC) No 807/2003, (OJ L 122, 16.5.2003, p. 36).

([4]) OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2004/61/EC, (OJ L 127, 29.4.2004, p. 81).

([5]) OJ L 221, 7.8.1986, p. 43. Directive as last amended by Directive 2004/61/EC.

([6]) OJ L 350, 14.12.1990, p. 71. Directive as last amended by Directive 2004/61/EC.

(4) The production and consumption of plant and animal products play a very important role in the Community. The yield from plant production is continually being affected by harmful organisms. It is essential to protect plants and plant products against such organisms, not only to prevent a reduction in yield or damage to them but also in order to ensure the quality of the products harvested, to increase agricultural productivity, and to protect the natural environment by limiting the surface area needed for agricultural production.

(5) One of the most important methods of protecting plants and plant products from the effects of harmful organisms is the use of active substances in plant protection products. However, a possible consequence of their use may be the presence of residues in the treated products, in animals feeding on those products and in honey produced by bees exposed to those substances. It is necessary to ensure that such residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals.

(6) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]) provides that Member States, when issuing authorisations, are to prescribe that plant protection products be used properly. Proper use includes the application of the principles of good plant protection practice as well as the principles of integrated control. Where the MRLs arising from an authorised use of a pesticide under Directive 91/414/EEC present a risk to the consumer such use should be revised to decrease the levels of pesticide residues. The Community should encourage the use of methods or products favouring a reduction in risk, and a reduction in the amounts of pesticides used to levels consistent with efficient pest control.

(7) A number of active substances are banned under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances ([2]). At the same time, many other active substances are not currently authorised under Directive 91/414/EEC. The residues of active substances in products of plant and animal origin arising from unauthorised use or from environmental contamination or from use in third countries should be carefully controlled and monitored.

(8) The basic rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([3]).

(9) In addition to those basic rules, more specific rules are needed to ensure the effective functioning of the internal market and trade with third countries in relation to fresh, processed and/or composite plant and animal products intended for human consumption or animal feed in which pesticide residues may be present, whilst providing the basis for securing a high level of protection for human and animal health and the interests of consumers. Such rules should include the establishment of specific MRLs for each pesticide in food and feed products and the quality of the data underlying these MRLs.

(10) Notwithstanding the fact that the principles of the general food law laid down in Regulation (EC) No 178/2002 apply only to feed for food-producing animals, in view of the difficulty of segregating products to be used as feed intended for animals which are not destined for food production and in order to facilitate the control and the enforcement of the provisions of this Regulation, it is appropriate to apply them also to feed which is not intended for food-producing animals. However, this Regulation should not be an obstacle to the tests which are necessary in order to assess pesticides.

(11) Directive 91/414/EEC lays down basic rules with respect to the use and placing on the market of plant protection products. In particular the use of those products should have no harmful effects on humans or on animals. Pesticide residues resulting from uses of plant protection products may have harmful effects on the health of consumers. It is therefore appropriate that rules for MRLs for products intended for human consumption be defined that are linked to the authorisation for use of plant protection products as defined under Directive 91/414/EEC. Similarly that Directive needs to be adapted in order to take into account the Community procedure for the establishment of MRLs under this Regulation. Pursuant to that Directive, a Member State may be designated as rapporteur for the evaluation of an active substance. It is appropriate to use the expertise in that Member State for the purposes of this Regulation.

(12) It is appropriate that specific rules concerning the control of pesticide residues be introduced to complement the general Community provisions on the control of food and feed.

([1]) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/71/EC (OJ L 127, 29.4.2004, p. 14).

([2]) OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 807/2003.

([3]) OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(13) Specific rules for animal feed including marketing, storage of feed and feeding of animals are provided for in Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed ([1]). For certain products it is not possible to determine whether they will be transformed into food or animal feed. Therefore the pesticide residues in such products should be safe both for human and, where relevant, for animal consumption. Accordingly it is appropriate that the rules set out in this Regulation also apply to those products in addition to the specific rules for animal nutrition.

(14) It is necessary to define at Community level certain terms used for the setting and control of MRLs for products of plant and animal origin.

(15) Directive 76/895/EEC provides that Member States may authorise higher levels of MRLs than are currently authorised at Community level. That possibility should cease to exist as, in view of the internal market, it could create obstacles to intra-Community trade.

(16) The determination of MRLs for pesticides requires lengthy technical consideration and includes an assessment of potential risks to consumers. Therefore, MRLs cannot be set immediately for the residues of pesticides currently regulated by Directive 76/895/EEC or for pesticides for which Community MRLs have not yet been set.

(17) It is appropriate that the minimum data requirements to be used when considering the setting of MRLs for pesticides be laid down at Community level.

(18) In exceptional circumstances, and in particular for unauthorised pesticides that may be present in the environment, it is appropriate to permit the use of monitoring data in setting MRLs.

(19) MRLs for pesticides should be continually monitored and should be changed to take account of new information and data. MRLs should be set at the lower level of analytical determination where authorised uses of plant protection products do not result in detectable levels of pesticide residues. Where uses of pesticides are not authorised at Community level, MRLs should be set at an appropriately low level to protect the consumer from the intake of unauthorised or excessive levels of pesticides residues. In order to facilitate control of residues of pesticides, a default value is to be set for pesticide residues present in products or groups of products covered by Annex I for which no MRLs have been established in Annexes II or III, unless the active substance in question is listed in Annex IV. It is appropriate to set the default value at 0,01 mg/kg and to provide for the possibility of setting it at a different level for active substances covered by Annex V, taking into account the routine analytical methods available and/or consumer protection.

(20) For food and feed produced outside the Community, different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Community. It is therefore appropriate that MRLs be fixed for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce.

(21) Regulation (EC) No 178/2002 establishes procedures for taking emergency measures in relation to food and feed of Community origin or imported from a third country. Those procedures allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned. It is appropriate that these measures and their effect on humans and, where relevant, animals be assessed by the European Food Safety Authority ('the Authority').

(22) The lifetime exposure, and where appropriate the acute exposure of consumers to pesticide residues via food products, should be evaluated in accordance with Community procedures and practices, taking account of guidelines published by the World Health Organisation.

(23) Through the World Trade Organisation, the Community's trading partners should be consulted about the MRLs proposed, and their observations should be taken into account before the MRLs are adopted. MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set.

(24) It is necessary that the Authority assess MRL applications and evaluation reports prepared by the Member States with a view to determining the associated risks to consumers and, where relevant, to animals.

(25) Member States should lay down rules on sanctions applicable to infringements of this Regulation and ensure that they are implemented. Those sanctions are to be effective, proportionate and dissuasive.

([1]) OJ L 140, 30.5.2002, p. 10. Directive as last amended by Commission Directive 2003/100/EC (OJ L 285, 1.11.2003, p. 33).

(26) The development of a Community-harmonised system for MRLs entails the development of guidelines, databases and other activities with associated costs. It is appropriate for the Community in certain cases to make a contribution to those costs.

(27) It is good administrative practice and technically desirable to coordinate the timing of decisions on MRLs for active substances with decisions taken for those substances under Directive 91/414/EEC. For many substances for which Community MRLs have not yet been set, decisions are not due to be taken under that Directive before the date of entry into force of this Regulation.

(28) It is therefore necessary to adopt separate rules providing for temporary but mandatory harmonised MRLs, with a view to setting MRLs progressively as decisions are taken on individual active substances as part of the evaluations under Directive 91/414/EEC. Such temporary harmonised MRLs should be based, in particular, on existing national MRLs established by the Member States and should respect the national arrangements by which they were established, provided that the MRLs do not present an unacceptable risk to consumers.

(29) Following the inclusion of existing active substances in Annex I to Directive 91/414/EEC, Member States are to re-evaluate each plant protection product containing those active substances within four years of the date of inclusion. The MRLs concerned should be retained for a period of up to four years to provide for continuity of authorisations and, on completion of re-evaluation, should be made definitive if they are supported by dossiers which satisfy Annex III to Directive 91/414/EEC, or be set to a default level if they are not so supported.

(30) This Regulation establishes MRLs for the control of pesticide residues in food and feed. It is therefore appropriate that Member States establish national programmes to control these residues. The results of the national control programmes are to be submitted to the Commission, the Authority and the other Member States and included in the Community annual report.

(31) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(32) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objectives of facilitating trade whilst protecting the consumer to lay down rules on MRLs for products of plant and animal origin. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin.

Article 2

Scope

1. This Regulation shall apply to products of plant and animal origin or parts thereof covered by Annex I to be used as fresh, processed and/or composite food or feed in or on which pesticide residues may be present.

2. This Regulation shall not apply to the products covered by Annex I where it may be established by appropriate evidence that they are intended for:

(a) the manufacture of products other than food or feed; or

(b) sowing or planting; or

(c) activities authorised by national law for the testing of active substances.

3. Maximum residue levels for pesticides set in accordance with this Regulation shall not apply to products covered by Annex I intended for export to third countries and treated before export, where it has been established by appropriate evidence that the third country of destination requires or agrees with that particular treatment in order to prevent the introduction of harmful organisms into its territory.

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

4. This Regulation shall apply without prejudice to Directives 98/8/EC [1] and 2002/32/EC and Regulation (EEC) No 2377/90 [2].

Article 3

Definitions

1. For the purpose of this Regulation, the definitions in Regulation (EC) No 178/2002 and in Article 2(1) and (4) of Directive 91/414/EEC shall apply.

2. The following definitions shall also apply:

(a) 'good agricultural practice' (GAP): means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed;

(b) 'critical GAP': means the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL;

(c) 'pesticide residues': means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2(1) of Directive 91/414/EEC, which are present in or on the products covered by Annex I to this Regulation, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide;

(d) 'maximum residue level' (MRL): means the upper legal level of concentration for a pesticide residue in or on food or feed;

(e) 'CXL': means an MRL set by the Codex Alimentarius Commission;

(f) 'limit of determination' (LOD): means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;

(g) 'import tolerance': means an MRL set for imported products where:

— the use of the active substance in a plant protection product on a given product is not authorised in the Community; or

— an existing Community MRL is not sufficient to meet the needs of international trade;

(h) 'proficiency test': means a comparative test in which several laboratories perform analyses on identical samples, allowing an evaluation of the quality of the analysis performed by each laboratory;

(i) 'acute reference dose': means the estimate of the amount of substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation;

(j) 'acceptable daily intake': means the estimate of the amount of substance in food expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation.

Article 4

List of groups of products for which harmonised MRLs shall apply

1. The products, product groups and/or parts of products referred to in Article 2(1) to which harmonised MRLs shall apply shall be defined in and covered by Annex I in accordance with the procedure referred to in Article 45(2). Annex I shall include all products for which MRLs are set, as well as the other products for which it is appropriate to apply harmonised MRLs in particular in view of their relevance in the diet of consumers or in trade. Products shall be grouped in such a way that MRLs may as far as possible be set for a group of similar or related products.

2. Annex I shall be first established within three months from the entry into force of this Regulation and shall be revised when appropriate, in particular at the request of a Member State.

Article 5

Establishment of a list of active substances for which no MRLs are required

1. Active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required shall be defined in accordance with the procedure referred to in Article 45(2) of this Regulation and listed in Annex IV hereto, taking into account the uses of those active substances and the matters referred to in Article 14(2), (a), (c) and (d) of this Regulation.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1). Directive as last amended by Regulation (EC) No 1882/2003, (OJ L 284, 31.10.2003, p. 1).

[2] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 546/2004 (OJ L 87, 25.3.2004, p. 13).

2. Annex IV shall be first established within 12 months from the entry into force of this Regulation.

CHAPTER II

PROCEDURE FOR APPLICATIONS FOR MRLS

SECTION 1

SUBMISSION OF APPLICATIONS FOR MRLS

Article 6

Applications

1. Where a Member State envisages granting an authorisation or a provisional authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, that Member State shall consider whether, as a result of such use, an existing MRL set out in Annex II or III to this Regulation needs to be modified, whether it is necessary to set a new MRL, or whether the active substance should be included in Annex IV. If necessary it shall require the party requesting the authorisation to submit an application in accordance with Article 7.

2. Parties demonstrating, through adequate evidence, a legitimate interest, including manufacturers, growers and producers of products covered by Annex I may also submit an application to a Member State in accordance with Article 7.

3. Where a Member State considers that the setting, modification or deletion of an MRL is necessary, that Member State may also compile and evaluate an application for setting, modifying or deleting the MRL in accordance with Article 7.

4. Applications for import tolerances shall be submitted to rapporteur Member States designated pursuant to Directive 91/414/EEC or, if no such rapporteur has been designated, applications shall be made to Member States designated by the Commission in accordance with procedure referred to in Article 45(2) of this Regulation at the request of the applicant. Such applications shall be made in accordance with Article 7 of this Regulation.

Article 7

Requirements relating to applications for MRLs

1. The applicant shall include in an application for an MRL the following particulars and documents:

(a) the name and address of the applicant;

(b) a presentation of the application dossier including:

(i) a summary of the application;

(ii) the main substantive arguments;

(iii) an index of the documentation;

(iv) a copy of the relevant GAP applying to the specific use of that active substance;

(c) where appropriate, scientifically substantiated reasons for concern;

(d) the data listed in Annexes II and III to Directive 91/414/EEC relating to data requirements for the setting of MRLs for pesticides including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories, as well as plant and animal metabolism data.

However, where relevant data are already publicly available, in particular when an active substance has already been evaluated under Directive 91/414/EEC or when a CXL exists and such data are submitted by the applicant, a Member State may also use such information in evaluating an application. In such cases, the evaluation report shall include a justification for using or not using such data.

2. The evaluating Member State may, where appropriate, request the applicant to provide supplementary information in addition to information required under paragraph 1 within a time limit specified by the Member State.

Article 8

Evaluation of applications

1. A Member State to which an application complying with Article 7 is submitted pursuant to Article 6 shall immediately forward a copy to the European Food Safety Authority established by Regulation (EC) No 178/2002 (hereinafter referred to as 'the Authority') and the Commission and draw up an evaluation report without undue delay.

2. Applications shall be evaluated in accordance with the relevant provisions of the Uniform Principles for the Evaluation and Authorisation of Plant Protection Products set out in Annex VI to Directive 91/414/EEC or specific evaluation principles to be laid down in a Commission Regulation in accordance with the procedure referred to in Article 45(2) of this Regulation.

3. By way of derogation from paragraph 1 and by agreement between the Member States concerned, evaluation of the application may be carried out by the rapporteur Member State designated pursuant to Directive 91/414/EEC for that active substance.

4. Where a Member State encounters difficulties in evaluating an application or in order to avoid duplication of work, it may be decided in accordance with the procedure referred to in Article 45(2) which Member State shall evaluate particular applications.

Article 9

Submission of evaluated applications to the Commission and the Authority

1. After completion of the evaluation report, the Member State shall forward it to the Commission. The Commission shall without delay inform the Member States and forward the application, the evaluation report and the supporting dossier to the Authority.

2. The Authority shall acknowledge in writing receipt of the application to the applicant, the evaluating Member State and the Commission without delay. The acknowledgement shall state the date of receipt of the application and the accompanying documents.

SECTION 2

CONSIDERATION OF APPLICATIONS CONCERNING MRLS BY THE AUTHORITY

Article 10

The Authority's opinion on applications concerning MRLs

1. The Authority shall assess the applications and the evaluation reports and give a reasoned opinion on, in particular, the risks to the consumer and where relevant to animals associated with the setting, modification or deletion of an MRL. That opinion shall include:

(a) an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;

(b) the anticipated LOD for the pesticide/product combination;

(c) an assessment of the risks of the acceptable daily intake or acute reference dose being exceeded as a result of the modification of the MRL; the contribution to the intake due to the residues in the product for which the MRLs was requested;

(d) any other element relevant to the risk assessment.

2. The Authority shall forward its reasoned opinion to the applicant, the Commission and the Member States. The reasoned opinion shall clearly define the basis for each conclusion reached.

3. Without prejudice to Article 39 of Regulation (EC) No 178/2002, the Authority shall make its reasoned opinion public.

Article 11

Time limits for the Authority's opinion on applications concerning MRLs

1. The Authority shall give its reasoned opinion as provided for in Article 10 as soon as possible and at the latest within three months from the date of receipt of the application.

2. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until that information has been provided. Such suspensions are subject to Article 13.

Article 12

Assessment of existing MRLs by the Authority

1. The Authority shall, within a period of 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC after the entry into force of this Regulation, submit a reasoned opinion based in particular on the relevant assessment report prepared under Directive 91/414/EEC to the Commission and the Member States on:

(a) existing MRLs for that active substance set out in Annex II or III to this Regulation;

(b) the necessity of setting new MRLs for that active substance, or its inclusion in Annex IV to this Regulation;

(c) specific processing factors as referred to in Article 20(2) of this Regulation that may be needed for that active substance;

(d) MRLs which the Commission may consider including in Annex II and/or Annex III to this Regulation and on those MRLs which may be deleted related to that active substance.

2. For substances included in Annex I to Directive 91/414/EEC before the entry into force of this Regulation, the reasoned opinion referred to in paragraph 1 of this Article shall be delivered within 12 months of the entry into force of this Regulation.

Article 13

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

For that purpose, a request shall be submitted to the Commission within two months after the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act within a set time-limit.

SECTION 3

SETTING, MODIFYING OR DELETION OF MRLS

Article 14

Decisions on applications concerning MRLs

1. Upon receipt of the opinion of the Authority and taking into account that opinion, a Regulation on the setting, modification or deletion of an MRL or a Decision rejecting the application shall be prepared by the Commission without delay and at the latest within three months, and submitted for adoption in accordance with the procedure referred to in Article 45(2).

2. With regard to the acts referred to in paragraph 1, account shall be taken of:

(a) the scientific and technical knowledge available;

(b) the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances;

(c) the results of an assessment of any potential risks to the consumer and, where appropriate, to animals;

(d) the results of any evaluations and decisions to modify the uses of plant protection products;

(e) a CXL or a GAP implemented in a third country for the legal use of an active substance in that country;

(f) other legitimate factors relevant to the matter under consideration.

3. The Commission may request at any time that supplementary information be provided by the applicant or by the Authority. The Commission shall make available any supplementary information received to the Member States and the Authority.

Article 15

Inclusion of new or modified MRLs in Annexes II and III

1. The Regulation referred in Article 14(1) shall:

(a) set new or modified MRLs and list them in Annex II to this Regulation where the active substances have been included in Annex I to Directive 91/414/EEC; or

(b) where the active substances have not been included in Annex I to Directive 91/414/EEC and where they are not included in Annex II to this Regulation, set or modify temporary MRLs and list them in Annex III to this Regulation; or

(c) in the cases mentioned in Article 16, set temporary MRLs and list them in Annex III to this Regulation.

2. Where a temporary MRL is set as provided for in paragraph 1(b), it shall be deleted from Annex III by a Regulation one year after the date of the inclusion or non-inclusion in Annex I to Directive 91/414/EEC of the active substance concerned, in accordance with the procedure referred to in Article 45(2) of this Regulation. However, where one or more Member States so requests, it may be maintained for an additional year pending confirmation that any scientific studies necessary for supporting an application for setting a MRL have been undertaken. In cases where such confirmation is provided, the temporary MRL shall be maintained for a further two years, provided that no unacceptable safety concerns for the consumer have been identified.

Article 16

Procedure for setting temporary MRLs in certain circumstances

1. The Regulation referred to in Article 14(1) may also set a temporary MRL to be included in Annex III in the following circumstances:

(a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Article 8(4) of Directive 91/414/EEC; or

(b) where the products concerned constitute a minor component of the diet of consumers and, where relevant, of animals; or

(c) for honey; or

(d) where essential uses of plant protection products have been identified by a Decision to delete an active substance from, or not to include an active substance in, Annex I to Directive 91/414/EEC.

2. The inclusion of temporary MRLs as referred to in paragraph 1 shall be based on the opinion of the Authority, monitoring data and an assessment demonstrating that there are no unacceptable risks to consumers or animals.

The continued validity of the temporary MRLs referred to in paragraph 1(a), (b) and (c) shall be reassessed at least once every 10 years and any such MRLs shall be modified or deleted as appropriate.

The MRLs referred to in paragraph 1(d) shall be reassessed at the expiry of the period for which the essential use was authorised.

Article 17

Modifications of MRL following revocation of authorisations of plant protection products

Amendments to Annexes II or III needed to delete an MRL following the revocation of an existing authorisation for a plant protection product may be adopted without seeking the opinion of the Authority.

CHAPTER III

MRLS APPLICABLE TO PRODUCTS OF PLANT AND ANIMAL ORIGIN

Article 18

Compliance with MRLs

1. The products covered by Annex I shall not contain, from the time they are placed on the market as food or feed, or fed to animals, any pesticide residue exceeding:

(a) the MRLs for those products set out in Annexes II and III;

(b) 0,01 mg/kg for those products for which no specific MRL is set out in Annexes II or III, or for active substances not listed in Annex IV unless different default values are fixed for an active substance in accordance with the procedure referred to in Article 45(2) while taking into account the routine analytical methods available. Such default values shall be listed in Annex V.

2. Member States may not prohibit or impede the placing on the market or the feeding to food-producing animals within their territories of the products covered by Annex I on the grounds that they contain pesticide residues provided that:

(a) such products comply with Articles 18(1) and 20; or

(b) the active substance is listed in Annex IV.

3. By way of derogation from paragraph 1, Member States may authorise, further to a post-harvest treatment with a fumigant on their own territory, residue levels for an active substance which exceed the limits specified in Annexes II and III for a product covered by Annex I where the active substance/product combinations are listed in Annex VII provided that:

(a) such products are not intended for immediate consumption;

(b) appropriate controls are in place to ensure that such products cannot be made available to the end user or consumer, if they are supplied directly to the latter, until the residues no longer exceed the maximum levels specified in Annexes II or III;

(c) the other Member States and the Commission have been informed of the measures taken.

The active substance/product combinations listed in Annex VII shall be defined in accordance with the procedure referred to in Article 45(2).

4. In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or in pursuance of obligations in Directive 2000/29/EC [1], a Member State may authorise the placing on the market and/or the feeding to animals within its territory of treated food or feed not complying with paragraph 1, provided that such food or feed does not constitute an unacceptable risk. Such authorisations shall immediately be notified to the other Member States, the Commission and the Authority, together with an appropriate risk assessment for consideration without undue delay in accordance with the procedure referred to in Article 45(2), with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products.

Article 19

Prohibition concerning processed and/or composite products

The processing, and/or mixing for dilution purposes with the same or other products, of the products covered by Annex I not complying with Articles 18(1) or 20 with a view to placing them on the market as food or feed or feeding them to animals shall be prohibited.

Article 20

MRLs applicable to processed and/or composite products

1. Where MRLs are not set out in Annexes II or III for processed and/or composite food or feed, the MRLs applicable shall be those provided in Article 18(1) for the relevant product covered by Annex I, taking into account changes in the levels of pesticide residues caused by processing and/or mixing.

2. Specific concentration or dilution factors for certain processing and/or mixing operations or for certain processed and/or composite products may be included in the list in Annex VI in accordance with the procedure referred to in Article 45(2).

[1] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1). Directive as last amended by Commission Directive 2004/70/EC (OJ L 127, 29.4.2004, p. 97).

CHAPTER IV

SPECIAL PROVISIONS RELATING TO THE INCORPORATION OF EXISTING MRLS INTO THIS REGULATION

Article 21

First establishment of MRLs

1. MRLs for products covered by Annex I shall be first established and listed in Annex II in accordance with the procedure referred to in Article 45(2), incorporating the MRLs provided for under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC, taking into account the criteria mentioned in Article 14(2) of this Regulation.

2. Annex II shall be established within 12 months from the entry into force of this Regulation.

Article 22

First establishment of temporary MRLs

1. Temporary MRLs for active substances for which a decision on inclusion or non-inclusion in Annex I to Directive 91/414/EEC has not yet been taken shall be first established and listed in Annex III to this Regulation, unless already listed in Annex II hereto, in accordance with the procedure referred to in Article 45(2), taking into account the information provided by the Member States, where relevant the reasoned opinion mentioned in Article 24, the factors referred to in Article 14(2) and the following MRLs:

(a) remaining MRLs in the Annex to Directive 76/895/EEC; and

(b) hitherto unharmonised national MRLs.

2. Annex III shall be established within 12 months from the entry into force of this Regulation in accordance with Articles 23, 24 and 25.

Article 23

Information to be provided by the Member States on national MRLs

Where an active substance is not yet included in Annex I to Directive 91/414/EEC and where a Member State has set, by the date of entry into force of Annex I to this Regulation at the latest, a national MRL for that active substance for a product covered by Annex I to this Regulation, or has decided that no MRL is required for that active substance, the Member State concerned shall notify the Commission, in a format and by a date to be established in accordance with the procedure referred to in Article 45(2) of the national MRL, or the fact that no MRL is required for an active substance, and where relevant and at the request of the Commission:

(a) the GAP;

(b) where the critical GAP is applied in the Member State and, where available, summary data on supervised trials and/or monitoring data;

(c) the acceptable daily intake and, if relevant, the acute reference dose used for the national risk assessment, as well as the outcome of the assessment.

Article 24

Opinion of the Authority on data underlying national MRLs

1. At the request of the Commission, the Authority shall provide a reasoned opinion to the Commission on potential risks to consumer health arising from:

(a) temporary MRLs that may be included in Annex III;

(b) active substances that may be included in Annex IV.

2. In preparing the reasoned opinion referred to in paragraph 1, the Authority shall take into account the scientific and technical knowledge available, and in particular, information provided by the Member States as required by Article 23.

Article 25

Setting of temporary MRLs

Taking into account the opinion of the Authority, if such opinion is requested, temporary MRLs for active substances referred to in Article 23 may be set and listed in Annex III pursuant to Article 22(1) or, as appropriate, the active substance may be included in Annex IV pursuant to Article 5(1).

CHAPTER V

OFFICIAL CONTROLS, REPORTS AND SANCTIONS

SECTION 1

OFFICIAL CONTROLS OF MRLS

Article 26

Official controls

1. Without prejudice to Directive 96/23/EC [1], Member States shall carry out official controls on pesticide residues in order to enforce compliance with this Regulation, in accordance with the relevant provisions of Community law relating to official controls for food and feed.

2. Such controls on pesticide residues shall, in particular, consist of sampling and subsequent analysis of the samples and identification of the pesticides present and their respective residue levels.

Article 27

Sampling

1. Each Member State shall take a sufficient number and range of samples to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of supply as is reasonable, to allow for any subsequent enforcement action to be taken.

2. The sampling methods necessary for carrying out such controls of pesticide residues in products other than those provided for in Directive 2002/63/EC [2] shall be determined in accordance with the procedure referred to in Article 45(2) of this Regulation.

Article 28

Methods of Analysis

1. The methods of analysis of pesticide residues shall comply with the criteria set out in the relevant provisions of Community law relating to official controls for food and feed.

2. Technical guidelines dealing with the specific validation criteria and quality control procedures in relation to methods of analysis for the determination of pesticide residues may be adopted in accordance with the procedure referred to in Article 45(2).

3. All laboratories analysing samples for the official controls on pesticide residues shall participate in the Community Proficiency Tests for pesticide residues organised by the Commission.

SECTION 2

COMMUNITY CONTROL PROGRAMME

Article 29

Community Control Programme

1. The Commission shall prepare a coordinated multiannual Community control programme, identifying specific samples to be included in the national control programmes and taking into account problems that have been identified regarding compliance with the MRLs set out in this Regulation, with a view to assessing consumer exposure and the application of current legislation.

2. The Community control programme shall be adopted and updated every year in accordance with the procedure referred to in Article 45(2). The draft Community control programme shall be presented to the Committee referred to in Article 45(1) at least six months before the end of each calendar year.

SECTION 3

NATIONAL CONTROL PROGRAMMES

Article 30

National control programmes for pesticide residues

1. Member States shall establish multiannual national control programmes for pesticide residues. They shall update their multiannual programme every year.

Those programmes shall be risk-based and aimed in particular at assessing consumer exposure and compliance with current legislation. They shall specify at least the following:

(a) the products to be sampled;

(b) the number of samples to be taken and analyses to be carried out;

(c) the pesticides to be analysed;

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[1] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

[2] Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC (OJ L 187, 16.7.2002, p. 30).

(d) the criteria applied in drawing up such programmes, including:

(i) the pesticide-product combinations to be selected;

(ii) the number of samples taken for domestic and non-domestic products respectively;

(iii) consumption of the products as a share of the national diet;

(iv) the Community Control Programme, and

(v) the results of previous control programmes.

2. Member States shall submit their updated national control programmes for pesticide residues, as mentioned in paragraph 1, to the Commission and to the Authority at least three months before the end of each calendar year.

3. Member States shall participate in the Community Control Programme as provided for in Article 29.

SECTION 4

INFORMATION BY THE MEMBER STATES AND ANNUAL REPORT

Article 31

Information by the Member States

1. Member States shall submit the following information concerning the previous calendar year to the Commission, the Authority and the other Member States by 31 August each year:

(a) the results of the official controls provided for in Article 26(1);

(b) the LODs applied in the national control programmes referred to in Article 30 and under the Community Control Programme referred to in Article 29;

(c) details of the participation of the analytical laboratories in the Community proficiency tests referred to in Article 28(3) and other proficiency tests relevant to the pesticide-product combinations sampled in the national control programme;

(d) details of the accreditation status of the analytical laboratories involved in the controls referred to in point (a);

(e) where permitted by national legislation, details of enforcement measures taken.

2. Implementing measures relating to the submission of information by the Member States may be established in accordance with the procedure referred to in Article 45(2) after consultation with the Authority.

Article 32

The Annual Report on pesticide residues

1. On the basis of the information provided by the Member States under Article 31(1) the Authority shall draw up an Annual Report on pesticide residues.

2. The Authority shall include information on at least the following in the Annual Report:

(a) an analysis of the results of the controls provided for in Article 26(2);

(b) a statement of the possible reasons why the MRLs were exceeded, together with any appropriate observations regarding risk management options;

(c) an analysis of chronic and acute risks to the health of consumers from pesticide residues;

(d) an assessment of consumer exposure to pesticide residues based on the information provided under point (a) and any other relevant available information, including reports submitted under Directive 96/23/EC.

3. Where a Member State has not provided information in accordance with Article 31, the Authority may disregard the information relating to that Member State when compiling the Annual Report.

4. The format of the Annual Report may be decided in accordance with the procedure referred to in Article 45(2).

5. The Authority shall submit the Annual Report to the Commission by the last day of February each year.

6. The Annual Report may include an opinion on the pesticides to be covered in future programmes.

7. The Authority shall make public the Annual Report, as well as any comments by the Commission or Member States.

Article 33

Submission of the Annual Report on pesticide residues to the Committee

The Commission shall submit the Annual Report on pesticide residues to the Committee referred to in Article 45(1) without delay, for review and recommendations on any necessary measures to be taken regarding reported infringements of the MRLs set out in Annexes II and III.

SECTION 5

SANCTIONS

Article 34

Sanctions

The Member States shall lay down rules on the sanctions applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

The Member States shall notify those rules and any subsequent amendment to the Commission without delay.

CHAPTER VI

EMERGENCY MEASURES

Article 35

Emergency measures

Articles 53 and 54 of Regulation (EC) 178/2002 shall apply where, as a result of new information or of a reassessment of existing information, pesticide residues or MRLs covered by this Regulation may endanger human or animal health requiring immediate action.

CHAPTER VII

SUPPORT MEASURES RELATING TO HARMONISED PESTICIDE MRLS

Article 36

Support measures relating to harmonised pesticide MRLs

1. Support measures relating to harmonised pesticide MRLs shall be established at Community level, including:

(a) a consolidated database for Community legislation on MRLs of pesticide residues and for making such information publicly available;

(b) Community proficiency tests as referred to in Article 28(3);

(c) studies and other measures necessary for the preparation and development of legislation and of technical guidelines on pesticide residues;

(d) studies necessary for estimating the exposure of consumers and animals to pesticide residues;

(e) studies necessary to support control laboratories where analytical methods are not capable of controlling the MRLs established.

2. Any necessary implementing provisions concerning the measures referred to in paragraph 1 may be adopted in accordance with the procedure referred to in Article 45(2).

Article 37

Community contribution to the support measures for harmonised pesticide MRLs

1. The Community may make a financial contribution of up to 100 % of the cost of the measures provided for in Article 36.

2. The appropriations shall be authorised each financial year as part of the budgetary procedure.

CHAPTER VIII

COORDINATION OF APPLICATIONS FOR MRLS

Article 38

Designation of national authorities

Each Member State shall designate one or more national authorities to coordinate cooperation with the Commission, the Authority, other Member States, manufacturers, producers and growers for the purposes of this Regulation. Where more than one authority is designated by a Member State, it shall indicate which of the designated authorities shall act as a contact point.

The national authorities may delegate tasks to other bodies.

Each Member State shall inform the Commission and the Authority of the names and addresses of the designated national authorities.

Article 39

Coordination by the Authority of information on MRLs

The Authority shall:

(a) coordinate with the rapporteur Member State designated in accordance with Directive 91/414/EEC for an active substance;

(b) coordinate with the Member States and the Commission regarding MRLs, in particular for the purpose of fulfilling the requirements of Article 41.

Article 40

Information to be submitted by the Member States

Member States shall submit to the Authority, at its request, any available information necessary for the assessment of the safety of MRLs.

Article 41

Database of the Authority on MRLs

Without prejudice to the applicable provisions of Community and national law on access to documents, the Authority shall develop and maintain a database, accessible to the Commission and to the competent authorities of the Member States, containing the relevant scientific information and GAPs relating to the MRLs, the active substances and the processing factors set out in Annexes II, III, IV and VII. In particular it shall contain dietary intake assessments, processing factors and toxicological endpoints.

Article 42

Member States and Fees

1. Member States may recover the costs of work associated with setting, modifying or deleting MRLs, or with any other work arising from obligations under this Regulation, by means of a fee or charge.

2. Member States shall ensure that the fee or charge referred to in paragraph 1:

(a) is established in a transparent manner; and

(b) corresponds to the actual cost of the work involved.

It may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

CHAPTER IX

IMPLEMENTATION

Article 43

Scientific opinion of the Authority

The Commission or the Member States may request the Authority for a scientific opinion on any measure related to the assessment of risks under this Regulation. The Commission may specify the time limit within which such an opinion shall be provided.

Article 44

Procedure for the adoption of the Authority's opinions

1. When the Authority's opinions pursuant to this Regulation require only scientific or technical work involving the application of well-established scientific or technical principles they may, unless the Commission or a Member State objects, be issued by the Authority without consulting the scientific committee or the scientific panels mentioned in Article 28 of Regulation (EC) No 178/2002.

2. The implementing rules pursuant to Article 29(6)(a) of Regulation (EC) No 178/2002 shall specify the cases in which paragraph 1 above shall apply.

Article 45

Committee Procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) No 178/2002 (hereinafter referred to as 'the Committee'.)

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 46

Implementing measures

In accordance with the procedure referred to in Article 45(2) and, where appropriate, taking into account the opinion of the Authority, the following shall be established or may be amended:

(a) implementing measures to ensure the uniform application of this Regulation;

(b) the dates in Articles 23, 29(2), 30(2), 31(1) and 32(5);

(c) technical guidance documents to assist in the application of this Regulation;

(d) detailed rules concerning the scientific data required for the setting of MRLs.

Article 47

Report on implementation of this Regulation

Not later than 10 years after the entry into force of this Regulation, the Commission shall forward to the European Parliament and to the Council a report on its implementation and any appropriate proposals.

CHAPTER X

FINAL PROVISIONS

Article 48

Repeal and adaptation of legislation

1. Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC are hereby repealed with effect from the date referred to in the second paragraph of Article 50.

2. Article 4(1)(f) of Directive 91/414/EEC shall be replaced by the following:

'(f) where appropriate, the MRLs for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No …/2004 (*).

(*) OJ L .... .'

Article 49

Transitional Measures

1. The requirements of Chapter III shall not apply to products lawfully produced or imported into the Community before the date referred to in the second paragraph of Article 50.

However, in order to ensure a high level of consumer protection, appropriate measures concerning those products may be taken in accordance with the procedure referred to in Article 45(2).

2. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, further transitional measures may be laid down for the implementation of certain MRLs provided for in Articles 15, 16, 21, 22, and 25.

Those measures, which shall be without prejudice to the obligation to ensure a high level of consumer protection, shall be adopted in accordance with the procedure referred to in Article 45(2).

Article 50

Entry into force

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

Chapters II, III and V shall apply as from six months from the publication of the last of the Regulations establishing Annexes I, II, III and IV.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 14 March 2003 the Council received from the Commission a proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin.

The European Parliament adopted its opinion at a first reading on 20 April 2004. The European Economic and Social Committee adopted its opinion on 16 July 2003.

The Council adopted its common position on 19 July 2004, in accordance with the procedure laid down in Article 251 of the Treaty.

II. OBJECTIVES

The proposal overhauls and streamlines European pesticides legislation by replacing four existing Council Directives with a single Regulation. The aim of the new, harmonised provisions is twofold: to *facilitate trade* within the Single Market and with third countries, import tolerances being granted to exporters to the EU in certain cases, and to ensure a *consistent level of consumer protection* across the Community. The proposal also provides for the *role of the European Food Safety Authority (EFSA)* in this field. Under the new provisions, as amended by the Council, following a transitional period, MRLs would only be set at Community level through a procedure where Member States assess the need for an MRL and submit an evaluation report to the Commission. EFSA would be responsible for *risk assessment* based on the Member State evaluation report and data received from applicants, while the Commission would handle *risk management* by setting MRLs.

III. ANALYSIS OF THE COMMON POSITION

A. GENERAL OBSERVATIONS

The Council's common position broadly accords with the positions taken by the Commission and the Parliament, inasmuch as it:

— confirms the objectives and most of the arrangements proposed by the Commission and supported by the European Parliament;

— includes a large number of the amendments adopted at first reading by the European Parliament.

In particular, the Council agreed with a series of parliamentary amendments aiming to ensure the smooth functioning of the new procedures and to increase consistency between the new Regulation and other Community legislation. In addition, the Council felt that it was appropriate to introduce further amendments, for example, to allow Member States the flexibility to deal with MRL exceedences that arise in certain exceptional cases. The Council also reordered and reformatted parts of the text of the Regulation so as to clarify the roles of the Member States, EFSA and the Commission and to separate transitional provisions from the standard procedures under the new regime. A number of technical and editorial amendments were also introduced.

B. SPECIFIC COMMENTS

(a) Application procedure: the respective roles of the EFSA and the Member States

In its proposal, the Commission had foreseen an exclusive role for EFSA in scientific evaluation work and the setting of MRLs. However, the Council agreed with the Parliament that Member States should perform a preliminary analysis of MRL applications in line with established procedures under Directive 91/414/EEC. In addition, the Council agreed that a copy of MRL applications received by Member States should immediately be sent to the Commission and to EFSA (Article 8).

(b) **Procedure for routine work performed by EFSA**

In the light of the substantial workload foreseen for EFSA, the Council introduced a new article designed to avoid unnecessary consultation of scientific bodies on matters of routine, i.e. in cases where EFSA issues opinions purely based on well-established scientific principles (Article 44). This provision is analogous to Article 31 of Regulation 178/2002/EC.

(c) **Administrative review**

A new article was added with a view to providing a form of legal redress regarding decisions taken by EFSA and also in the event of non-action by EFSA (Article 13).

(d) **Time scale and transition to the new procedures**

To ensure a smooth transition to the new provisions, the Council followed the Parliament in setting down specific deadlines for the completion of the principal technical annexes, which will set out a list of harmonised MRLs (Annex II), a list of harmonised temporary MRLs (Annex III) and a list of active substances for which no MRLs are required (Annex IV). In the same spirit, the Council also introduced a deadline for drawing up the annex listing the products to which harmonised MRLs will apply (Annex I). Like Parliament, the Council considered that the Regulation should not apply in full until after the crucial annexes have been drawn up (Articles 4, 5, 21, 22 and 50).

(e) **Possibility to extend the validity of temporary MRLs**

In order to facilitate a smooth transition to a fully harmonised regime (e.g. where Member States indicate that extra time is required to complete scientific studies on substances that have been authorised nationally), the Council decided that it should be possible for temporary MRLs, which will normally be valid for one year, to be maintained in Annex III for up to three additional years in certain cases (Article 15).

(f) **The use of pesticides for post-harvest treatment**

A derogation was introduced in order to provide for the practice of post-harvest fumigation of products (e.g. with a view to protecting them against pests during storage and transport, which can entail the temporary exceedence of MRLs while the product remains in storage or transit) (Article 18(3)).

(g) **The use of pesticides in exceptional circumstances**

In order to provide for exceptional circumstances (e.g. when an emergency use of a plant protection product is required to control pest(s) in accordance with Article 8(4) of Directive 91/414/EEC), emergency provisions were introduced allowing a Member State to authorise the placing on the market and/or the feeding to animals within its territory of food or feed that is not in compliance with the MRLs laid down in the Regulation. Such authorisations are to be notified to the other Member States, the Commission and EFSA, with a view to setting temporary MRLs and taking any other necessary actions. Such authorisations can only be granted provided that the treated food or feed does not constitute an unacceptable risk to consumers (Article 18(4)).

(h) **Definitions**

In redrafting the text to improve legal clarity, the Council added two new definitions, namely 'critical GAP' (i.e. the Good Agricultural Practice that forms the basis for a harmonised MRL under the Regulation) and 'CXL' (i.e. an MRL set by the Codex Alimentarius Commission), and deleted the definition of 'composite foodstuffs'. In addition, the Council followed the European Parliament in clarifying the definition of 'pesticide residues' (Article 3).

(i) **Technical and editorial amendments**

A large number of other changes, including technical adjustments and clarifications, were also made.

(j) **Amendments not accepted by Council**

Further discussion is needed, in particular, on issues associated with *risk assessment*, and on provisions concerning *the use of plant protection products*, where Council was unable to agree to a number of Parliament's amendments at this stage. Such items concern, in particular, approaches to exposure assessment in the context of MRL-setting, considerations surrounding the most appropriate way of providing information to the public, and the drafting of provisions concerning good agricultural practice and pest management.

COMMON POSITION (EC) No 2/2005

adopted by the Council on 24 September 2004

with a view to the adoption of Decision No.../2005/EC of the European Parliament and of the Council of... establishing a multiannual Community programme to make digital content in Europe more accessible, usable and exploitable

(Text with EEA relevance)

(2005/C 25E/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 157(3) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) The evolution of the information society and the emergence of broadband will influence the life of every citizen in the European Union by, inter alia, stimulating access to knowledge and new ways of acquiring knowledge, thus increasing the demand for new content, applications and services.

(2) Internet penetration in the Community is still growing considerably. The opportunities offered by the Internet should be exploited in order to enable every individual and organisation in the Community to enjoy the social and economic benefits of sharing information and knowledge. The stage has now been set in Europe to exploit the potential of digital content.

(3) The conclusions of the European Council held in Lisbon on 23 and 24 March 2000 stressed that the shift to a digital, knowledge-based economy, prompted by new goods and services, will be a powerful engine for growth, competitiveness and jobs. On that occasion the role of the content industries in creating added value by exploiting and networking European cultural diversity was specifically recognised.

(4) The eEurope 2005 Action Plan, developing the Lisbon strategy, calls for actions to stimulate the emergence of secure services, applications and content over broadband networks and thus to provide a favourable environment for private investment, for the creation of new jobs, to boost productivity, to modernise public services and to give everyone the opportunity to participate in the global information society.

(5) The demand for quality digital content in Europe, with balanced access and user rights, by a broad community, be they citizens in society, students, researchers, SMEs and other business users, or people with special needs wishing to augment their knowledge, or 're-users' wishing to exploit digital content resources to create services, is increasingly apparent.

(6) Digital content stakeholders are content providers (including public and private organisations and institutions that create, collect or own digital content) and content users (including organisations and entreprises that are end-users that re-use and/or add value to digital content). Particular attention should be given to the participation of SMEs.

(7) The *e*Content Programme (2001 to 2004) adopted by Council Decision 2001/48/EC of 22 December 2000 [3] favoured the development and use of European digital content on the Internet and the linguistic diversity of European websites in the information society. The Commission Communication of 10 October 2003 concerning the mid-term evaluation of the eContent Programme reaffirms the importance of acting in this field.

(8) Technological advances offer the potential to add value to content in the form of embedded knowledge and to improve interoperability at the service level, which is fundamental to accessing, using and distributing digital content. This is particularly relevant to those areas of public interest to be addressed by this programme.

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[1] OJ C 117, 30.4.2004, p. 49.

[2] Opinion of the European Parliament of 22 April 2004 (OJ C 104 E, 30.4.2004), Council Common Position of 24 September 2004 and Position of the European Parliament of ……. (not yet published in the Official Journal).

[3] OJ L 14, 18.1.2001, p. 32.

(9) Fostering of solid business models will enhance the continuity of the projects initiated under this programme, and will thus improve the conditions for greater economic return from services based on access to, and reuse of, digital content.

(10) A legislative framework has been defined to deal with the challenges of digital content in the information society ([1]) ([2]) ([3]).

(11) Different practices among Member States continue to pose technical obstacles impeding wide access, use, reuse and exploitation of public sector information in the Community.

(12) Where the digital content involves personal data, Directives 95/46/EC ([4]) and 2002/58/EC ([5]) should be respected and the technologies used should respect and, where possible, enhance privacy.

(13) Community actions undertaken concerning the content of information should promote the Community's multilingual and multicultural specificity.

(14) The measures necessary for the implementation of this Decision should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([6]).

(15) The Commission should ensure complementarity and synergy with related Community initiatives and programmes, in particular those related to education and culture and to the European Interoperability Framework.

(16) This Decision lays down, for the entire duration of the programme, a financial framework constituting the prime reference, within the meaning of point 33 of the Interinstitutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure ([7]), for the budgetary authority during the annual budgetary procedure.

(17) Since the objectives of the proposed action, namely aiming at making digital content in Europe more accessible, usable and exploitable, cannot be sufficiently achieved by the Member States due to the transnational character of the issues at stake and can therefore, by reason of the European scope and effects of the actions, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives,

HAVE DECIDED AS FOLLOWS:

Article 1

Objective of the Programme

1. This Decision establishes a Community programme for the period 2005 to 2008 to make digital content in Europe more accessible, usable and exploitable, facilitating the creation and diffusion of information — in areas of public interest — at Community level.

The programme shall be known as the '*e*Content*plus*' programme (hereinafter 'the Programme').

2. In order to attain the overall aim of the Programme, the following lines of action shall be addressed:

(a) facilitating at Community level access to digital content, its use and exploitation;

(b) facilitating improvement of quality and enhancing best practice related to digital content between content providers and users, and across sectors;

(c) reinforcing cooperation between digital content stakeholders and awareness.

([1]) Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the reuse of public sector information (OJ L 345, 31.12.2003, p. 90).

([2]) Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, (OJ L 167, 22.6.2001, p. 10).

([3]) Directive 96/9 EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20).

([4]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31). Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

([5]) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

([6]) OJ L 184, 17.7.1999, p. 23.

([7]) OJ C 172, 18.6.1999, p. 1. Agreement as amended by Decision 2003/429/EC of the European Parliament and of the Council (OJ L 147, 14.6.2003, p. 25).

The activities to be carried out under those lines of action target areas of public sector information, spatial data and educational, cultural and scientific content as set out in Annex I. The Programme shall be implemented in accordance with Annex II.

Article 2

Participation

1. Participation in the Programme shall be open to legal entities established in the Member States. It shall also be open to participation of legal entities established in the candidate countries in accordance with bilateral agreements in existence or to be concluded with those countries.

2. Participation in the Programme may be opened to legal entities established in EFTA States which are contracting parties to the EEA Agreement, in accordance with the provisions of that Agreement.

3. Participation in the Programme may be opened, without financial support by the Community, to legal entities established in third countries and to international organisations, where such participation contributes effectively to the implementation of the Programme. The decision to allow such participation shall be adopted in accordance with the procedure referred to in Article 4(2).

Article 3

Competences of the Commission

1. The Commission shall be responsible for the implementation of the Programme.

2. The Commission shall draw up a work programme on the basis of this Decision.

3. In the implementation of the Programme, the Commission shall, in close cooperation with the Member States, ensure general consistency and complementarity with other relevant Community policies, programmes and actions that impinge upon the development and use of European digital content and the promotion of linguistic diversity in the information society, in particular the Community research and technological development programmes, IDA, *e*TEN, eInclusion, eLearning, MODINIS and Safer Internet.

4. The Commission shall act in accordance with the procedure referred to in Article 4(2) for the purposes of the following:

(a) adoption and modifications of the work programme;

(b) determination of the criteria and content of calls for proposals, in line with the objectives set out in Article 1;

(c) assessment of the projects proposed under calls for proposals for Community funding of an estimated amount of Community contribution equal to, or more than, EUR 1 million;

(d) any departure from the rules set out in Annex II.

5. The Commission shall inform the committee referred to in Article 4 of progress with the implementation of the Programme.

Article 4

Committee

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 5

Monitoring and Evaluation

1. In order to ensure that Community aid is used efficiently, the Commission shall ensure that actions under this Decision are subject to prior appraisal, follow-up and subsequent evaluation.

2. The Commission shall monitor the implementation of projects under the Programme. The Commission shall evaluate the manner in which the projects have been carried out and the impact of their implementation in order to assess whether the original objectives have been achieved.

3. The Commission shall report on the implementation of the lines of action referred to in Article 1(2) to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions by mid-2006 at the latest. In this context, the Commission shall report on the consistency of the amount for 2007 and 2008 with the financial perspective. If applicable, the Commission shall take the necessary steps within the budgetary procedures for 2007 and 2008 to ensure the consistency of the annual appropriations with the financial perspective. The Commission shall submit a final evaluation report at the end of the Programme.

4. The Commission shall forward the results of its quantitative and qualitative evaluations to the European Parliament and the Council together with any appropriate proposals for the amendment of this Decision. The results shall be forwarded before presentation of the draft general budget of the European Union for the years 2007 and 2009 respectively.

Article 6

Financial framework

1. The financial framework for the implementation of the Community actions under this Decision for the period from 1 January 2005 to 31 December 2008 is hereby set at EUR 135 million, of which EUR 55,6 million is for the period until 31 December 2006.

2. For the period following 31 December 2006, the amount shall be deemed to be confirmed if it is consistent for this phase with the financial perspective in force for the period commencing in 2007.

3. The annual appropriations for the period from 2005 to 2008 shall be authorised by the budgetary authority within the limits of the financial perspective. An indicative breakdown of expenditure is given in Annex III.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

ACTIONS

I. INTRODUCTION

*e*Content*plus* has the overall aim of making digital content in Europe more accessible, usable and exploitable, facilitating the creation and diffusion of information – in areas of public interest – at Community level.

It will create better conditions for accessing and managing digital content and services in multilingual and multicultural environments. It will broaden users' choice and support new ways of interacting with knowledge-enhanced digital content, a feature which is becoming essential to make content more dynamic and tailored to specific contexts (learning, cultural, people with special needs, etc.).

The Programme will pave the way for a structured framework for quality digital content in Europe — The European Digital Content Area — by facilitating transfer of experiences, best practice and cross-fertilisation between content sectors, content providers and users.

Three lines of action are foreseen:

(a) facilitating at Community level access to digital content, its use and exploitation;

(b) facilitating improvement of quality and enhancing best practice related to digital content between content providers and users, and across sectors;

(c) reinforcing cooperation between digital content stakeholders and awareness.

II. LINES OF ACTION

A. **Facilitating at Community level access to digital content, its use and exploitation**

The activities to be carried out under this line of action encompass the establishment of networks and alliances between stakeholders, encouraging the creation of new services.

Target areas are public sector information, spatial data, learning and cultural content.

The focus will be on:

(a) supporting a wider recognition of the importance of public sector information (PSI), its commercial value and associated societal implications of its use. Activities shall improve effective cross-border use and exploitation of PSI between public sector organisations and private companies, including SMEs, for added-value information products and services;

(b) encouraging a wider use of spatial data by public sector bodies, private companies, including SMEs, and citizens through cooperation mechanisms at European level. Activities should tackle both technical and organisational issues, avoiding duplications and underdeveloped territorial data sets. They should promote cross-border interoperability, supporting coordination between mapping agencies and fostering the emergence of new services at European level for mobile users. They should also support the use of open standards;

(c) fostering the proliferation of open European knowledge pools of digital objects, for education and research communities, as well as the individual. The activities will support the creation of trans-European brokering services for digital learning content, with associated business models. The activities should also encourage the use of open standards, and the creation of large user groups analysing and testing pre-standardisation and specifications schemes with a view to conveying European multilingual and multicultural aspects into the process of definition of global standards for digital learning content;

(d) promoting the emergence of trans-European information infrastructures for accessing and using high quality European digital cultural and scientific resources through the linking of virtual libraries, community memories, etc. Activities should encompass coordinated approaches to digitisation and collection building, preservation of digital objects and inventories of cultural and scientific digital resources. They should improve access to digital cultural and scientific assets through effective licensing schemes and collective pre-emptive clearing of rights.

B. **Facilitating improvement of quality and enhancing best practice related to digital content between content providers and users, and across sectors**

The activities to be carried out under this line of action are intended to facilitate the identification and wide diffusion of best practice in methods, processes and operations to achieve higher quality, greater efficiency and effectiveness in the creation, use and distribution of digital content.

These activities encompass experiments that demonstrate searchability, usability, reusability, composability and interoperability of digital content within the context of the existing legal framework while meeting from the early stage of the process the requirements of different target groups and markets in an increasingly multilingual and multicultural environment, and extending beyond mere localisation technologies.

These activities will exploit the benefits of enhancing digital content with machine-understandable data (semantically well-defined metadata based on relevant descriptive terminology, vocabularies and ontologies).

The experiments will be conducted in thematic clusters. The gathering, dissemination and cross-sector fertilisation of gained knowledge will be an integral part of the experiments.

Target application areas are public sector information, spatial data, digital learning and cultural content, as well as scientific and scholarly digital content.

C. **Reinforcing cooperation between digital content stakeholders and awareness**

The activities to be carried out under this line of action include measures accompanying relevant legislation relating to digital content, and fostering increased collaboration between digital content stakeholders, as well as awareness building. These activities will support the development of benchmarking, monitoring and analysis tools, the impact assessment of the Programme and the dissemination of results. They will identify and analyse emerging opportunities and problems (e.g. trust, quality marking, intellectual property rights in education) and propose, as appropriate, solutions.

ANNEX II

THE MEANS FOR IMPLEMENTING THE PROGRAMME

1. The Commission will implement the Programme in accordance with the technical content specified in Annex I.
2. The Programme will be executed through indirect action comprising:
   (a) *shared-cost actions*
      (i) Projects designed to increase knowledge so as to improve existing products, processes and/or services and/or to meet the needs of Community policies. The Community funding will normally not exceed 50 % of the cost of the project. Public sector bodies may be reimbursed on the basis of 100 % of additional costs;
      (ii) Best practice actions to spread knowledge. They will normally be conducted in thematic clusters and linked through thematic networks. The Community contribution for the measures set out under this point will be limited to direct costs deemed necessary or appropriate for achieving the specific objectives of the action;
      (iii) Thematic networks: networks bringing together a variety of stakeholders around a given technological and organisational objective, so as to facilitate coordination activities and the transfer of knowledge. They may be linked to best practice actions. Support will be granted towards the additional eligible costs of coordinating and implementing the network. The Community participation may cover the additional eligible costs of these measures.
   (b) *accompanying measures*

   Accompanying measures will contribute to the implementation of the Programme or the preparation of future activities. Measures devoted to the commercialisation of products, process or services, marketing activities and sales promotion are excluded.
      (i) studies in support of the Programme, including the preparation of future activities;
      (ii) exchange of information, conferences, seminars, workshops or other meetings and the management of clustered activities;
      (iii) dissemination, information and communication activities.
3. The selection of shared-cost actions will be based on calls for proposals published on the Commission's Internet site in accordance with the financial provisions in force.
4. Applications for Community support should provide, where appropriate, a financial plan listing all the components of the funding of the projects, including the financial support requested from the Community, and any other requests for or grants of support from other sources.
5. Accompanying measures will be implemented through calls for tenders in accordance with the financial provisions in force.

ANNEX III

INDICATIVE BREAKDOWN OF EXPENDITURE

1. Facilitating at Community level access to digital content, its use and exploitation	40 – 50 %
2. Facilitating improvement of quality and enhancing best practice related to digital content between content providers and users, and across sectors	45 – 55 %
3. Reinforcing cooperation between digital content stakeholders and awareness	8 – 12 %

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 13 February 2004 the Commission adopted the above proposal for a Decision of the European Parliament and of the Council ([1]). The proposal is based on Article 157(3) of the Treaty.

2. The European Parliament delivered its opinion on 22 April 2004 and the Economic and Social Committee on 29 April 2004 and the Committee of Regions did not give an opinion.

3. The Commission forwarded its amended proposal to the European Parliament and the Council on 4 May 2004.

4. On 24 September 2004 the Council adopted its common position in accordance with Article 251 of the Treaty.

II. OBJECTIVE

The purpose of this proposal is to create conditions for broader access to and use of digital content and where necessary for greater economic return from services based on access and (re)use of digital content through making a significant contribution to the eEurope strategy in sectors such as e-learning, e-government etc (a succession programme to the current eContent programme expiring end-2004).

III. ANALYSIS OF THE COMMON POSITION

The common position shares the overall objective of the proposal submitted by the Commission, and also, in general terms, the proposed means of attaining that objective. However, in the course of discussion within the Council, the text of the proposal has partly been reworded. The main points of the common position which differ from the Commission proposal and the European Parliaments amendments (see below point IV) are as follows:

1. Given the size of the projects envisaged in the proposal, the Council considered it appropriate to make a reference to the SMEs and the particular attention to be given to their participation (Recitals 5 and 6 as well as Annex I.II.A). Moreover, a reference to people with special needs was added to Recital 5 and Annex I.I.

2. The common position modifies Article 3 by adding a new paragraph specifying the consistency and complementarity of the programme with other relevant Community policies, programmes and actions.

3. The Council considers that in implementing the programme, the Commission should work in close cooperation with the Member States and ensure transparency. The common position has consequently modified Articles 3 and 4 as far as comitology is concerned in favour of a management procedure. These changes are further clarified in Recital 14.

4. As far as the financial framework (Article 6) of the programme is concerned, the common position reduces the total amount proposed by the Commission. The Commission had proposed a substantial increase of the budget from the current programme and, while all Member States recognised the importance of the programme, a lesser increase was considered appropriate. In line with other legislation a break clause was inserted to maintain budget discipline as the programme extends beyond the current financial perspective.

5. The common position also modifies the indicative breakdown of expenditure in Annex III. The Council considered it appropriate to give more impetus on Action line 1.

([1]) OJ C 98, 23.4.2004, p. 39.

IV. **EUROPEAN PARLIAMENT AMENDMENTS**

1. **European Parliament amendments accepted by the Commission and adopted by the Council**

— Amendment 1 has been incorporated into the common position as Recital 6 with an addition from the Council concerning the SMEs.

— Amendment 2 was incorporated into Article 1(1).

— Amendments 3, 4 and 5 have been incorporated into Article 1(2) of the common position except for the reference to 'areas for public interest' which the Council considered already covered in paragraph 1 of the same Article. Moreover, the Council has kept in the reference to 'awareness' in paragraph 2, which it considers of importance. This is also valid for the related amendments 11, 12, 13, 14 and 16 which the Council has incorporated into Annexes I and III.

— The Council incorporated the amendments 6 and 7 into Article 5 of its common position, although in a slightly redrafted wording for amendment 6.

— The amendments 8, 9 and 10 have all been incorporated to Article 6 of the Common position except for the total amount of the financial framework, which the Council changed according to reasons given above.

2. **European Parliament amendments accepted by the Commission but not adopted by the Council**

— The Council has not adopted amendment 15 as it feels that awareness building is an important part of the programme.

COMMON POSITION (EC) No 3/2005

adopted by the Council on 7 October 2004

with a view to the adoption of Directive 2005/..../EC of the European Parliament and of the Council of... on ship-source pollution and on the introduction of sanctions for infringements

(Text with EEA relevance)

(2005/C 25E/03)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

WHEREAS:

(1) The Community's maritime safety policy is aimed at a high level of safety and environmental protection and is based on the understanding that all parties involved in the transport of goods by sea have a responsibility for ensuring that ships used in Community waters comply with applicable rules and standards.

(2) The material standards in all Member States for discharges of polluting substances from ships are based upon the Marpol 73/78 Convention; however these rules are being ignored on a daily basis by a very large number of ships sailing in Community waters, without corrective action being taken.

(3) The implementation of Marpol 73/78 shows discrepancies among Member States and there is thus a need to harmonise its implementation at Community level; in particular the practices of Member States relating to the imposition of sanctions for discharges of polluting substances from ships differ significantly.

(4) Measures of a dissuasive nature form an integral part of the Community's maritime safety policy, as they ensure a link between the responsibility of each of the parties involved in the transport of polluting goods by sea and their exposure to sanctions; in order to achieve effective protection of the environment, there is therefore a need for effective, dissuasive and proportionate sanctions.

(5) To that end it is essential to approximate existing legal provisions, in particular, on the one hand, the precise definition of the infringement in question and the cases of exemption, which are the subject of this Directive and, on the other hand, minimum rules for penalties, liability and jurisdiction, which are the subject of Council Framework Decision 2005/../JHA of…. to strengthen the criminal law framework for the enforcement of the law against ship-source pollution.

(6) The purpose of this Directive is, among other things, to provide a definition of discharges and consequently to render more effective the implementation of Framework Decision 2005/.../JHA in order to prevent such infringements.

(7) Neither the international regime for the civil liability and compensation of oil pollution nor that relating to pollution by other hazardous or noxious substances provides sufficient dissuasive effects to discourage the parties involved in the transport of hazardous cargoes by sea from engaging in substandard practices; the required dissuasive effects can only be achieved through the introduction of sanctions applying to any person who causes or contributes to marine pollution; sanctions should be applicable not only to the shipowner or the master of the ship, but also the owner of the cargo, the classification society or any other person involved.

(8) Ship-source discharges of polluting substances should be regarded as infringements if committed with intent, recklessly or by serious negligence.

(9) Sanctions for discharges of polluting substances from ships are not related to the civil liability of the parties concerned and are thus not subject to any rules relating to the limitation or channelling of civil liabilities, nor do they limit the efficient compensation of victims of pollution incidents.

(10) There is a need for further effective cooperation among Member States to ensure that discharges of polluting substances from ships are detected in time and that the offenders are identified.

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[1] OJ C 220, 16.9.2003, p. 72.

[2] Opinion of the European Parliament of 13 January 2004 (OJ C 92E, 21.4.2004, p. 77).

(11) Where there is clear, objective evidence of a discharge causing major damage or a threat of major damage, Member States should submit the matter to their competent authorities with a view to instituting proceedings consistent with Article 220 of the 1982 United Nations Convention on the Law of the Sea.

(12) This Directive is in accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty. The incorporation of the international ship-source pollution standards into Community law and the establishment of sanctions, which may include criminal or administrative sanctions, for violations of them is a necessary measure to achieve a high level of safety and environmental protection in maritime transport. This can be effectively achieved by the Community only by means of harmonised rules. The Directive confines itself to the minimum required in order to achieve this objective and does not go beyond what is necessary for that purpose. It does not prevent Member States from taking more stringent measures against ship-source pollution in conformity with international law.

(13) This Directive fully respects the Charter of fundamental rights of the European Union,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Purpose

1. The purpose of this Directive is to ensure that persons responsible for ship-source pollution are subject to appropriate sanctions, in order to improve maritime safety and to enhance protection of the marine environment from pollution by ships.

2. This Directive does not prevent Member States from taking more stringent measures against ship-source pollution in conformity with international law.

Article 2

Definitions

For the purpose of this Directive:

1. 'Marpol 73/78' shall mean the International Convention for the Prevention of Pollution from Ships of 1973 and its 1978 Protocol, as amended from time to time.

2. 'Polluting substances' shall mean substances covered by Annexes I (oil) and II (noxious liquid substances in bulk) to Marpol 73/78.

3. 'Discharge' shall mean any release howsoever caused from a ship, as referred to in Article 2 of Marpol 73/78.

4. 'Ship' shall mean a seagoing vessel, irrespective of its flag, of any type whatsoever operating in the marine environment and shall include hydrofoil boats, air-cushion vehicles, submersibles and floating craft.

Article 3

Scope

1. This Directive shall apply, in accordance with international law, to discharges of polluting substances in:

(a) the internal waters, including ports, of a Member State, insofar as the Marpol regime is applicable;

(b) the territorial sea of a Member State;

(c) straits used for international navigation subject to the regime of transit passage, as laid down in Part III, section 2, of the 1982 United Nations Convention on the Law of the Sea, to the extent a Member State exercises jurisdiction over such straits;

(d) the exclusive economic zone or equivalent zone of a Member State, established in accordance with international law; and

(e) the high seas.

2. This Directive shall apply to discharges of polluting substances from any ship, irrespective of its flag, with the exception of any warship, naval auxiliary or other ship owned or operated by a State and used, for the time being, only on government non-commercial service.

Article 4

Infringements

Member States shall ensure that ship-source discharges of polluting substances into any of the areas referred to in Article 3(1) are regarded as infringements if committed with intent, recklessly or by serious negligence.

Article 5

Exceptions

1. A discharge of polluting substances into any of the areas referred to in Article 3(1) shall not be regarded as an infringement if it satisfies the conditions set out in Annex I, Regulations 11(a) or 11(c) or in Annex II, Regulations 6(a) or 6(c) of Marpol 73/78.

2. A discharge of polluting substances into the areas referred to in Article 3(1)(c), (d) and (e) shall not be regarded as an infringement for the owner, the master or the crew when acting under the master's responsibility if it satisfies the conditions set out in Annex I, Regulation 11(b) or in Annex II, Regulation 6(b) of Marpol 73/78.

3. A discharge of polluting substances into any of the areas referred to in Article 3(1) shall not be regarded as an infringement if it satisfies the conditions set out in Annex I, Regulations 9 or 10 or in Annex II, Regulation 5 of Marpol 73/78.

Article 6

Enforcement measures with respect to ships within a port of a Member State

1. If irregularities or information give rise to a suspicion that a ship which is voluntarily within a port or at an off-shore terminal of a Member State has been engaged in or is engaging in a discharge of polluting substances into any of the areas referred to in Article 3(1), that Member State shall ensure that an appropriate inspection, taking into account the relevant guidelines adopted by the International Maritime Organisation (IMO) is undertaken in accordance with its national law.

2. Insofar as the inspection referred to in paragraph 1 reveals facts that could indicate an infringement within the meaning of Article 4, the competent authorities of that Member State and of the flag State shall be informed.

Article 7

Enforcement measures by coastal States with respect to ships in transit

1. If the suspected discharge of polluting substances takes place in the areas referred to in Article 3(1)(b), (c), (d) or (e) and the ship which is suspected of the discharge does not call at a port of the Member State holding the information relating to the suspected discharge, the following shall apply:

(a) If the next port of call of the ship is another Member State, the Member States concerned shall cooperate closely in the inspection referred to in Article 6(1) and in deciding on the appropriate administrative measures in respect of any such discharge;

(b) If the next port of call of the ship is a port of a State outside the Community, the Member State shall take the necessary measures to ensure that the next port of call of the ship is informed about the suspected discharge and shall request the State of the next port of call to take the appropriate measures in respect of any such discharge.

2. Where there is clear objective evidence that a ship navigating in the areas referred to in Article 3(1)(b) or (d) has, in the area referred to in Article 3(1)(d), committed an infringement resulting in a discharge causing major damage or a threat of major damage to the coastline or related interests of the Member State concerned, or to any resources of the areas referred to in Article 3(1)(b) or (d), that State shall, subject to Part XII, Section 7 of the 1982 United Nations Convention on the Law of the Sea, provided that the evidence so warrants, submit the matter to its competent authorities with a view to instituting proceedings, including detention of the ship, in accordance with its national law.

3. In any case, the authorities of the flag State shall be informed.

Article 8

Sanctions

1. Member States shall take the necessary measures to ensure that the infringements referred to in Article 4 are subject to effective, proportionate and dissuasive sanctions, which may include criminal or administrative sanctions.

2. Each Member State shall take the measures necessary to ensure that the sanctions referred to in paragraph 1 apply to any person who is found responsible for an infringement as referred to in Article 4.

Article 9

Compliance with international law

Member States shall apply the provisions of this Directive without any discrimination in form or in fact among foreign ships and in accordance with applicable international law, including Section 7 of Part XII of the 1982 United Nations Convention on the Law of the Sea, and they shall promptly notify the flag State of the vessel and any other State concerned of measures taken in accordance with this Directive.

Article 10

Accompanying measures

For the purposes of this Directive, Member States and the Commission shall cooperate, where appropriate, in close collaboration with the European Maritime Safety Agency and, where appropriate, in the framework of the action programme to respond to accidental or deliberate marine pollution as set up by Decision No 2850/2000/EC [1] in order to:

(a) develop the necessary information systems required for the effective implementation of this Directive;

(b) establish common practices and guidelines on the basis of those existing at international level for, in particular:

— the monitoring and early identification of ships discharging polluting substances in violation of this Directive, including, where appropriate, on-board monitoring equipment;

— reliable methods of tracing polluting substances in the sea to a particular ship; and

— the effective enforcement of this Directive.

Article 11

Reporting

Every three years, Member States shall transmit a report to the Commission on the application of this Directive by the competent authorities. On the basis of these reports, the Commission shall submit a Community report to the European Parliament and the Council.

Article 12

Committee

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS), created by Article 3 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS). [2]

2. The Commission shall regularly inform the Committee set up by Decision No 2850/2000/EC of any proposed measures or other relevant activities concerning the response to marine pollution.

Article 13

Amendment procedure

Amendments to Marpol 73/78 as referred to in Article 2, point 1 may be excluded from the scope of this Directive, pursuant to Article 5 of Regulation (EC) No 2099/2002.

Article 14

Implementation

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than..... [3] and forthwith inform the Commission thereof.

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

Article 15

Entry into force

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

Article 16

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

[1] Decision No 2850/2000/EC of the European Parliament and of the Council of 20 December 2000 setting up a Community framework for cooperation in the field of accidental or deliberate marine pollution (OJ L 332, 28.12.2000, p. 1). Decision amended by Decision No 787/2004/EC (OJ L 138, 30.4.2004, p. 12).

[2] OJ L 324, 29.11.2002, p. 1. Regulation as amended by Commission Regulation (EC) No 415/2004 (OJ L 68, 6.3.2004, p. 10).

[3] 18 months following the date of its entry into force.

ANNEX

Summary, for reference purposes, of the Marpol 73/78 discharge regulations relating to discharges of oil and noxious liquid substances, as referred to in Article 2.2

PART I: OIL (MARPOL 73/78, ANNEX I)

For the purposes of Marpol 73/78 Annex I, 'oil' means petroleum in any form including crude oil, fuel oil, sludge, oil refuse and refined products (other than petrochemicals which are subject to the provisions of Marpol 73/78 Annex II) and 'oily mixture' means a mixture with any oil content.

Excerpts of the relevant provisions of Marpol 73/78 Annex I:

Regulation 9: Control of discharge of oil

1. Subject to the provisions of regulations 10 and 11 of this Annex and paragraph 2 of this regulation, any discharge into the sea of oil or oily mixtures from ships to which this Annex applies shall be prohibited except when all the following conditions are satisfied:

   (a) for an oil tanker, except as provided for in subparagraph (b) of this paragraph:

      (i) the tanker is not within a special area;

      (ii) the tanker is more than 50 nautical miles from the nearest land;

      (iii) the tanker is proceeding en route;

      (iv) the instantaneous rate of discharge of oil content does not exceed 30 litres per nautical mile;

      (v) the total quantity of oil discharged into the sea does not exceed for existing tankers 1/15 000 of the total quantity of the particular cargo of which the residue formed a part, and for new tankers 1/30 000 of the total quantity of the particular cargo of which the residue formed a part; and

      (vi) the tanker has in operation an oil discharge monitoring and control system and a slop tank arrangement as required by regulation 15 of this Annex.

   (b) from a ship of 400 tons gross tonnage and above other than an oil tanker and from machinery space bilges excluding cargo pump-room bilges of an oil tanker unless mixed with oil cargo residue:

      (i) the ship is not within a special area;

      (ii) the ship is proceeding en route;

      (iii) the oil content of the effluent without dilution does not exceed 15 parts per million; and

      (iv) the ship has in operation [monitoring, control and filtering equipment] as required by regulation 16 of this Annex.

2. In the case of a ship of less than 400 tons gross tonnage other than an oil tanker whilst outside the special area, the [flag State] Administration shall ensure that it is equipped as far as practicable and reasonable with installations to ensure the storage of oil residues on board and their discharge to reception facilities or into the sea in compliance with the requirements of paragraph 1(b) of this regulation.

   […]

3. The provisions of paragraph 1 of this regulation shall not apply to the discharge of clean or segregated ballast or unprocessed oily mixtures which without dilution have an oil content not exceeding 15 parts per million and which do not originate from cargo pump-room bilges and are not mixed with oil cargo residues.

4. No discharge into the sea shall contain chemicals or other substances in quantities or concentrations which are hazardous to the marine environment or chemicals or other substances introduced for the purpose of circumventing the conditions of discharge specified in this regulation.

5. The oil residues which cannot be discharged into the sea in compliance with paragraphs 1, 2 and 4 of this regulation shall be retained on board or discharged to reception facilities.

   […]

Regulation 10: Methods for the prevention of oil pollution from ships while operating in special areas

1. For the purpose of this Annex, the special areas are the Mediterranean Sea area, the Baltic Sea area, the Black Sea area, the Red Sea area, the 'Gulfs area', the Gulf of Aden area, the Antarctic area and the northwest European waters [as further defined and specified].

2. Subject to the provisions of regulation 11 of this Annex:

   (a) Any discharge into the sea of oil or oily mixture from any oil tanker and any ship of 400 tons gross tonnage and above other than an oil tanker shall be prohibited while in a special area. […]

   (b) […] Any discharge into the sea of oil or oily mixture from a ship of less than 400 tons gross tonnage, other than an oil tanker, shall be prohibited while in a special area, except when the oil content of the effluent without dilution does not exceed 15 parts per million.

3. (a) The provisions of paragraph 2 of this regulation shall not apply to the discharge of clean or segregated ballast.

   (b) The provisions of subparagraph 2(a) of this regulation shall not apply to the discharge of processed bilge water from machinery spaces, provided that all of the following conditions are satisfied:

      (i) the bilge water does not originate from cargo pump-room bilges;

      (ii) the bilge water is not mixed with oil cargo residues;

      (iii) the ship is proceeding en route;

      (iv) the oil content of the effluent without dilution does not exceed 15 parts per million;

      (v) the ship has in operation oil filtering equipment complying with regulation 16(5) of this Annex; and

      (vi) the filtering system is equipped with a stopping device which will ensure that the discharge is automatically stopped when the oil content of the effluent exceeds 15 parts per million.

4. (a) No discharge into the sea shall contain chemicals or other substances in quantities or concentrations which are hazardous to the marine environment or chemicals or other substances introduced for the purpose of circumventing the conditions of discharge specified in this regulation.

   (b) The oil residues which cannot be discharged into the sea in compliance with paragraphs 2 or 3 of this regulation shall be retained on board or discharged to reception facilities.

5. Nothing in this regulation shall prohibit a ship on a voyage only part of which is in a special area from discharging outside the special area in accordance with regulation 9 of this Annex.

   […]

Regulation 11: Exceptions

Regulations 9 and 10 of this Annex shall not apply to:

(a) the discharge into the sea of oil or oily mixture necessary for the purpose of securing the safety of a ship or saving life at sea; or

(b) the discharge into the sea of oil or oily mixture resulting from damage to a ship or its equipment:

   (i) provided that all reasonable precautions have been taken after the occurrence of the damage or discovery of the discharge for the purpose of preventing or minimising the discharge; and

   (ii) except if the owner or the master acted either with intent to cause damage, or recklessly and with knowledge that damage would probably result; or

(c) the discharge into the sea of substances containing oil, approved by the [flag State] Administration, when being used for the purpose of combating specific pollution incidents in order to minimise the damage from pollution. Any such discharge shall be subject to the approval of any Government in whose jurisdiction it is contemplated the discharge will occur.

PART II: NOXIOUS LIQUID SUBSTANCES (MARPOL 73/78 ANNEX II)

Excerpts of the relevant provisions of Marpol 73/78 Annex II:

Regulation 3: Categorisation and listing of noxious liquid substances

1. For the purpose of the regulations of this Annex, noxious liquid substances shall be divided into four categories as follows:

   (a) Category A: noxious liquid substances which if discharged into the sea from tank cleaning or deballasting operations would present a major hazard to either marine resources or human health or cause serious harm to amenities or other legitimate uses of the sea and therefore justify the application of stringent anti-pollution measures.

   (b) Category B: noxious liquid substances which if discharged into the sea from tank cleaning or deballasting operations would present a hazard to either marine resources or human health or cause harm to amenities or other legitimate uses of the sea and therefore justify the application of special anti-pollution measures.

   (c) Category C: noxious liquid substances which if discharged into the sea from tank cleaning or deballasting operations would present a minor hazard to either marine resources or human health or cause minor harm to amenities or other legitimate uses of the sea and therefore require special operational conditions.

   (d) Category D: noxious liquid substances which if discharged into the sea from tank cleaning or deballasting operations would present a recognisable hazard to either marine resources or human health or cause minimal harm to amenities or other legitimate uses of the sea and therefore require some attention in operational conditions.

   […]

   [Further guidelines on the categorisation of substances, including a list of categorised substances are given in regulations 3(2)(4) and 4 and the appendices of Marpol 73/78 Annex II].

   […]

Regulation 5: Discharge of noxious liquid substances

Category A, B and C substances outside special areas and Category D substances in all areas

Subject to the provisions of […] regulation 6 of this Annex,

1. The discharge into the sea of substances in Category A as defined in regulation 3(1)(a) of this Annex or of those provisionally assessed as such or ballast water, tank washings or other residues or mixtures containing such substances shall be prohibited. If tanks containing such substances or mixtures are to be washed, the resulting residues shall be discharged to a reception facility until the concentration of the substance in the effluent to such facility is at or below 0,1 % by weight and until the tank is empty, with the exception of phosphorus, yellow or white, for which the residual concentration shall be 0,01 % by weight. Any water subsequently added to the tank may be discharged into the sea when all the following conditions are satisfied:

   (a) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

   (b) the discharge is made below the waterline, taking into account the location of the seawater intakes; and

   (c) the discharge is made at a distance of not less than 12 nautical miles from the nearest land in a depth of water of not less than 25 m.

2. The discharge into the sea of substances in Category B as defined in regulation 3(1)(b) of this Annex or of those provisionally assessed as such, or ballast water, tank washings or other residues or mixtures containing such substances shall be prohibited except when all the following conditions are satisfied:

   (a) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

(b) the procedures and arrangements for discharge are approved by the [flag State] Administration. Such procedures and arrangements shall be based upon standards developed by the [IMO] and shall ensure that the concentration and rate of discharge of the effluent is such that the concentration of the substance in the wake astern of the ship does not exceed 1 part per million;

(c) the maximum quantity of cargo discharged from each tank and its associated piping system does not exceed the maximum quantity approved in accordance with the procedures referred to in subparagraph (b) of this paragraph, which shall in no case exceed the greater of 1 m^3 or 1/3 000 of the tank capacity in m^3;

(d) the discharge is made below the waterline, taking into account the location of the seawater intakes; and

(e) the discharge is made at a distance of not less than 12 nautical miles from the nearest land and in a depth of water of not less than 25 m.

3. The discharge into the sea of substances in Category C as defined in regulation 3(1)(c) of this Annex or of those provisionally assessed as such, or ballast water, tank washings or other residues or mixtures containing such substances shall be prohibited except when all the following conditions are satisfied:

(a) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

(b) the procedures and arrangements for discharge are approved by the [flag State] Administration. Such procedures and arrangements shall be based upon standards developed by the [IMO] and shall ensure that the concentration and rate of discharge of the effluent is such that the concentration of the substance in the wake astern of the ship does not exceed 10 parts per million;

(c) the maximum quantity of cargo discharged from each tank and its associated piping system does not exceed the maximum quantity approved in accordance with the procedures referred to in subparagraph (b) of this paragraph, which shall in no case exceed the greater of 3 m^3 or 1/1 000 of the tank capacity in m^3;

(d) the discharge is made below the waterline, taking into account the location of the seawater intakes; and

(e) the discharge is made at a distance of not less than 12 nautical miles from the nearest land and in a depth of water of not less than 25 m.

4. The discharge into the sea of substances in Category D as defined in regulation 3(1)(d) of this Annex, or of those provisionally assessed as such, or ballast water, tank washings, or other residues or mixtures containing such substances shall be prohibited except when all the following conditions are satisfied:

(a) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

(b) such mixtures are of a concentration not greater than one part of the substance in ten parts of water; and

(c) the discharge is made at a distance of not less than 12 nautical miles from the nearest land.

5. Ventilation procedures approved by the [flag State] Administration may be used to remove cargo residues from a tank. Such procedures shall be based upon standards developed by the [IMO]. Any water subsequently introduced into the tank shall be regarded as clean and shall not be subject to paragraphs 1, 2, 3 or 4 of this regulation.

6. The discharge into the sea of substances which have not been categorised, provisionally assessed, or evaluated as referred to in regulation 4(1) of this Annex, or of ballast water, tank washings, or other residues or mixtures containing such substances shall be prohibited.

Category A, B and C substances within special areas [as defined in Marpol 73/78 Annex II, Regulation 1, including the Baltic Sea]

Subject to the provisions of paragraph 14 of this regulation and regulation 6 of this Annex,

7. The discharge into the sea of substances in Category A as defined in regulation 3(1)(a) of this Annex or of those provisionally assessed as such, or ballast water, tank washings, or other residues or mixtures containing such substances shall be prohibited. If tanks containing such substances or mixtures are to be washed, the resulting residues shall be discharged to a reception facility which the States bordering the special area shall provide in accordance with regulation 7 of this Annex, until the concentration of the substance in the effluent to such facility is at or below 0,05 % by weight and until the tank is empty, with the exception of phosphorus, yellow or white, for which the residual concentration shall be 0,005 % by weight. Any water subsequently added to the tank may be discharged into the sea when all the following conditions are satisfied:

   (a) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

   (b) the discharge is made below the waterline, taking into account the location of the seawater intakes; and

   (c) the discharge is made at a distance of not less than 12 nautical miles from the nearest land and in a depth of water of not less than 25 m.

8. The discharge into the sea of substances in Category B as defined in regulation (3)(1)(b) of this Annex or of those provisionally assessed as such, or ballast water, tank washings, or other residues or mixtures containing such substances shall be prohibited except when all the following conditions are satisfied:

   (a) the tank has been prewashed in accordance with the procedure approved by the [flag State] Administration and based on standards developed by the [IMO] and the resulting tank washings have been discharged to a reception facility;

   (b) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

   (c) the procedures and arrangements for discharge and washings are approved by the [flag State] Administration. Such procedures and arrangements shall be based upon standards developed by the [IMO] and shall ensure that the concentration and rate of discharge of the effluent is such that the concentration of the substance in the wake astern of the ship does not exceed 1 part per million;

   (d) the discharge is made below the waterline, taking into account the location of the seawater intakes; and

   (e) the discharge is made at a distance of not less than 12 nautical miles from the nearest land and in a depth of water of not less than 25 m.

9. The discharge into the sea of substances in Category C as defined in regulation 3(1)(c) of this Annex or of those provisionally assessed as such, or ballast water, tank washings, or other residues or mixtures containing such substances shall be prohibited except when all the following conditions are satisfied:

   (a) the ship is proceeding en route at a speed of at least 7 knots in the case of self-propelled ships or at least 4 knots in the case of ships which are not self-propelled;

   (b) the procedures and arrangements for discharge are approved by the [flag State] Administration. Such procedures and arrangements shall be based upon standards developed by the [IMO] and shall ensure that the concentration and rate of discharge of the effluent is such that the concentration of the substance in the wake astern of the ship does not exceed 1 part per million;

   (c) the maximum quantity of cargo discharged from each tank and its associated piping system does not exceed the maximum quantity approved in accordance with the procedures referred to in subparagraph (b) of this paragraph which shall in no case exceed the greater of 1 m^3 or 1/3 000 of the tank capacity in m^3;

   (d) the discharge is made below the waterline, taking into account the location of the seawater intakes; and

   (e) the discharge is made at a distance of not less than 12 nautical miles from the nearest land and in a depth of water of not less than 25 m.

10. Ventilation procedures approved by the [flag State] Administration may be used to remove cargo residues from a tank. Such procedures shall be based upon standards developed by the [IMO]. Any water subsequently introduced into the tank shall be regarded as clean and shall not be subject to paragraph (7), (8) or (9) of this regulation.

11. The discharge into the sea of substances which have not been categorised, provisionally assessed or evaluated as referred to in regulation 4(1) of this Annex, or of ballast water, tank washings, or other residues or mixtures containing such substances shall be prohibited.

12. Nothing in this regulation shall prohibit a ship from retaining on board the residues from a Category B or C cargo and discharging such residues into the sea outside a special area in accordance with paragraphs 2 or 3 of this regulation, respectively.

Regulation 6: Exceptions

Regulation 5 of this Annex shall not apply to:

(a) the discharge into the sea of noxious liquid substances or mixtures containing such substances necessary for the purpose of securing the safety of a ship or saving life at sea; or

(b) the discharge into the sea of noxious liquid substances or mixtures containing such substances resulting from damage to a ship or its equipment:

  (i) provided that all reasonable precautions have been taken after the occurrence of the damage or discovery of the discharge for the purpose of preventing or minimising the discharge; and

  (ii) except if the owner or the master acted either with intent to cause damage, or recklessly and with knowledge that damage would probably result; or

(c) the discharge into the sea of noxious liquid substances or mixtures containing such substances, approved by the [flag State] Administration, when being used for the purpose of combating specific pollution incidents in order to minimise the damage from pollution. Any such discharge shall be subject to the approval of any Government in whose jurisdiction it is contemplated the discharge will occur.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

In the framework of the codecision procedure (Article 251/TEC), the Council reached, on 11 June 2004, a political agreement on the draft Directive of the European Parliament and of the Council on ship-source pollution and on the introduction of sanctions for infringements ([1]). Following legal/linguistic revision, the Council adopted its common position on 7 October 2004.

In taking its position, the Council took account of the opinion of the European Parliament in its first reading on 13 January 2004 ([2]) and of the opinion of the Economic and Social Committee ([3]) ([4]).

The Directive aims at transposing into Community law the international rules on ship-source pollution of the Marpol Convention, by providing that violations of the discharge rules are infringements, and establishing harmonised rules for their enforcement. It also aims at extending the rules, on the one hand, to cover discharges of oil resulting from damages when committed intentionally, recklessly or by serious negligence and, on the other hand, to ensure the widest possible enforcement under the United Nations Convention on the Law of the Sea (Unclos).

II. ANALYSIS OF THE COMMON POSITION

In the aftermath of the accident of the oil tanker Prestige, the Council emphasised not only the importance of the maritime safety policy but the necessity to ensure that any person who has caused or contributed to a pollution incident through grossly negligent behaviour should be subject to appropriate sanctions. The approach adopted by the Council to this Commission proposal, submitted in March 2003 and backed by a European Council conclusion that same month highlighting the choice of the appropriate legal basis, is founded on the principle of making full use of the Community's rights under Unclos, whilst complying with Member States' obligations under the International Convention for the Prevention of Pollution from Ships (Marpol).

The Council considers that the transposition of the Marpol regime regarding ship-source pollution into Community law will ensure a stricter and more harmonised application and enforcement in the Member States. It shares the view that it is necessary to establish that all discharges of polluting substances are considered infringements if they are committed with intent, recklessly or by serious negligence.

Following the principle of respecting the Marpol provisions, exceptions are provided in the case when a discharge is made in order to save lives or the ship itself. The exception under the Marpol Convention concerning the owner and the master in cases of discharges resulting from accidents applies in international sea areas and the exclusive economic or equivalent zone of Member States. In these cases, as a logical consequence of the Marpol provisions, the crew is protected when acting under the master's responsibility. In Member States' internal waters and territorial sea, on the other hand, the Council deems it appropriate to exercise the Community's rights under Article 211(4) of Unclos, in order to enhance the protection of the coastline, and to lift the exception provided for discharges resulting from accidents.

The Council considers that sanctions against infringements of ship-source pollution have to be effective, proportionate and dissuasive and may include criminal or administrative sanctions. It also agrees that these sanctions have to apply to any person found responsible for marine pollution, i.e. shall cover the whole chain of responsibility. Whilst the infringements are defined in the Directive, the Council is of the view that the minimum binding rules for criminal penalties, liability and jurisdiction should be established in the parallel Framework Decision proposed by the Commission and examined by the Council in its 'Justice and Home Affairs' formation.

([1]) The Commission presented its proposal on 7 March 2003 (OJ C 76, 25.3.2004, p. 5) under the title 'Proposal for a Directive of the European Parliament and of the Council on ship-source pollution and on the introduction of sanctions, including criminal sanctions, for pollution offences'.

([2]) Doc. 5181/04 CODEC 24 MAR 2 ENV 8 DROIPEN 1 (not yet published in the Official Journal).

([3]) OJ C 220, 16. 9.2003, p. 72.

([4]) The Committee of the Regions decided not to deliver an opinion.

The Council welcomes the streamlining of strict enforcement measures against ships calling at any port of a Member State in line with the relevant international guidelines. It endorses the enhanced information sharing on suspected discharges between Member States and third countries, either as port or as flag States, in order to facilitate the enforcement of the appropriate measures.

Finally, the Council is of the view that all possibilities under the Unclos Convention to protect the coastline and the resources of this area shall be used, including enforcement measures by coastal States with respect to ships in transit navigating in the territorial sea or exclusive economic or equivalent zone in accordance with Article 220(6) of Unclos, when there is clear objective evidence of a discharge causing major damage or threat of major damage to the coastline or any resources of the territorial sea or the exclusive economic or equivalent zone. In this case, the Member State concerned shall submit the matter to its competent authorities with a view to instituting proceedings, including detention of the ship, in accordance with its national law.

III. **AMENDMENTS**

Considering the fact that the Council follows a considerably different approach to this draft Directive compared to the originally proposed text, as pointed out above, it was not possible to reflect the major part of the amendments proposed by the European Parliament in first reading in the common position.

— The concept of setting up a European coastguard (amendments 6 and 22) was not part of the original Commission proposal. Whilst the Council considers it important to address means enhancing the protection of the European coastline, it does not want to prejudge any Commission initiative to that effect, possibly leading to a separate legislative act, which the Council will consider with interest.

— Although the Council shares the EP's concerns with regard to the implementation of Community legislation on maritime safety (amendments 3, 19, 20 and 31), it feels that the enforcement of existing legislative acts, like Directive 2000/59/EC on port reception facilities, falls into the competence of the Member States and its monitoring is one of the tasks of the Commission under the Treaty.

— As the objective of this Directive is to clearly define discharges of polluting substances from ships as infringements under Community law, the Council is of the opinion that other technical provisions like onboard monitoring equipment or oil registers (amendments 30 and 32) go beyond the scope of this proposal.

— According to the basic principle of the Council's approach laid out above, the Marpol provisions for discharges, including the exception concerning the owner and the master in cases of discharges resulting from accidents (amendment 10), apply in international sea areas and the exclusive economic or equivalent zone of Member States. In these cases, the crew is also explicitly excluded when acting under the master's responsibility. In the internal waters and territorial sea of the Member States, on the contrary, this exception is not granted in accordance with the possibilities under Article 211(4) of Unclos.

— Concerning the scope of the Directive, the Council considers it appropriate to treat all ships, regardless of their flag, in a certain sea area on an equal footing with a view to avoiding a disadvantageous position for ships sailing under the flag of a Member State (amendment 11 and 13).

— While the common position does not include any detailed provision on the nature of penalties (see deletion of paragraphs 4 to 6 of Article 8/amendments 17 and 18) given that the minimum rules towards a harmonisation of criminal penalties are subject of the parallel Framework Decision, Article 7 paragraph 2 refers to enforcement measures by coastal States in accordance with Unclos 220(6), including the detention of the ship, in the specific cases referred to in this Article.

The common position includes some other smaller modifications and clarifications to the Commission proposal. On a few points, amendments proposed by the European Parliament were partially or totally integrated with a view to ensuring a consistent legislative text.

COMMON POSITION (EC) No 4/2005

adopted by the Council on 21 October 2004

with a view to the adoption of Decision No.../2005/EC of the European Parliament and of the Council of... amending Decision No 1419/1999/EC establishing a Community action for the European Capital of Culture event for the years 2005 to 2019

(2005/C 25E/04)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 151 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Committee of the Regions [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Decision 1419/1999/EC of the European Parliament and of the Council of 25 May 1999 establishing a Community action for the European Capital of Culture event for the years 2005 to 2019 [3] is geared towards highlighting the wealth, diversity and shared characteristics of European cultures and contributing to improving European citizens' mutual knowledge.

(2) Annex I to Decision 1419/1999/EC sets out the chronological order according to which the Member States can submit nominations for this event. That Annex is limited to the Member States at the time the Decision was adopted on 25 May 1999.

(3) Article 6 of Decision 1419/1999/EC states that that decision may be revised, in particular with a view to the future enlargement of the European Union.

(4) In the light of the 2004 enlargement, it is important that the new Member States should likewise be able within a short period of time to submit nominations in the context of the European Capital of Culture event, without changing the order for the other Member States so that, from 2009 onwards and until the end of the current Community action, two capitals may be selected each year in the Member States.

(5) Decision 1419/1999/EC should therefore be amended,

HAVE DECIDED AS FOLLOWS:

Article 1

Decision 1419/1999/EC is hereby amended as follows:

1. The following Recital shall be inserted:

   '(12a) Whereas account should be taken of the financial consequences of this Decision in such a way as to ensure that there is adequate and appropriate Community funding for the designation of two European Capitals of Culture;';

2. Article 2(1) shall be replaced by the following:

   '1. Cities in Member States shall be designated as European Capital of Culture, in turn, as set out on the list contained in Annex I. Up until 2008 inclusive the designation shall apply to one city of the Member State appearing on the list. From 2009 onwards, the designation shall apply to one city of each of the Member States appearing on the list. The chronological order set out in Annex I may be altered by mutual agreement between the Member States concerned. Each Member State shall submit, in turn, its nomination of one or more cities to the European Parliament, the Council, the Commission and the Committee of the Regions. This nomination shall be submitted no later than four years before the event in question is due to begin and may be accompanied by a recommendation from the Member State concerned.';

3. Annex I shall be replaced by the text appearing in the Annex to this Decision.

Article 2

This Decision shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2004.

Done at Luxembourg,

For the European Parliament	*For the Council*
The President	*The President*

[1] OJ C 121, 30.4.2004, p. 15.

[2] Opinion of the European Parliament of 22 April 2004 (OJ C 104 E, 30.4.2004), Council Common Position of 21 October 2004 and Position of the European Parliament of … (not yet published in the Official Journal).

[3] OJ L 166, 1.7.1999, p. 1.

ANNEX

ORDER OF ENTITLEMENT TO NOMINATE A 'EUROPEAN CAPITAL OF CULTURE'

2005	Ireland	
2006	Greece [1]	
2007	Luxembourg	
2008	United Kingdom	
2009	Austria	Lithuania
2010	Germany	Hungary
2011	Finland	Estonia
2012	Portugal	Slovenia
2013	France	Slovakia
2014	Sweden	Latvia
2015	Belgium	Czech Republic
2016	Spain	Poland
2017	Denmark	Cyprus
2018	Netherlands [1]	Malta
2019	Italy	

[1] The Culture/Audiovisual Council, at its meeting of 28 May 1998, noted the exchange of positions between Greece and the Netherlands in accordance with Article 2(1) of Decision 1419/1999/EC.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 17 November 2003, the Commission submitted to the European Parliament and to the Council a proposal for a decision, based on article 151 of the EC Treaty, amending Decision 1419/1999/EC establishing a Community action for the 'European Capital of Culture' event for the years 2005 to 2019.
2. The European Parliament delivered its opinion at a first reading on 22 April 2004. The Commission made an oral presentation of its modified proposal on 29 April 2004.
3. The Committee of the Regions delivered its opinion on 21 April 2004 [1].
4. On 21 October 2004, the Council adopted its common position in accordance with Article 251(2) of the EC Treaty.

II. AIM OF THE PROPOSAL

The proposal aims to allow the new Member States to participate in the European Capital of Culture event before the current decision expires in 2019. It does not change the existing order of entitlement for nominations from Member States, but establishes a new system appointing two Member States eligible to submit nominations each year from 2009 onwards, so that two capitals may be selected in the Member States.

III. ANALYSIS OF THE COMMON POSITION

1. General comments

The Council did not make any amendment to the Commission's proposal. The Commission accepted in full one of the five amendments proposed by the Parliament (amendment 1).

2. Amendments made by the European Parliament

2.1. *Amendments accepted by the Council*

The Council endorsed in full the amendment proposed by the Parliament and accepted by the Commission (amendment 1).

2.2. *Amendments not integrated by the Council*

The Council, like the Commission, considered that amendments 2, 3, 4 and 5 went beyond the scope of the proposal and did not regard it as appropriate to incorporate them.

III. CONCLUSIONS

The Council considers that its common position is balanced and fully in line with the main objective of the Commission's proposal, thereby facilitating the participation of the new Member States in the European Capital of Culture event as soon as possible.

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[1] OJ C 121, 30.4.2004, p. 15.

COMMON POSITION (EC) No 5/2005

adopted by the Council on 12 November 2004

with a view to the adoption of Regulation (EC) No.../2005 of the European Parliament and of the Council of... on conditions for access to the natural gas transmission networks

(Text with EEA relevance)

(2005/C 25E/05)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

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

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [1],

Whereas:

(1) Directive 2003/55/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in natural gas [2] has made a significant contribution towards the creation of an internal market for gas. It is now necessary to provide structural changes in the regulatory framework to tackle remaining barriers to the completion of the internal market in particular regarding the trade of gas. Additional technical rules are necessary, in particular regarding third party access services, principles of capacity allocation mechanisms, congestion management procedures and transparency requirements.

(2) Experience gained in the implementation and monitoring of a first set of Guidelines for Good Practice, adopted by the European Gas Regulatory Forum (the Forum) in 2002, demonstrates that in order to ensure the full implementation of the rules set out in the Guidelines in all Member States, and in order to provide a minimum guarantee of equal market access conditions in practice, it is necessary to provide for them to become legally enforceable.

(3) A second set of common rules entitled 'the Second Guidelines for Good Practice' was adopted at the meeting of the Forum on 24 and 25 September 2003 and the purpose of this Regulation is to lay down, on the basis of those Guidelines, basic principles and rules regarding network access and third party access services, congestion management, transparency, balancing and the trading of capacity rights.

(4) Article 15 of Directive 2003/55/EC allows for a combined transmission and distribution system operator. Therefore, the rules set out in this Regulation do not require modification of the organisation of national transmission and distribution systems that are consistent with the relevant provisions of Directive 2003/55/EC and in particular Article 15 thereof.

(5) High pressure pipelines linking up local distributors to the gas network which are not primarily used in the context of local distribution are included in the scope of this Regulation.

(6) It is necessary to specify the criteria according to which tariffs for access to the network are determined, in order to ensure that they fully comply with the principle of non-discrimination and the needs of a well-functioning internal market and take fully into account the need for system integrity and reflect actual costs incurred, whilst ensuring appropriate incentives with respect to efficiency, including appropriate return on investments, and where appropriate taking account of the benchmarking of tariffs by the regulatory authorities.

(7) In calculating tariffs for access to networks it is important to take account of actual costs incurred, as well as of the need to provide appropriate return on investments and incentives to construct new infrastructure. In this respect, and in particular if effective pipeline-to-pipeline competition exists, the benchmarking of tariffs will be a relevant consideration.

(8) The use of market-based arrangements, such as auctions, to determine tariffs has to be compatible with the provisions laid down in Directive 2003/55/EC.

(9) A common minimum set of third party access services is necessary to provide a common minimum standard of access in practice throughout the Community, to ensure that third party access services are sufficiently compatible and to allow the benefits accruing from a well-functioning internal market for gas to be exploited.

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[1] Opinion of the European Parliament of 20 April 2004 (OJ C 104 E, 30.4.2004) and Council Decision of ....

[2] OJ L 176, 15.7.2003, p. 57.

(10) References to harmonised transportation contracts in the context of non-discriminatory access to the network of transmission system operators do not mean that the terms and conditions of the transportation contracts of a particular system operator in a Member State must be the same as those of another transmission system operator in that Member State or in another Member State, unless minimum requirements are set which must be met by all transportation contracts.

(11) The management of contractual congestion of networks is an important issue in completing the internal gas market. It is necessary to develop common rules which balance the need to free up unused capacity in accordance with the 'use-it-or-lose-it' principle with the rights of the holders of the capacity to use it when necessary, while at the same time enhancing liquidity of capacity.

(12) Although physical congestion of networks is rarely a problem at present in the Community, it may become one in the future. It is important therefore to provide the basic principle for the allocation of congested capacity in such circumstances.

(13) For network users to gain effective access to gas networks they need information in particular on technical requirements and available capacity to enable them to exploit business opportunities occurring within the framework of the internal market. Common minimum standards on such transparency requirements are necessary. The publication of such information may be done by different means, including electronic means.

(14) Non-discriminatory and transparent balancing systems for gas, operated by transmission system operators, are important mechanisms, particularly for new market entrants which may have more difficulty balancing their overall sales portfolio than companies already established within a relevant market. It is therefore necessary to lay down rules to ensure that transmission system operators operate such mechanisms in a manner compatible with non-discriminatory, transparent and effective access conditions to the network.

(15) The trading of primary capacity rights is an important part of developing a competitive market and creating liquidity. This Regulation should therefore lay down basic rules on that issue.

(16) It is necessary to ensure that undertakings acquiring capacity rights are able to sell them to other licensed undertakings in order to ensure an appropriate level of liquidity on the capacity market. This approach, however, does not preclude a system where capacity unused for a given period, determined at national level, is made re-available to the market on a firm basis.

(17) National regulatory authorities should ensure compliance with the rules contained in this Regulation and the guidelines adopted pursuant to it.

(18) In the Guidelines annexed to this Regulation, specific detailed implementing rules are defined on the basis of the second Guidelines for Good Practice. Where appropriate, these rules will evolve over time, taking into account the differences of national gas systems.

(19) When proposing to amend the Guidelines laid down in the Annex to this Regulation, the Commission should ensure prior consultation of all relevant parties concerned with the Guidelines, represented by the professional organisations, and of the Member States within the Forum and should request the input of the European Regulators Group for Electricity and Gas.

(20) The Member States and the competent national authorities should be required to provide relevant information to the Commission. Such information should be treated confidentially by the Commission.

(21) This Regulation and the guidelines adopted in accordance with it are without prejudice to the application of the Community rules on competition.

(22) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedure for the exercise of implementing powers conferred on the Commission [1].

(23) Since the objective of this Regulation, namely the setting of fair rules for access conditions to natural gas transmission systems, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the action, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

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

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation aims at setting non-discriminatory rules for access conditions to natural gas transmission systems taking into account the specificities of national and regional markets with a view to ensuring the proper functioning of the internal gas market.

This objective shall include the setting of harmonised principles for tariffs, or the methodologies underlying their calculation, for access to the network, the establishment of third party access services and harmonised principles for capacity allocation and congestion management, the determination of transparency requirements, balancing rules and imbalance charges and facilitating capacity trading.

2. Member States may establish an entity or body set up in compliance with Directive 2003/55/EC for the purpose of carrying out one or more functions typically attributed to the transmission system operator, which shall be subject to the requirements of this Regulation.

Article 2

Definitions

1. For the purpose of this Regulation, the following definitions shall apply:

(1) 'transmission' means the transport of natural gas through a network, which mainly contains high pressure pipelines, other than an upstream pipeline network and other than the part of high pressure pipelines primarily used in the context of local distribution of natural gas, with a view to its delivery to customers, but not including supply;

(2) 'transportation contract' means a contract which the transmission system operator has concluded with a network user with a view to carrying out transmission;

(3) 'capacity' means the maximum flow, expressed in normal cubic meters per time unit or in energy unit per time unit, to which the network user is entitled in accordance with the provisions of the transportation contract;

(4) 'unused capacity' means firm capacity which a network user has acquired under a transportation contract but which that user has not nominated;

(5) 'congestion management' means management of the capacity portfolio of the transmission system operator with a view to optimal and maximum use of the technical capacity and the timely detection of future congestion and saturation points;

(6) 'secondary market' means the market of the capacity traded otherwise than on the primary market;

(7) 'nomination' means the prior reporting by the network user to the transmission system operator of the actual flow that he wishes to inject into or withdraw from the system;

(8) 'renomination' means the subsequent reporting of a corrected nomination;

(9) 'system integrity' means any situation in respect of a transmission network including necessary transmission facilities in which the pressure and the quality of the natural gas remain within the minimum and maximum limits laid down by the transmission system operator, so that the transmission of natural gas is guaranteed from a technical standpoint;

(10) 'balancing period' means the period within which the offtake of an amount of natural gas, expressed in units of energy, must be offset by every network user by means of the injection of the same amount of natural gas into the transmission network in accordance with the transportation contract or the network code;

(11) 'network user' means a customer or a potential customer of a transmission system operator, and transmission system operators themselves in so far as it is necessary for them to carry out their functions in relation to transmission;

(12) 'interruptible services' means services offered by the transmission system operator in relation to interruptible capacity;

(13) 'interruptible capacity' means gas transmission capacity that can be interrupted by the transmission system operator according to the conditions stipulated in the transportation contract;

(14) 'long-term services' means services offered by the transmission system operator with a duration of one year or more;

(15) 'short-term services' means services offered by the transmission system operator with a duration of less than one year;

(16) 'firm capacity' means gas transmission capacity contractually guaranteed as uninterruptible by the transmission system operator;

(17) 'firm services' mean services offered by the transmission system operator in relation to firm capacity;

(18) 'technical capacity' means the maximum firm capacity that the transmission system operator can offer to the network users, taking account of system integrity and the operational requirements of the transmission network;

(19) 'contracted capacity' means capacity that the transmission system operator has allocated to a network user by means of a transportation contract;

(20) 'available capacity' means the part of the technical capacity that is not allocated and is still available to the system at that moment;

(21) 'contractual congestion' means a situation where the level of firm capacity demand exceeds the technical capacity;

(22) 'primary market' means the market of the capacity traded directly by the transmission system operator;

(23) 'physical congestion' means a situation where the level of demand for actual deliveries exceeds the technical capacity at some point in time.

2. The definitions contained in Article 2 of Directive 2003/55/EC, which are relevant for the application of this Regulation, shall also apply with the exception of the definition of transmission in point 3 of that Article.

Article 3

Tariffs for access to networks

1. Tariffs, or the methodologies used to calculate them, applied by transmission system operators and approved by the regulatory authorities pursuant to Article 25(2) of Directive 2003/55/EC, as well as tariffs published pursuant to Article 18(1) of that Directive, shall be transparent, take into account the need for system integrity and its improvement and reflect actual costs incurred whilst ensuring appropriate incentives with respect to efficiency, including appropriate return on investments, and where appropriate taking account of the benchmarking of tariffs by the regulatory authorities. Tariffs, or the methodologies used to calculate them, shall be applied in a non-discriminatory manner.

Member States may decide that tariffs may also be determined through market-based arrangements, such as auctions, provided that such arrangements and the revenues arising therefrom are approved by the regulatory authority.

Tariffs, or the methodologies used to calculate them, shall facilitate efficient gas trade and competition, while at the same time avoiding cross-subsidies between network users and providing incentives for investment and maintaining or creating interoperability for transmission networks.

2. Tariffs for network access shall not restrict market liquidity nor distort trade across borders of different transmission systems. Where differences in tariff structures or balancing mechanisms would hamper trade across transmission systems, and notwithstanding Article 25(2) of Directive 2003/55/EC, transmission system operators shall, in close cooperation with the relevant national authorities, actively pursue convergence of tariff structures and charging principles including in relation to balancing.

Article 4

Third party access services

1. Transmission system operators shall:

(a) ensure that they offer services on a non-discriminatory basis to all network users. In particular, where a transmission system operator offers the same service to different customers, it shall do so under equivalent contractual terms and conditions, either using harmonised transportation contracts or a network code approved by the competent authority in accordance with the procedure laid down in Article 25 of Directive 2003/55/EC;

(b) provide both firm and interruptible third party access services. The price of interruptible capacity shall reflect the probability of interruption;

(c) offer to network users both long and short-term services.

2. Transportation contracts signed with non-standard start dates or with a shorter duration than a standard annual transportation contract shall not result in arbitrarily higher or lower tariffs not reflecting the market value of the service, in accordance with the principles laid down in Article 3(1).

3. Where appropriate, third party access services may be granted subject to appropriate guarantees from network users with respect to the creditworthiness of such users. Such guarantees must not constitute any undue market entry barriers and must be non-discriminatory, transparent and proportionate.

Article 5

Principles of capacity allocation mechanisms and congestion management procedures

1. The maximum capacity at all relevant points referred to in Article 6(3) shall be made available to market participants, taking into account system integrity and efficient network operation.

2. Transmission system operators shall implement and publish non-discriminatory and transparent capacity allocation mechanisms, which shall:

(a) provide appropriate economic signals for efficient and maximum use of technical capacity and facilitate investment in new infrastructure;

(b) be compatible with the market mechanisms including spot markets and trading hubs, while being flexible and capable of adapting to evolving market circumstances;

(c) be compatible with the network access systems of the Member States.

3. When transmission system operators conclude new transportation contracts or renegotiate existing transportation contracts, these contracts shall take into account the following principles:

(a) in the event of contractual congestion, the transmission system operator shall offer unused capacity on the primary market at least on a day-ahead and interruptible basis,

(b) network users who wish to resell or sublet their unused contracted capacity on the secondary market shall be entitled to do so. Member States may require notification or information of the transmission system operator by network users.

4. When capacity contracted under existing transportation contracts remains unused and contractual congestion occurs, transmission system operators shall apply paragraph 3 unless this would infringe the requirements of the existing transportation contracts. Where this would infringe the existing transportation contracts, transmission system operators shall, following consultation with the competent authorities, submit a request to the network user for the use on the secondary market of unused capacity in accordance with paragraph 3.

5. In the event that physical congestion exists, non-discriminatory, transparent capacity allocation mechanisms shall be applied by the transmission system operator or, as appropriate, the regulatory authorities.

Article 6

Transparency requirements

1. Transmission system operators shall make public detailed information regarding the services they offer and the relevant conditions applied, together with the technical information necessary for network users to gain effective network access.

2. In order to ensure transparent, objective and non-discriminatory tariffs and facilitate efficient utilisation of the gas network, transmission system operators or relevant national authorities shall publish reasonably and sufficiently detailed information on tariff derivation, methodology and structure.

3. For the services provided, each transmission system operator shall make public information on technical, contracted and available capacities on a numerical basis for all relevant points including entry and exit points on a regular and rolling basis and in a user-friendly standardised manner.

4. The relevant points of a transmission system on which the information must be made public shall be approved by the competent authorities after consultation with network users.

5. Where a transmission system operator considers that it is not entitled for confidentiality reasons to make public all the data required, it shall seek the authorisation of the competent authorities to limit publication with respect to the point or points in question.

The competent authorities shall grant or refuse the authorisation on a case-by-case basis, taking into account in particular the need to respect legitimate commercial confidentiality and the objective of creating a competitive internal gas market. If the authorisation is granted, available capacity shall be published without indicating the numerical data that would contravene confidentiality.

No such authorisation as referred to in this paragraph shall be granted where three or more network users have contracted capacity at the same point.

6. Transmission system operators shall always disclose the information required by this Regulation in a meaningful, quantifiably clear and easily accessible way and on a non-discriminatory basis.

Article 7

Balancing rules and imbalance charges

1. Balancing rules shall be designed in a fair, non-discriminatory and transparent manner and shall be based on objective criteria. Balancing rules shall reflect genuine system needs taking into account the resources available to the transmission system operator.

2. In the case of non-market based balancing systems, tolerance levels shall be designed in a way that either reflects seasonality or results in a tolerance level higher than that resulting from seasonality, and that reflects the actual technical capabilities of the transmission system. Tolerance levels shall reflect genuine system needs taking into account the resources available to the transmission system operator.

3. Imbalance charges shall be broadly cost-reflective, whilst providing appropriate incentives on network users to balance their input and off-take of gas. They shall avoid cross-subsidisation between network users and shall not hamper the entry of new market entrants.

Any calculation methodology for imbalance charges as well as the final tariffs shall be made public by the competent authorities or the transmission system operator as appropriate.

4. Transmission system operators may impose penalty charges on network users whose input into and off-take from the transmission system is not in balance according to the balancing rules referred to in paragraph 1.

5. Penalty charges which exceed the actual balancing costs incurred shall be taken into account when calculating tariffs in a way that does not reduce the interest in balancing and shall be approved by the competent authorities.

6. In order to enable network users to take timely corrective action, transmission system operators shall provide sufficient, well-timed and reliable on-line based information on the balancing status of network users. The level of information provided shall reflect the level of information available to the transmission system operator. Where they exist, charges for the provision of such information shall be approved by the competent authorities and shall be made public by the transmission system operator.

7. Member States shall ensure that transmission system operators endeavour to harmonise balancing regimes and streamline structures and levels of balancing charges in order to facilitate gas trade.

Article 8

Trading of capacity rights

Each transmission system operator shall take reasonable steps to allow capacity rights to be freely tradable and to facilitate such trade. Each such operator shall develop harmonised transportation contracts and procedures on the primary market to facilitate secondary trade of capacity and recognise the transfer of primary capacity rights where notified by network users. The harmonised transportation contracts and procedures shall be notified to the regulatory authorities.

Article 9

Guidelines

1. Where appropriate, Guidelines providing the minimum degree of harmonisation required to achieve the aim of this Regulation shall specify:

(a) details of third party access services including the character, duration and other requirements of these services, in accordance with Article 4;

(b) details of the principles underlying capacity allocation mechanisms and on the application of congestion management procedures in the event of contractual congestion, in accordance with Article 5;

(c) details on the definition of the technical information necessary for network users to gain effective access to the system and the definition of all relevant points for transparency requirements, including the information to be published at all relevant points and the time schedule according to which this information shall be published, in accordance with Article 6.

2. Guidelines on the issues listed in paragraph 1 are laid down in the Annex. They may be amended by the Commission; this shall be done in accordance with the procedure referred to in Article 14(2).

3. The application and amendment of Guidelines adopted pursuant to this Regulation shall reflect differences between national gas systems, and shall therefore not require uniform detailed terms and conditions of third party access at Community level. They may, however, set minimum requirements to be met to achieve non-discriminatory and transparent network access conditions necessary for an internal gas market, which may then be applied in the light of differences between national gas systems.

Article 10

Regulatory authorities

When carrying out their responsibilities under this Regulation, the regulatory authorities of the Member States established under Article 25 of Directive 2003/55/EC shall ensure compliance with this Regulation and the Guidelines adopted pursuant to Article 9 of this Regulation.

Where appropriate they shall cooperate with each other and with the Commission.

Article 11

Provision of information

Member States and the regulatory authorities shall, on request, provide to the Commission all information necessary for the purposes of Article 9.

The Commission shall fix a reasonable time limit within which the information is to be provided, taking into account the complexity of the information required and the urgency with which the information is needed.

Article 12

Right of Member States to provide for more detailed measures

This Regulation shall be without prejudice to the rights of Member States to maintain or introduce measures that contain more detailed provisions than those set out in this Regulation and the Guidelines referred to in Article 9.

Article 13

Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 1 July 2006 at the latest and shall notify it without delay of any subsequent amendment affecting them.

2. Penalties provided for pursuant to paragraph 1 shall not be of a criminal law nature.

Article 14

Committee procedure

1. The Commission shall be assisted by the Committee set up by Article 30 of Directive 2003/55/EC.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 15

Commission Report

The Commission shall monitor the implementation of this Regulation. In its report under Article 31(3) of Directive 2003/55/EC, the Commission shall also report on the experience gained in the application of this Regulation. In particular the report shall examine to what extent the Regulation has been successful in ensuring non-discriminatory and cost-reflective network access conditions for gas transmission networks in order to contribute to customer choice in a well functioning internal market and to long-term security of supply. If necessary, the report shall be accompanied by appropriate proposals and/or recommendations.

Article 16

Derogations and exemptions

This Regulation shall not apply to:

(a) natural gas transmission systems situated in Member States for the duration of derogations granted under Article 28 of Directive 2003/55/EC; Member States which have been granted derogations under Article 28 of Directive 2003/55/EC may apply to the Commission for a temporary derogation from the application of this Regulation, for a period of up to two years from the date at which the derogation referred to in this point expires …;

(b) interconnectors between Member States and significant increases of capacity in existing infrastructures and modifications of such infrastructures which enable the development of new sources of gas supply as referred to in Article 22(1) and (2) of Directive 2003/55/EC which are exempted from the provisions of Articles 18, 19, 20 and 25(2), (3) and (4) of that Directive as long as they are exempted from the provisions referred to in this subparagraph; or

(c) natural gas transmission systems which have been granted derogations under Article 27 of Directive 2003/55/EC.

Article 17

Entry into force

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2006 with the exception of the second sentence of Article 9(2), which shall apply from 1 January 2007.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

GUIDELINES ON

1. **THIRD PARTY ACCESS SERVICES**

2. **PRINCIPLES UNDERLYING THE CAPACITY ALLOCATION MECHANISMS, CONGESTION MANAGEMENT PROCEDURES AND THEIR APPLICATION IN THE EVENT OF CONTRACTUAL CONGESTION, AND**

3. **DEFINITION OF THE TECHNICAL INFORMATION NECESSARY FOR NETWORK USERS TO GAIN EFFECTIVE ACCESS TO THE SYSTEM, THE DEFINITION OF ALL RELEVANT POINTS FOR TRANSPARENCY REQUIREMENTS AND THE INFORMATION TO BE PUBLISHED AT ALL RELEVANT POINTS AND THE TIME SCHEDULE ACCORDING TO WHICH THIS INFORMATION SHALL BE PUBLISHED**

1. THIRD PARTY ACCESS SERVICES

(1) Transmission system operators shall offer firm and interruptible services down to a minimum period of one day.

(2) Harmonised transportation contracts and common network code shall be designed in a manner that facilitates trading and reutilisation of capacity contracted by network users without hampering capacity release.

(3) Transmission system operators shall develop network codes and harmonised contracts following proper consultation with network users.

(4) Transmission system operators shall implement standardised nomination and renomination procedures, once agreed within the European Association for the Streamlining of the Exchange of Energy Gas (EASEE-gas). They shall develop information systems and electronic communication means to provide adequate data to network users and to simplify transactions, such as nominations, capacity contracting and transfer of capacity rights between network users.

(5) Transmission system operators shall harmonise formalised request procedures and response times according to best industry practice with the aim of minimising response times. They shall provide for on-line screen based capacity booking and confirmation systems, nominations and renominations procedures no later than 1 July 2006 if such procedures have been agreed within EASEE-gas.

(6) Transmission system operators shall not separately charge network users for information requests and transactions associated with their transportation contracts and which are carried out according to standard rules and procedures.

(7) Information requests that require extraordinary or excessive expenses such as feasibility studies may be charged separately, provided the charges can be duly substantiated.

(8) Transmission system operators shall cooperate with other transmission system operators in coordinating the maintenance of their respective networks in order to minimise any disruption of transmission services to network users and transmission system operators in other areas and in order to ensure equal benefits with respect to security of supply including in relation to transit.

(9) Transmission system operators shall publish at least once a year, by a predetermined deadline, all planned maintenance periods that might affect network users' rights from transportation contracts and corresponding operational information with adequate advance notice. This shall include publishing on a prompt and non-discriminatory basis any changes to planned maintenance periods and notification of unplanned maintenance, as soon as that information becomes available to the transmission system operator. During maintenance periods, transmission system operators shall publish regularly updated information on the details of and expected duration and effect of the maintenance.

(10) Transmission system operators shall maintain and make available to the competent authority upon request a daily log of the actual maintenance and flow disruptions that have occurred. Information shall also be made available on request to those affected by any disruption.

2. PRINCIPLES UNDERLYING CAPACITY ALLOCATION MECHANISMS, CONGESTION MANAGEMENT PROCEDURES AND THEIR APPLICATION IN THE EVENT OF CONTRACTUAL CONGESTION

2.1. **Principles underlying capacity allocation mechanisms and congestion management procedures**

(1) Capacity allocation mechanisms and congestion management procedures shall facilitate the development of competition and liquid trading of capacity and shall be compatible with market mechanisms including spot markets and trading hubs. They shall be flexible and capable of adapting to evolving market circumstances.

(2) These mechanisms and procedures shall take into account the integrity of the system concerned as well as security of supply.

(3) These mechanisms and procedures shall neither hamper the entry of new market participants nor create undue barriers to market entry. They shall not prevent market participants, including new market entrants and companies with a small market share, from competing effectively.

(4) These mechanisms and procedures shall provide appropriate economic signals for efficient and maximum use of technical capacity and facilitate investment in new infrastructure.

(5) Network users shall be advised about the type of circumstance that could affect the availability of contracted capacity. Information on interruption should reflect the level of information available to the transmission system operator.

(6) Should difficulties in meeting contractual delivery obligations arise due to system integrity reasons, transmission system operators should notify network users and seek a non-discriminatory solution without delay.

Transmission system operators shall consult network users regarding procedures prior to their implementation and agree them with the regulatory authority.

2.2. **Congestion management procedures in the event of contractual congestion**

(1) In the event that contracted capacity goes unused, transmission system operators shall make this capacity available on the primary market on an interruptible basis via contracts of differing duration, as long as this capacity is not offered by the relevant network user on the secondary market at a reasonable price.

(2) Revenues from released interruptible capacity shall be split according to rules laid down or approved by the relevant regulatory authority. These rules shall be compatible with the requirement of an effective and efficient use of the system.

(3) A reasonable price for released interruptible capacity may be determined by the relevant regulatory authorities taking into account the specific circumstances prevailing.

(4) Where appropriate, transmission system operators shall make reasonable endeavours to offer at least parts of the unused capacity to the market as firm capacity.

3. DEFINITION OF THE TECHNICAL INFORMATION NECESSARY FOR NETWORK USERS TO GAIN EFFECTIVE ACCESS TO THE SYSTEM, THE DEFINITION OF ALL RELEVANT POINTS FOR TRANSPARENCY REQUIREMENTS AND THE INFORMATION TO BE PUBLISHED AT ALL RELEVANT POINTS AND THE TIME SCHEDULE ACCORDING TO WHICH THIS INFORMATION SHALL BE PUBLISHED

3.1. **Definition of the technical information necessary for network users to gain effective access to the system**

Transmission system operators shall publish at least the following information about their systems and services:

(a) a detailed and comprehensive description of the different services offered and their charges;

(b) the different types of transportation contracts available for these services and, as applicable, the network code and/or the standard conditions outlining the rights and responsibilities of all network users including harmonised transportation contracts and other relevant documents;

(c) the harmonised procedures applied when using the transmission system, including the definition of key terms;

(d) provisions on capacity allocation, congestion management and anti-hoarding and reutilisation procedures;

(e) the rules applicable for capacity trade on the secondary market *vis-à-vis* the transmission system operator;

(f) if applicable, the flexibility and tolerance levels included in transportation and other services without separate charge, as well as any flexibility offered in addition to this and the corresponding charges;

(g) a detailed description of the gas system of the transmission system operator indicating all relevant points interconnecting its system with that of other transmission system operators and/or gas infrastructure such as liquefied natural gas (LNG) and infrastructure necessary for providing ancillary services as defined by Article 2(14) of Directive 2003/55/EC;

(h) information on gas quality and pressure requirements;

(i) the rules applicable for connection to the system operated by the transmission system operator;

(j) any information, in a timely manner, on proposed and/or actual changes to the services or conditions, including the items listed in points (a) to (i).

3.2. **Definition of all relevant points for transparency requirements**

Relevant points shall include at least:

(a) all entry points to a network operated by a transmission system operator;

(b) the most important exit points and exit zones covering at least 50 % of total exit capacity of the network of a given transmission system operator, including all exit points or exit zones covering more than 2 % of total exit capacity of the network;

(c) all points connecting different networks of transmission system operators;

(d) all points connecting the network of a transmission system operator with an LNG terminal;

(e) all essential points within the network of a given transmission system operator including points connecting to gas hubs. All points are considered essential which, based on experience, are likely to experience physical congestion;

(f) all points connecting the network of a given transmission system operator to infrastructure necessary for providing ancillary services as defined by Article 2(14) of Directive 2003/55/EC.

3.3. **Information to be published at all relevant points and the time schedule according to which this information should be published**

(1) At all relevant points, transmission system operators shall publish the following information about the capacity situation down to daily periods on the Internet on a regular/rolling basis and in a user-friendly standardised manner:

(a) the maximum technical capacity for flows in both directions,

(b) the total contracted and interruptible capacity,

(c) the available capacity.

(2) For all relevant points, transmission system operators shall publish available capacities for a period of at least 18 months ahead and shall update this information at least every month or more frequently, if new information becomes available.

(3) Transmission system operators shall publish daily updates of availability of short-term services (day-ahead and week-ahead) based, inter alia, on nominations, prevailing contractual commitments and regular long-term forecasts of available capacities on an annual basis for up to 10 years for all relevant points.

(4) Transmission system operators shall publish historical maximum and minimum monthly capacity utilisation rates and annual average flows at all relevant points for the past three years on a rolling basis.

(5) Transmission system operators shall keep a daily log of actual aggregated flows for at least three months.

(6) Transmission system operators shall keep effective records of all capacity contracts and all other relevant information in relation to calculating and providing access to available capacities, to which relevant national authorities shall have access to fulfil their duties.

(7) Transmission system operators shall provide user-friendly instruments for calculating tariffs for the services available and for verifying on-line the capacity available.

(8) Where transmission system operators are unable to publish information in accordance with paragraphs 1, 3 and 7, they shall consult with their relevant national authorities and set up an Action Plan for implementation as soon as possible, but not later than 31 December 2006.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 12 December 2003, the Commission presented a proposal for a European Parliament and Council Regulation on conditions for access to the gas transmission networks based on Article 95 of the EC Treaty.

2. The Economic and Social Committee delivered its Opinion on 2 June 2004.

3. The European Parliament adopted its Opinion at first reading on 20 April 2004, approving 41 amendments. The Commission will not present a modified proposal.

4. On 12 November 2004, the Council adopted its Common Position in accordance with Article 251 of the Treaty.

II. OBJECTIVE OF THE PROPOSAL

The proposal aims at completing the Internal Gas Market Directive (2003/55/EC) adopted last year by setting fair and detailed rules for third party access to the gas transmission networks of Member States, taking into account the specificities of national and regional markets. It can be seen as a parallel to Regulation (EC) 1228/2003 on conditions for access to the network for cross-border exchanges in electricity, adopted as part of the internal market package. The proposal builds on a set of guidelines agreed on a voluntary basis by the European Gas Regulatory Forum (Madrid Forum) which will receive a binding character through the proposed Regulation.

III. ANALYSIS OF THE COMMON POSITION

1. GENERAL REMARKS

(a) Concerning the *41 amendments of the European Parliament*, the Council has followed the Commission in

— accepting the following 22 amendments:

— fully (sometimes with redrafting): 7, 12, 15, 18 to 21, 23, 26, 32, 34 and 39 to 41;

— partly: 1, 4, 25;

— in principle: 3, 13, 29, 36 and 38, and

— rejecting the following 18 amendments: 2, 5, 8 to 11, 14, 16 and 17, 22, 24, 27, 30 and 31, 35, 37, 42 and 43, on grounds of substance and/or of form.

The Council also accepted implicitly amendment 33.

(b) Concerning the *Commission proposal*, the Council has introduced certain other modifications (of substance and/or of form) which are reflected below.

All the changes which the Council has introduced to the Commission proposal have been accepted by the Commission.

2. SPECIFIC REMARKS

(a) The **main changes** introduced by the Council in the draft Regulation concern the Guidelines referred to in *Article 9*, the scope of which the Council has reduced; in particular the Commission's possibility to adopt *new* Guidelines through the committee procedure has been deleted from the Commission proposal, leaving for the Commission the competence to *amend* the Guidelines laid down in the Annex of the draft Regulation; these Guidelines concern third party access services, the principles of capacity allocation mechanisms and congestion management procedures, and transparency requirements. The Council has also introduced an additional paragraph to Article 9 where it is made clear that differences between national gas systems should be reflected in the Guidelines and their application and future amendments.

Moreover, the Council has introduced a new Article (*Article 16*) which confirms that the relevant derogations and exemptions granted under Directive 2003/55/EC apply also to this Regulation.

The Council has also delayed the date of application of the Regulation from 1 July 2005 to 1 July 2006 except for Article 9(2) for which the date of application is 1 January 2007 (*Article 17*).

(b) Other changes concern in particular

— *Article 2(1(1))*: the Council has slightly changed the definition of transmission to clarify to which pipelines the definition applies; along with this change goes the introduction of *recital 5*;

— *Article 2(1(4) and (18))*: the Council has introduced two new definitions (of 'unused capacity' and of 'firm services');

— *Article 2(1(23) and (24))*: the Council has deleted the definitions of *new market entrants* and of *small player*, considering that the Regulation should apply to all market actors in the same way;

— *Article 3(1)* where the Council has introduced a new *second subparagraph* to ensure that the use of auctions are a possible means to determine tariffs; along with this goes the introduction of *recital 8*;

— *Article 5(4) and Article 7(6)*: the Council has reformulated these provisions for clarification purposes;

— *Article 6(4)*: the second sentence of this paragraph has been changed with a view to giving it a more precise scope, and has been transferred to the Annex (point 3.2(b)), in particular because of its level of detail;

— *Article 11(2) to (5)*: the Council has deleted these paragraphs and subsequently also paragraph 1 of *Article 13*;

— A number of cross-references to Directive 2003/55/EC have been introduced for clarification purposes (Articles 1(2) (new); 3(1) and (2); 4(1); 10; 14; 15 (see *amendment 36*));

— The Council has also introduced a number of *new recitals*, in addition to those already mentioned, in particular to reflect changes in the Articles (*recitals 4, 7, 10, 16 and 19* (corresponding to *amendment 3*).

IV. **CONCLUSIONS**

The Council believes that to a large extent the common position meets the substance of most of the wishes expressed by the European Parliament, and that it will contribute to the achievement and the proper functioning of the internal gas market.