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Contents

[1] Text with EEA relevance

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(Continued overleaf)

Contents (continued)

EN

(Continued on inside back cover)

Contents (continued)

[1] Text with EEA relevance

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(Acts whose publication is obligatory)

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and Article 152(4)(b) thereof,

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

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

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure referred to in Article 251 of the Treaty [4],

Whereas:

(1) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [5]. This procedure should be streamlined and made more transparent.

(6) Regulation (EC) No 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990 [6] and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [7]; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

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[1] OJ C 304 E, 30.10.2001, p. 221.
[2] OJ C 221, 17.9.2002, p. 114.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[5] OJ L 43, 14.2.1997, p. 1.
[6] OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.
[7] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

(9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by 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 ([1]). Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.

(10) Experience has shown that authorisation should not be granted for a single use, when a product is likely to be used both for food and feed purposes; therefore such products should only be authorised when fulfilling authorisation criteria for both food and feed.

(11) Under this Regulation, authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

(12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ([2]) provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC.

(13) Flavourings falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([3]) which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.

(14) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([4]) provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment. These feed materials containing, consisting of or produced from GMOs should fall instead within the scope of this Regulation.

(15) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([5]), provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall within the scope of this Regulation.

(16) This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore,

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).
([3]) OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).
([4]) OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).
([5]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

(17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

(18) Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([1]) provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

(19) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97, in Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC ([2]) and in Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms ([3]).

(20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.

(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

(22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

(23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([4]) ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.

(24) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.

(25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.

(26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for

([1]) OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).
([2]) OJ L 159, 3.6.1998, p. 4. Regulation as amended by Commission Regulation (EC) No 49/2000 (OJ L 6, 11.1.2000, p. 13).
([3]) OJ L 6, 11.1.2000, p. 15.

([4]) See page 24 of this Official Journal.

GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.

(27) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.

(28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.

(29) The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.

(30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed.

(31) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the Authority. However, as specific acts or omissions on the part of the Authority under this Regulation could produce direct legal effects on applicants, it is appropriate to provide for the possibility of an administrative review of such acts or omissions.

(32) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.

(33) Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.

(34) In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of Directives 68/193/EEC ([1]), 2002/53/EC ([2]) and 2002/55/EC ([3]), which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues; nor should they affect the provisions of Directives 66/401/EEC ([4]), 66/402/EEC ([5]), 68/193/EEC, 92/33/EEC ([6]), 92/34/EEC ([7]), 2002/54/EC ([8]), 2002/55/EC, 2002/56/EC ([9]) or 2002/57/EC ([10]) which regulate in particular the certification and the marketing of seeds and other plant-propagating materials.

([1]) OJ L 93, 17.4.1968, p. 15. Directive as last amended by Directive 2002/11/EC (OJ L 53, 23.2.2002, p. 20).
([2]) OJ L 193, 20.7.2002, p. 1.
([3]) OJ L 193, 20.7.2002, p. 33.
([4]) OJ 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2001/64/EC (OJ L 234, 1.9.2001, p. 60).
([5]) OJ 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2001/64/EC.
([6]) OJ L 157, 10.6.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
([7]) OJ L 157, 10.6.1992, p. 10. Directive as last amended by Regulation (EC) No 806/2003.
([8]) OJ L 193, 20.7.2002, p. 12.
([9]) OJ L 193, 20.7.2002, p. 60. Directive amended by Commission Decision 2003/66/EC (OJ L 25, 30.1.2003, p. 42).
([10]) OJ L 193, 20.7.2002, p. 74. Directive amended by Commission Directive 2003/45/EC (OJ L 138, 5.6.2003, p. 40).

(35) It is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory under Directive 2001/18/EC.

(36) To facilitate controls on genetically modified food and feed, applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.

(37) Technological progress and scientific developments should be taken into account when implementing this Regulation.

(38) Food and feed falling within the scope of this Regulation which have been lawfully placed on the Community market before the date of application of this Regulation should continue to be allowed on the market, subject to the transmission to the Commission by the operators of information concerning the risk assessment, methods for sampling, identification and detection as appropriate, including the transmission of samples of the food and feed and their control samples within six months after the date of application of this Regulation.

(39) A register of genetically modified food and feed authorised under this Regulation should be established, including product specific information, studies which demonstrate the safety of the product, including, where available, references to independent and peer-reviewed studies, and to methods for sampling, identification and detection. Non-confidential data should be made available to the public.

(40) In order to stimulate research and development into GMOs for food and/or feed use, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials which would be against the public interest.

(41) 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].

(42) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, or any other appropriate body established by the Commission, with a view to obtaining advice on ethical issues regarding the placing on the market of genetically modified food or feed. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(43) In order to provide a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles referred to in Regulation (EC) No 178/2002. The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.

(44) Certain instruments of Community law should be repealed and others amended as a result of this Regulation.

(45) The implementation of this Regulation should be reviewed in the light of experience gained in the short term, and the impact of the application of this Regulation on human and animal health, consumer protection, consumer information and the functioning of the internal market should be monitored by the Commission,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVE AND DEFINITIONS

Article 1

Objective

The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to:

(a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;

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

(b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;

(c) lay down provisions for the labelling of genetically modified food and feed.

Article 2

Definitions

For the purposes of this Regulation:

1. the definitions of 'food', 'feed', 'final consumer', 'food business' and 'feed business' given in Regulation (EC) No 178/2002 shall apply;

2. the definition of 'traceability', laid down in Regulation (EC) No 1830/2003;

3. 'operator' means the natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control;

4. the definitions of 'organism', 'deliberate release' and 'environmental risk assessment' referred to in Directive 2001/18/EC shall apply;

5. 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

6. 'genetically modified food' means food containing, consisting of or produced from GMOs;

7. 'genetically modified feed' means feed containing, consisting of or produced from GMOs;

8. 'genetically modified organism for food use' means a GMO that may be used as food or as a source material for the production of food;

9. 'genetically modified organism for feed use' means a GMO that may be used as feed or as a source material for the production of feed;

10. 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

11. 'control sample' means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample);

12. 'conventional counterpart' means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use;

13. 'ingredient' means 'ingredient' as referred to in Article 6(4) of Directive 2000/13/EC;

14. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

15. 'pre-packaged food' means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

16. 'mass caterer' means 'mass caterer' as referred to in Article 1 of Directive 2000/13/EC.

CHAPTER II

GENETICALLY MODIFIED FOOD

Section 1

Authorisation and supervision

Article 3

Scope

1. This Section shall apply to:

(a) GMOs for food use;

(b) food containing or consisting of GMOs;

(c) food produced from or containing ingredients produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of food falls within the scope of this Section.

Article 4

Requirements

1. Food referred to in Article 3(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the consumer;

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

2. No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4. The authorisation referred to in paragraph 2 may cover:

(a) a GMO and foods containing or consisting of that GMO as well as foods produced from or containing ingredients produced from that GMO; or

(b) food produced from a GMO as well as foods produced from or containing that food;

(c) an ingredient produced from a GMO as well as food containing that ingredient.

5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Article 5

Application for authorisation

1. To obtain the authorisation referred to in Article 4(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the Authority); and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority

(i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.

3. The application shall be accompanied by the following:

(a) the name and the address of the applicant;

(b) the designation of the food, and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);

(d) where applicable, a detailed description of the method of production and manufacturing;

(e) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1);

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3);

(g) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b);

(h) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

(j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;

(l) a summary of the dossier in a standardised form.

4. In the case of an application relating to a GMO for food use, references to 'food' in paragraph 3 shall be interpreted as referring to food containing, consisting of or produced from the GMO in respect of which an application is made.

5. In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6. Where the application concerns a substance, the use and placing on the market of which is subject, under other provisions of Community law, to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

Article 6

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 5 and examine whether the food complies with the criteria referred to in Article 4(1);

(b) may ask the appropriate food assessment body of a Member State to carry out a safety assessment of the food in accordance with Article 36 of Regulation (EC) No 178/2002;

(c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;

(d) shall forward to the Community reference laboratory referred to in Article 32 the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;

(e) shall, in verifying the application of Article 13(2)(a), examine the information and data submitted by the applicant to show that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5. In the event of an opinion in favour of authorising the food, the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the food, and its specification;

(c) where applicable, the information required under Annex II to the Cartagena Protocol;

(d) the proposal for the labelling of the food and/or foods produced from it;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate, the monitoring plan referred to in Article 5(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the food and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

Article 7

Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 6(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in the Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 11. The authorised food shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

7. The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

Article 8

Status of existing products

1. By way of derogation from Article 4(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 or in accordance with the provisions referred to in Regulation (EC) No 258/97, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but are not covered by point (a), operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 5(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 7(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and food containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 9, 10 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure referred to in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

7. In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to Commission.

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

Article 9

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 5(3)(k) and/or monitoring as referred to in Article 5(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 5(2). Articles 5, 6 and 7 shall apply *mutatis mutandis*.

3. The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food. In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

Article 10

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 7.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

Article 11

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following:

(a) a copy of the authorisation for placing the food on the market;

(b) a report on the results of the monitoring, if so specified in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the food and the risks of the food to the consumer or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Section 2

Labelling

Article 12

Scope

1. This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:

(a) contain or consist of GMOs; or

(b) are produced from or contain ingredients produced from GMOs.

2. This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2) in particular in respect of foods containing or consisting of GMOs or in order to take into account advances in science and technology.

Article 13

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods falling within the scope of this Section shall be subject to the following specific labelling requirements:

(a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

(b) where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients;

(c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

2. In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

(a) where a food is different from its conventional counterpart as regards the following characteristics or properties:

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.

3. In addition to the labelling requirements referred to in paragraph 1 and as specified in the authorisation, the labelling of foods falling within the scope of this Section which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.

Article 14

Implementing measures

1. Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

2. Specific rules concerning the information to be given by mass caterers providing food to the final consumer may be adopted in accordance with the procedure referred to in Article 35(2).

In order to take into account the specific situation of mass caterers, such rules may provide for adaptation of the requirements of Article 13(1)(e).

CHAPTER III

GENETICALLY MODIFIED FEED

Section 1

Authorisation and supervision

Article 15

Scope

1. This Section shall apply to:

(a) GMOs for feed use;

(b) feed containing or consisting of GMOs;

(c) feed produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of feed falls within the scope of this Section.

Article 16

Requirements

1. Feed referred to in Article 15(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the user;

(c) harm or mislead the consumer by impairing the distinctive features of the animal products;

(d) differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

2. No person shall place on the market, use or process a product referred to in Article 15(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No product referred to in Article 15(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4. The authorisation referred to in paragraph 2 may cover:

(a) a GMO and feed containing or consisting of that GMO as well as feed produced from that GMO; or

(b) feed produced from a GMO as well as feeds produced from or containing that feed.

5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Article 17

Application for authorisation

1. To obtain the authorisation referred to in Article 16(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform the Authority without delay; and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority:

(i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.

3. The application shall be accompanied by the following:

(a) the name and the address of the applicant;

(b) the designation of the feed and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;

(d) where applicable, a detailed description of the method of production and manufacturing and intended uses of the feed;

(e) a copy of the studies including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the feed complies with the criteria referred to in Article 16(1), and, in particular for feed falling within the scope of Directive 82/471/EEC, the information required under Council Directive 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition [1];

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 25(2)(c), or a proposal for labelling the feed in accordance with Article 25(2)(c) and (3);

(g) either a reasoned statement that the feed does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 25(2)(d);

(h) where appropriate, the conditions for placing the feed on the market, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in the feed produced from it;

(j) samples of the feed and their control samples and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring for the use of the feed for animal consumption;

(l) a summary of the dossier in a standardised form.

4. In the case of an application relating to a GMO for feed use, references to 'feed' in paragraph 3 shall be interpreted as referring to feed containing, consisting of or produced from the GMO in respect of which an application is made.

5. In the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMOs has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6. Where the application concerns a substance, the use and placing on the market of which is subject under other provisions of Community law to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

[1] OJ L 126, 13.5.1983, p. 23.

Article 18

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to comply with a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion, the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 17, and examine whether the feed complies with the criteria laid down in Article 16(1);

(b) may ask the appropriate feed assessment body of a Member State to carry out a safety assessment of the feed in accordance with Article 36 of Regulation (EC) No 178/2002;

(c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;

(d) shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;

(e) shall, in verifying the application of Article 25(2)(c), examine the information and data submitted by the applicant to show that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or feed containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC, designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5. In the event of an opinion in favour of authorising the feed, the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the feed, and its specification;

(c) where applicable, the information required under Annex II to the Cartagena Protocol;

(d) the proposal for the labelling of the feed;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in feed produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate, the monitoring plan as referred to in Article 17(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

Article 19

Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 18(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 23. The authorised feed shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

7. The granting of authorisation shall not lessen the general civil and criminal liability of any feed operator in respect of the feed concerned.

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

Article 20

Status of existing products

1. By way of derogation from Article 16(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC, which are produced from GMOs, or under Directive 70/524/EEC, which contain, consist of or are produced from GMOs, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but which are not referred to in point (a), operators responsible for placing on the market in the Community the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 17(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 19(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure laid down in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

7. In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to the Commission.

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

Article 21

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and the parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 17(3)(k) and/or monitoring as referred to in Article 17(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 17(2). Articles 17, 18 and 19 shall apply *mutatis mutandis*.

3. The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the feed. In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent Authority of any third country in which the feed is placed on the market.

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

Article 22

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 19.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

Article 23

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following particulars and documents:

(a) a copy of the authorisation for placing the feed on the market;

(b) a report on the results of the monitoring, if so specified in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed and the risks of the feed to animals, humans or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Section 2

Labelling

Article 24

Scope

1. This Section shall apply to feed referred to in Article 15(1).

2. This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2), in particular in respect of feed containing or consisting of GMOs, or in order to take into account advances in science and technology.

Article 25

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) shall be subject to the specific labelling requirements laid down below.

2. No person shall place a feed referred to in Article 15(1) on the market unless the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto.

Each feed of which a particular feed is composed shall be subject to the following rules:

(a) for the feeds referred to in Article 15(1) (a) and (b), the words 'genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(b) for the feed referred to in Article 15(1)(c), the words 'produced from genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(c) as specified in the authorisation, any characteristic of the feed referred to in Article 15(1) such as those indicated hereunder, which is different from its conventional counterpart:

(i) composition;

(ii) nutritional properties;

(iii) intended use;

(iv) implications for the health of certain species or categories of animals;

(d) as specified in the authorisation, any characteristic or property where a feed may give rise to ethical or religious concerns.

3. In addition to the requirements referred to in paragraph 2(a) and (b) and as specified in the authorisation, the labelling or accompanying documents of feed falling within the scope of this Section which does not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the feed concerned.

Article 26

Implementing measures

Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

CHAPTER IV

COMMON PROVISIONS

Article 27

Products likely to be used as both food and feed

1. Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision.

2. The Authority shall consider whether the application for authorisation should be submitted both as food and feed.

Article 28

Community register

1. The Commission shall establish and maintain a Community register of genetically modified food and feed, hereinafter referred to as 'the Register'.

2. The Register shall be made available to the public.

Article 29

Public access

1. The application for authorisation, supplementary information from the applicant, opinions from the competent authorities designated in accordance with Article 4 of Directive 2001/18/EC, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public.

2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1] when handling applications for access to documents held by the Authority.

3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 30

Confidentiality

1. The applicant may indicate which information submitted under this Regulation it wishes to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision.

3. Information relating to the following shall not be considered confidential:

(a) name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;

(b) general description of the GMO and the name and address of the authorisation-holder;

(c) physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);

(d) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on human and animal health and on the environment;

(e) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;

(f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3(1) and 15(1);

(g) information on waste treatment and emergency response.

4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and Member States with all information in its possession.

5. The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.

6. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

7. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information as to the confidentiality of which the Commission and the applicant disagree.

Article 31

Data protection

The scientific data and other information in the application dossier required under Article 5(3) and (5) and Article 17(3) and (5) may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used.

On the expiry of this 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

Article 32

Community reference laboratory

The Community reference laboratory and its duties and tasks shall be those referred to in the Annex.

National reference laboratories may be established in accordance with the procedure referred to in Article 35(2).

Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the Community reference laboratory and the European Network of GMO laboratories mentioned in the Annex.

[1] OJ L 145, 31.5.2001, p. 43.

The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

Detailed rules for implementing this Article, the Annex and any changes to it may be adopted in accordance with the procedure referred to in Article 35(2).

Article 33

Consultation with the European Group on Ethics in Science and New Technologies

1. The Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics in Science and New Technologies or any other appropriate body it might establish, with a view to obtaining its opinion on ethical issues.

2. The Commission shall make these opinions available to the public.

Article 34

Emergency measures

Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 35

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 36

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.

To this effect a request shall be submitted to the Commission within two months from 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.

Article 37

Repeals

The following Regulations shall be repealed with effect from the date of application of this Regulation:

— Regulation (EC) No 1139/98,

— Regulation (EC) No 49/2000,

— Regulation (EC) No 50/2000.

Article 38

Amendments to Regulation (EC) No 258/97

Regulation (EC) No 258/97 is hereby amended with effect from the date of application of this Regulation as follows:

1. The following provisions shall be deleted:
   — Article 1(2)(a) and (b),
   — Article 3(2), second subparagraph, and (3),
   — Article 8(1)(d),
   — Article 9.

2. In Article 3, the first sentence of paragraph 4 shall be replaced by the following:

   '4. By way of derogation from paragraph 2, the procedure referred to in Article 5 shall apply to foods or food ingredients referred to in Article 1(2)(d) and (e) which, on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4(3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.'

Article 39

Amendment to Directive 82/471/EEC

The following paragraph shall be added to Article 1 of Directive 82/471/EEC with effect from the date of application of this Regulation:

'3. This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*).

(*) OJ L 268, 18.10.2003, p. 1.'

Article 40

Amendments to Directive 2002/53/EC

Directive 2002/53/EC is hereby amended with effect from the date of application of this Regulation as follows:

1. Article 4(5) shall be replaced by the following:

'5. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L 268, 18.10.2003, p. 1.'

2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of 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 (*) is accepted only if it has been authorised under the relevant legislation.

(*) OJ L 31, 1.2.2002, p. 1.'

Article 41

Amendments to Directive 2002/55/EC

Directive 2002/55/EC is hereby amended with effect from the date of application of this Regulation as follows:

1. Article 4(3) shall be replaced by the following:

'3. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L 268, 18.10.2003, p. 1.'

2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of 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 (*) is accepted only if it has been authorised under the relevant legislation.

(*) OJ L 31, 1.2.2002, p. 1.'

Article 42

Amendment to Directive 68/193/EEC

Article 5ba(3) of Directive 68/193/EEC shall be replaced by the following wording with effect from the date of application of this Regulation:

'3. (a) Where products derived from vine-propagating material are intended to be used as or in food falling within the scope of Article 3 or as or in a feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the vine variety concerned shall be accepted only if it has been authorised pursuant to the said Regulation.

(b) Member States shall ensure that a vine variety, from the propagating material of which products were derived intended for use in food and feed pursuant to Articles 2 and 3 of 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 (**) shall be accepted only if it has been authorised pursuant to the relevant legislation.

(*) OJ L 268, 18.10.2003, p. 1.
(**) OJ L 31, 1.2.2002, p. 1.'

Article 43

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is hereby amended with effect from the date of entry into force of this Regulation, as follows:

1. The following Article shall be inserted:

'*Article 12a*

Transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation

1. Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to

21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*).

2. This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.

(*) OJ L 268, 18.10.2003, p. 1.'

2. The following Article shall be inserted:

'*Article 26a*

Measures to avoid the unintended presence of GMOs

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.'

Article 44

Information to be provided in accordance with the Cartagena Protocol

1. Any authorisation, renewal, modification, suspension or revocation of authorisation of a GMO, food or feed referred to in Articles 3(1)(a) or (b) or 15(1)(a) or (b) shall be notified by the Commission to the Parties to the Cartagena Protocol through the biosafety clearing house in accordance with Article 11(1) or Article 12(1) of the Cartagena Protocol, as the case may be.

The Commission shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the biosafety clearing house.

2. The Commission shall also process requests for additional information made by any Party in accordance with Article 11(3) of the Cartagena Protocol and shall provide copies of the laws, regulations and guidelines in accordance with Article 11(5) of that Protocol.

Article 45

Penalties

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 six months after the date of entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 46

Transitional measures for requests, labelling and notifications

1. Requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be transformed into applications under Chapter II, Section 1 of this Regulation where the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of this Regulation.

2. The labelling requirements referred to in this Regulation shall not apply to products, the manufacturing process of which has commenced before the date of application of this Regulation, provided that these products are labelled in accordance with the legislation applicable to them before the date of application of this Regulation.

3. Notifications concerning products including their use as feed submitted under Article 13 of Directive 2001/18/EC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation where the assessment report provided for in Article 14 of Directive 2001/18/EC has not yet been sent to the Commission.

4. Requests submitted for products referred to in Article 15(1)(c) of this Regulation under Article 7 of Directive 82/471/EEC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation.

5. Requests submitted for products referred to in Article 15(1) of this Regulation under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be supplemented by applications under Chapter III, Section 1 of this Regulation.

Article 47

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

1. The presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0,5 % shall not be considered to be in breach of Article 4(2) or Article 16(2), provided that:

(a) this presence is adventitious or technically unavoidable;

(b) the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;

(c) the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and

(d) detection methods are publicly available.

2. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

3. The thresholds referred to in paragraph 1 may be lowered in accordance with the procedure referred to in Article 35(2), in particular for GMOs sold directly to the final consumer.

4. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

5. This Article shall remain applicable for a period of three years after the date of application of this Regulation.

Article 48

Review

1. No later than 7 November 2005 and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 47, accompanied, where appropriate, by any suitable proposal. The report and any proposal shall be made accessible to the public.

2. Without prejudice to the powers of national authorities, the Commission shall monitor the application of this Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 49

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from six months after the date of publication of this Regulation.

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

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

ANNEX

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory referred to in Article 32 is the Commission's Joint Research Centre.

2. For the tasks outlined in this Annex, the Commission's Joint Research Centre shall be assisted by a consortium of national reference laboratories, which will be referred to as the 'European Network of GMO laboratories'.

3. The Community reference laboratory shall be responsible, in particular, for:

   — reception, preparation, storage, maintenance and distribution to national reference laboratories of the appropriate positive and negative control samples,

   — testing and validation of the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed,

   — evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection,

   — submitting full evaluation reports to the Authority.

4. The Community reference laboratory shall play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.

REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95(1) thereof,

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

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

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [5] requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.

(2) Differences between national laws, regulations and administrative provisions concerning traceability and labelling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market. Directive 2001/18/EC should therefore be amended accordingly.

(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.

(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [6], so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.

(5) The transmission and holding of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provide the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.

(6) The transmission and holding of information that food and feed have been produced from GMOs also provide the basis for the appropriate traceability of products produced from GMOs.

(7) The Community legislation concerning GMOs as or in feed should also apply to feed intended for animals which are not destined for food production.

(8) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection and provide legal certainty for operators. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No 1829/2003.

(9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.

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[1] OJ C 304 E, 30.10.2001, p. 327 and OJ C 331 E, 31.12.2002, p. 308.
[2] OJ C 125, 27.5.2002, p. 69.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 21), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[5] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).
[6] See page 1 of this Official Journal.

(10) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material consisting, containing or produced from GMOs both when the marketing of such GMOs is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article 47 of Regulation (EC) No 1829/2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the above material in a food or feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.

(11) It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product.

(12) 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].

(13) Systems for the development and assignment of unique identifiers for GMOs should be established before the measures relating to traceability and labelling can be applied.

(14) The Commission should submit a report to the European Parliament and the Council on the implementation of this Regulation and, more specifically, on the effectiveness of the rules on traceability and labelling.

(15) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

Article 1

Objectives

This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

Article 2

Scope

1. This Regulation shall apply, at all stages of the placing on the market, to:

(a) products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;

(b) food produced from GMOs, placed on the market in accordance with Community legislation;

(c) feed produced from GMOs, placed on the market in accordance with Community legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93 [2].

Article 3

Definitions

For the purpose of this Regulation:

1. 'Genetically modified organism' or 'GMO' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;

2. 'Produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

3. 'Traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

4. 'Unique identifier' means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO;

5. 'Operator' means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the Community, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer;

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

[2] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (OJ L 214, 24.8.1993, p. 1). Regulation as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

6. 'Final consumer' means the ultimate consumer who will not use the product as part of any business operation or activity;

7. 'Food' means food as defined in Article 2 of Regulation (EC) No 178/2002 ([1]);

8. 'Ingredient' means ingredient as referred to in Article 6(4) of Directive 2000/13/EC ([2]);

9. 'Feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;

10. 'Placing on the market' means placing on the market as defined in the specific Community legislation under which the relevant product has been authorised; in other cases, it is defined as in Article 2(4) of Directive 2001/18/EC;

11. 'The first stage of the placing on the market of a product' means the initial transaction in the production and distribution chains, where a product is made available to a third party;

12. 'Pre-packaged product' means any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

Article 4

Traceability and labelling requirements for products consisting of or containing GMOs

A. TRACEABILITY

1. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) that it contains or consists of GMOs;

(b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

3. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

4. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.

5. Paragraphs 1 to 4 shall be without prejudice to other specific requirements in Community legislation.

B. LABELLING

6. For products consisting of or containing GMOs, operators shall ensure that:

(a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label;

(b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice to other specific requirements in Community legislation.

C. EXEMPTIONS

7. Paragraphs 1 to 6 shall not apply to traces of GMOs in products in a proportion no higher than the thresholds established in accordance with Article 21(2) or (3) of Directive 2001/18/EC and in other specific Community legislation, provided that these traces of GMOs are adventitious or technically unavoidable.

8. Paragraphs 1 to 6 shall not apply to traces of GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

([1]) 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 (OJ L 31, 1.2.2002, p. 1).

([2]) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

Article 5

Traceability requirements for products for food and feed produced from GMOs

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) an indication of each of the food ingredients which is produced from GMOs;

(b) an indication of each of the feed materials or additives which is produced from GMOs;

(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of the information specified in paragraph 1 and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products referred to in paragraph 1 have been made available.

3. Paragraphs 1 and 2 shall be without prejudice to other specific requirements in Community legislation.

4. Paragraphs 1, 2 and 3 shall not apply to traces of GMOs in products for food and feed produced from GMOs in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

Article 6

Exemptions

1. In cases where Community legislation provides for specific identification systems, such as lot numbering for prepackaged products, operators shall not be obliged to hold the information specified in Articles 4(1), 4(2), 4(3) and 5(1), provided that this information and the lot number is clearly marked on the package and that information about lot numbers is held for the periods of time referred to in Articles 4(4) and 5(2).

2. Paragraph 1 shall not apply to the first stage of placing on the market of a product or to primary manufacture or repackaging of a product.

Article 7

Amendment of Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

1. Article 4(6) is deleted;

2. the following paragraph is added to Article 21:

'3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9 % or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable.'

Article 8

Unique identifiers

In accordance with the procedure referred to in Article 10(2), the Commission shall:

(a) prior to the application of Articles 1 to 7 establish a system for development and assignment of unique identifiers to GMOs;

(b) adapt the system provided for in point (a), as appropriate.

In so doing, account shall be taken of developments in international fora.

Article 9

Inspection and control measures

1. Member States shall ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with this Regulation. Inspection and control measures may also include inspection and control regarding the holding of a product.

2. Prior to the application of Articles 1 to 7, the Commission, in accordance with the procedure referred to in Article 10(3), shall develop and publish technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1 of this Article. In developing the above technical guidance, the Commission shall take account of the work of national competent authorities, the committee referred to in Article 58(1) of Regulation (EC) No 178/2002 and the Community Reference Laboratory established under Regulation (EC) No 1829/2003.

3. In order to help the Member States meet the requirements set out in paragraphs 1 and 2, the Commission shall ensure that a central register is put in place at Community level, which shall contain all available sequencing information and reference material for GMOs authorised to be put into circulation in the Community. The competent authorities in the Member States shall have access to the register. The register shall also contain, where available, relevant information concerning GMOs which are not authorised in the European Union.

Article 10

Committee

1. The Commission shall be assisted by the committee set up by Article 30 of Directive 2001/18/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. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The Committee shall adopt its rules of procedure.

Article 11

Penalties

Member States shall lay down the rules on penalties applicable to infringements 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. Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them.

Article 12

Review clause

No later than 18 October 2005, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation, in particular with regard to Article 4(3) and, where appropriate, bring forward a proposal.

Article 13

Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. Articles 1 to 7 and Article 9(1) shall apply with effect from the 90th day following the date of publication in the *Official Journal of the European Union* of the measure referred to in Article 8(a).

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

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 September 2003
on additives for use in animal nutrition

(Text with EEA relevance)

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 [1],

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

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Livestock production occupies a very important place in the agriculture of the Community. Satisfactory results depend to a large extent on the use of safe and good-quality feedingstuffs.

(2) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(3) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(4) In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. Since pet food is not part of the human food chain and has no environmental impact on arable land, specific provisions for additives in pet food are appropriate.

(5) It is a principle of the Community food law enshrined in Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [4] that food and feed imported for placing on the market within the Community must comply with the relevant requirements of Community legislation or with conditions recognised by the Community to be at least equivalent thereto. It is therefore necessary to subject imports from third countries of additives for use in animal nutrition to requirements equivalent to those applying to additives produced in the Community.

(6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.

(7) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.

(8) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [5] has shown that it is necessary to review all the rules on additives in order to take into account the need to ensure a greater degree of protection of animal and human health and of the environment. It is also necessary to take into account the fact that technological progress and scientific developments have made available new types of additives, such as those to be used on silage or in water.

(9) This Regulation should also cover mixtures of additives sold to the end-user, and the marketing and use of those mixtures should comply with the conditions laid down in the authorisation of each single additive.

(10) Premixtures should not be regarded as preparations covered by the definition of additives.

(11) The basic principle in this field should be that only those additives approved under the procedure provided for in this Regulation may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation.

(12) Categories of feed additives should be defined in order to facilitate the assessment procedure with a view to authorisation. Amino acids, their salts and analogues, and urea and its derivatives, which are currently covered by Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition [6], should be included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation.

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[1] OJ C 203 E, 27.8.2002, p. 10.
[2] OJ C 61, 14.3.2003, p. 43.
[3] Opinion of the European Parliament of 21 November 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 1), Decision of the European Parliament of 19 June 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[4] OJ L 31, 1.2.2002, p. 1.
[5] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).
[6] OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

(13) Implementing rules concerning applications for authorisation of feed additives should take into account different documentation requirements for food-producing and other animals.

(14) In order to ensure a harmonised scientific assessment of feed additives, such assessment should be carried out by the European Food Safety Authority, established by Regulation (EC) No 178/2002. Applications should be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRLs).

(15) The Commission should establish guidelines for the authorisation of feed additives in cooperation with the European Food Safety Authority. In establishing these guidelines, attention should be paid to the possibility of extrapolating the results of the studies carried out on major species to minor species.

(16) It is also necessary to provide for a simplified authorisation procedure for those additives which have successfully undergone the authorisation procedure for food use provided for in Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption [1].

(17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products. Therefore, the authorisation of an additive should be granted by the Commission.

(18) In order to ensure the necessary level of protection for animal welfare and consumer safety, applicants should be encouraged to seek authorisation extensions for minor species by being granted one year's additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised.

(19) Competence for authorising feed additives and establishing conditions for their use and for maintaining and publishing a register of authorised feed additives should be conferred on the Commission in accordance with a procedure by which close collaboration between Member States and the Commission is guaranteed in the framework of the Standing Committee on the Food Chain and Animal Health.

(20) It is necessary to introduce, where appropriate, an obligation for the holder of the authorisation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment using a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law.

(21) In order to allow technological progress and scientific development to be taken into account, it is necessary to revise the authorisations of feed additives regularly. Time-limited authorisations should allow this review.

(22) A register of authorised feed additives should be established, including product-specific information and detection methods. Non-confidential data should be made available to the public.

(23) It is necessary to establish transitional rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids, their salts and analogues, urea and its derivatives, currently authorised under Directive 82/471/EEC, and silage agents, as well as additives for which the authorisation procedure is in progress. In particular, it is appropriate to provide that such products can remain on the market only insofar as notification with a view to their evaluation has been submitted to the Commission within one year after the entry into force of this Regulation.

(24) A number of silage additives are currently marketed and used in the Community without an authorisation granted pursuant to Directive 70/524/EEC. While it is indispensable to apply the provisions of this Regulation to such substances in view of their nature and use, it is appropriate to apply the same transitional arrangements. In this way it will be possible to obtain information on all the substances currently used and to establish a list of them, which would allow safeguard measures to be taken, where appropriate, for those substances that do not fulfil the authorisation criteria mentioned in Article 5 of this Regulation.

(25) The Scientific Steering Committee stated in its opinion of 28 May 1999 that: 'regarding the use of antimicrobials as growth promoting agents, the use of agents from classes which are or may be used in human or veterinary medicine (i.e. where there is a risk of selecting for cross-resistance to drugs used to treat bacterial infections) should be phased out as soon as possible and ultimately abolished'. The second opinion of the Scientific Steering Committee on antimicrobial resistance adopted on 10 and 11 May 2001 confirmed the need to provide a sufficient time to replace those antimicrobials by alternative products: 'Thus, the phase-out process must be planned and coordinated since precipitous actions could have repercussions for animal health'.

[1] OJ L 40, 11.2.1989, p. 27. Directive amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

(26) Therefore, it is necessary to set a date after which the use of the antibiotics still authorised for use as growth promoting agents will be forbidden, while allowing sufficient time for the development of alternative products to replace those antibiotics. Provision should also be made to forbid the authorisation of any further antibiotics for use as feed additives. Within the framework of the phasing out of antibiotics used as growth promoters and in order to ensure a high level of protection of animal health, the European Food Safety Authority will be asked to review the progress achieved in the development of alternative substances and alternative methods of management, feeding, hygiene, etc., before 2005.

(27) Certain substances with coccidiostatic and histomonostatic effects should be considered as feed additives for the purposes of this Regulation.

(28) Detailed labelling of the product should be required since it enables the end-user to make a choice with full knowledge of the facts, creates fewer obstacles to trade and facilitates fairness of transactions. In this respect, it is generally appropriate for requirements applying to feed additives to mirror the ones applying to food additives. It is therefore appropriate to provide for simplified labelling requirements for flavouring compounds similar to the ones applied to food flavourings; this should however be without prejudice to the possibility to provide for specific labelling requirements in the authorisation of individual additives.

(29) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1] provides for an authorisation procedure for the placing on the market of genetically modified food and feed, including feed additives consisting of, containing or produced from genetically modified organisms. Since the objectives of the said Regulation are different from those of this Regulation, feed additives should undergo an authorisation procedure in addition to the authorisation procedure provided for by that Regulation before they are placed on the market.

(30) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to feed of Community origin or imported from a third country. They allow such measures to be adopted in situations where feed 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.

(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 [2].

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

(33) Directive 70/524/EEC should be repealed. However labelling provisions applicable to compound feedingstuffs incorporating additives should be maintained until a revision of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs [3] is completed.

(34) Guidelines addressed to the Member States for the presentation of an application dossier are contained in Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition [4]. Verification of the conformity of dossiers is entrusted to the European Food Safety Authority. It is therefore necessary to repeal Directive 87/153/EEC. However, the Annex should remain in force until implementing rules are adopted.

(35) A transitional period is needed to avoid disruptions in the use of feed additives. Therefore, until the rules of this Regulation are applicable, the substances already authorised should be permitted to remain on the market and be used under the conditions of the current legislation,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Scope

1. The purpose of this Regulation is to establish a Community procedure for authorising the placing on the market and use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.

[1] See page 1 of this Official Journal.

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

[3] OJ L 86, 6.4.1979, p. 30. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

[4] OJ L 64, 7.3.1987, p. 19. Directive as last amended by Commission Directive 2001/79/EC (OJ L 267, 6.10.2001, p. 1).

2. This Regulation shall not apply to:

(a) processing aids;

(b) veterinary medicinal products as defined in Directive 2001/82/EC [1], with the exception of coccidiostats and histomonostats used as feed additives.

Article 2

Definitions

1. For the purpose of this Regulation, the definitions of 'feed', 'feedingstuff', 'feed business', 'feed business operator', 'placing on the market' and 'traceability' laid down in Regulation (EC) No 178/2002 shall apply.

2. The following definitions shall also apply:

(a) 'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);

(b) 'feed materials' means products as defined in Article 2(a) of Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials [2];

(c) 'compound feedingstuffs' means products as defined in Article 2(b) of Directive 79/373/EEC;

(d) 'complementary feedingstuffs' means products as defined in Article 2(e) of Directive 79/373/EEC;

(e) 'premixtures' means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals;

(f) 'daily ration' means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;

(g) 'complete feedingstuffs' means products as defined in Article 2(c) of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition [3];

(h) 'processing aids' means any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed;

(i) 'antimicrobials' means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

(j) 'antibiotic' means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the growth of other micro-organisms;

(k) 'coccidiostats' and 'histomonostats' means substances intended to kill or inhibit protozoa;

(l) 'maximum residue limit' means the maximum concentration of residue resulting from the use of an additive in animal nutrition which may be accepted by the Community as being legally permitted or recognised as acceptable in or on a food;

(m) 'micro-organism' means: colony-forming micro-organisms.

(n) 'first placing on the market' means the initial placing on the market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed.

3. Where necessary, it may be determined, in accordance with the procedure referred to in Article 22(2), whether a substance, micro-organism or preparation is a feed additive within the scope of this Regulation.

CHAPTER II

AUTHORISATION, USE, MONITORING AND TRANSITIONAL MEASURES APPLICABLE FOR FEED ADDITIVES

Article 3

Placing on the market, processing and use

1. No person shall place on the market, process or use a feed additive unless:

(a) it is covered by an authorisation granted in accordance with this Regulation;

(b) the conditions for use set out in this Regulation, including the general conditions set out in Annex IV, unless otherwise provided for in the authorisation, and in the authorisation of the substance are met; and

(c) the conditions on labelling set out in this Regulation are met.

2. For experiments for scientific purposes, Member States may authorise the use, as additives, of substances which are not authorised at Community level, with the exception of antibiotics, provided that the experiments are carried out in accordance with the principles and conditions laid down in Directive 87/153/EEC, Directive 83/228/EEC [4] or the guidelines set out in Article 7(4) of this Regulation and provided that there is adequate official supervision. The animals concerned may be used for food production only if the authorities establish that this will have no adverse effect on animal health, human health or the environment.

[1] OJ L 311, 28.11.2001, p. 1.
[2] OJ L 125, 23.5.1996, p. 35. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
[3] OJ L 115, 4.5.1999, p. 32. Directive as last amended by Regulation (EC) No 806/2003.
[4] OJ L 126, 13.5.1983, p. 23.

3. In the case of additives belonging to categories (d) and (e) of Article 6(1) and of those additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs), no person other than the holder of the authorisation named in the authorisation Regulation referred to in Article 9, his legal successor or successors, or a person acting under his written authority, shall first place the product on the market.

4. Unless otherwise specified, the mixing of additives to be sold directly to the end-user shall be allowed, subject to compliance with the conditions for use laid down in the authorisation for each single additive. Consequently, the mixing of authorised additives shall not be subject to specific authorisations other than the requirements laid down in Directive 95/69/EC [1].

5. Where necessary as a result of technological progress or scientific development, the general conditions set out in Annex IV may be adapted in accordance with the procedure referred to in Article 22(2).

Article 4

Authorisation

1. Any person seeking an authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

2. An authorisation shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation, or in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002.

3. The applicant for an authorisation or his representative shall be established in the Community.

Article 5

Conditions for authorisation

1. No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated in accordance with the implementing measures referred to in Article 7 that, when used in accordance with conditions to be set out in the Regulation authorising the use of the additive, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3.

2. The feed additive shall not:

(a) have an adverse effect on animal health, human health or the environment,

(b) be presented in a manner which may mislead the user,

(c) harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.

3. The feed additive shall:

(a) favourably affect the characteristics of feed,

(b) favourably affect the characteristics of animal products,

(c) favourably affect the colour of ornamental fish and birds,

(d) satisfy the nutritional needs of animals,

(e) favourably affect the environmental consequences of animal production,

(f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or

(g) have a coccidiostatic or histomonostatic effect.

4. Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.

Article 6

Categories of feed additives

1. A feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, in accordance with the procedure set out at Articles 7, 8 and 9:

(a) technological additives: any substance added to feed for a technological purpose;

(b) sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;

(c) nutritional additives;

(d) zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;

(e) coccidiostats and histomonostats.

2. Within the categories referred to in paragraph 1, feed additives shall further be allocated within one or more of the functional groups mentioned in Annex I, according to their principal function or functions, in accordance with the procedure specified in Articles 7, 8 and 9.

3. Where necessary as a result of technological progress or scientific development, additional feed additive categories and functional groups may be established in accordance with the procedure referred to in Article 22(2).

[1] Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC (OJ L 332, 30.12.1995, p. 15). Directive as last amended by Regulation (EC) No 806/2003.

Article 7

Application for authorisation

1. An application for an authorisation as provided for in Article 4 shall be sent to the Commission. The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority (hereinafter referred to as the Authority).

2. The Authority shall:

(a) acknowledge receipt of the application, including the particulars and documents referred to in paragraph 3, in writing, to the applicant within 15 days of its receipt, stating the date of receipt;

(b) make any information supplied by the applicant available to the Member States and the Commission;

(c) make the summary of the dossier mentioned in paragraph 3(h) available to the public, subject to the confidentiality requirements laid down in Article 18(2).

3. At the time of application, the applicant shall send the following particulars and documents directly to the Authority:

(a) his name and address;

(b) the identification of the feed additive, a proposal for its classification by category and functional group under Article 6, and its specifications, including, where applicable, purity criteria;

(c) a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;

(d) a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(2) and (3);

(e) proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary feedingstuffs and animal species and categories for which the feed additive is intended;

(f) a written statement that three samples of the feed additive have been sent by the applicant directly to the Community reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex II;

(g) for additives which, according to the proposal under point (b), do not belong to either category (a) or category (b) referred to in Article 6(1), and for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, a proposal for post-market monitoring;

(h) a summary containing the information provided under points (a) to (g);

(i) for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted in accordance with the applicable legislation.

4. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure laid down in Article 22(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

Until such implementing rules are adopted, the application shall be made in accordance with the Annex to Directive 87/153/EEC.

5. After the Authority has been consulted, specific guidelines for the authorisation of additives shall be established, where necessary for each category of additive referred to in Article 6(1) in accordance with the procedure laid down in Article 22(2). These guidelines shall take account of the possibility of extrapolating the results of the studies carried out on major species to minor species.

After the Authority has been consulted, further rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 22(2). These rules should, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets. The implementing rules shall include provisions which allow for simplified procedures for the authorisation of additives which have been authorised for use in food.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Article 8

Opinion of the Authority

1. The Authority shall give an opinion within six months of receipt of a valid application. This time limit shall be extended whenever the Authority seeks supplementary information from the applicant under paragraph 2.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority after consultation with the applicant.

3. In order to prepare its opinion, the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 7 and undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5;

(b) shall verify the report of the Community Reference Laboratory.

4. In the event of an opinion in favour of authorising the feed additive, the opinion shall also include the following elements:

(a) the name and address of the applicant;

(b) the designation of the feed additive including its categorisation and allocation within functional groups provided for in Article 6, its specification, including, where applicable, purity criteria and method of analysis;

(c) depending on the outcome of the assessment, specific conditions or restrictions in relation to handling, post-market monitoring requirements and use, including animal species and categories of animal species for which the additive is to be used;

(d) specific additional requirements for the labelling of the feed additive necessary as a result of conditions and restrictions imposed under (c);

(e) a proposal for the establishment of Maximum Residues Limits (MRLs) in the relevant foodstuffs of animal origin, unless the opinion of the Authority concludes that the establishment of MRLs is not necessary for the protection of consumers or MRLs have already been established in Annex I or III to 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 [1].

5. The Authority shall without delay forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed additive and stating the reasons for its conclusion.

6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 18(2).

Article 9

Authorisation by the Community

1. Within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft Regulation to grant authorisation or to deny authorisation. This draft shall take into account the requirements of Article 5(2) and (3), Community law and other legitimate factors relevant to the matter under consideration and in particular benefits for animal health and welfare and for the consumer of animal products.

Where the draft is not in accordance with the opinion of the Authority, it shall provide an explanation of the reasons for the differences.

In exceptionally complex cases, the three-month deadline may be extended.

2. The draft shall be adopted in accordance with the procedure referred to in Article 22(2).

3. Rules for the implementation of this Article and in particular concerning an identification number for authorised additives may be established in accordance with the procedure referred to in Article 22(2).

4. The Commission shall without delay inform the applicant of the Regulation adopted in accordance with paragraph 2.

5. A Regulation granting the authorisation shall include the elements mentioned in Article 8(4)(b), (c), (d) and (e) and an identification number.

6. A Regulation granting authorisation for additives belonging to categories (d) and (e) referred to in Article 6(1) and also for additives consisting of, containing or produced from GMOs, shall include the name of the holder of the authorisation, and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [2].

7. Where the levels of residues of an additive in food from animals fed with that additive might have a detrimental effect on human health, the Regulation shall include MRLs for the active substance or for its metabolites in the relevant foodstuffs of animal origin. In this case the active substance shall be considered for the purposes of Council Directive 96/23/EC [3] as falling under Annex I to that Directive. Where an MRL for the substance concerned has already been established in Community rules, that MRL shall also apply to residues of the active substance or its metabolites originating from the use of the substance as a feed additive.

8. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 14. The authorised feed additive shall be entered in the Register referred to in Article 17 (hereinafter referred to as the Register). Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7.

9. The granting of authorisation shall be without prejudice to the general civil and criminal liability of any feed operator in respect of the feed additive concerned.

Article 10

Status of existing products

1. By way of derogation from Article 3, a feed additive which has been placed on the market pursuant to Directive 70/524/EEC and urea and derivatives, an amino acid, salt of an amino acid or analogous substance, which was listed in points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC, may be placed on the market and used in accordance with the conditions specified in Directives 70/524/EEC or 82/471/EEC and their implementing measures, including in particular specific labelling provisions concerning compound feed and feed materials, provided that the following conditions are met:

[1] OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1490/2003 (OJ L 214, 26.8.2003, p. 3).

[2] See page 24 of this Official Journal.

[3] OJ L 125, 23.5.1996, p. 10.

(a) within one year of the entry into force of this Regulation, persons first placing the feed additive on the market or any other interested parties shall notify this fact to the Commission. At the same time, the particulars mentioned in Article 7(3)(a), (b) and (c) shall be directly sent to the Authority;

(b) within one year of the notification mentioned under (a), the Authority shall, after verification that all the information required has been submitted, notify the Commission that it has received the information required under this Article. The products concerned shall be entered in the Register. Each entry in the Register shall mention the date on which the product concerned was first entered in the Register and, where applicable, the expiry date of the existing authorisation.

2. An application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC. A detailed calendar listing in order of priority the different classes of additives to be re-evaluated may be adopted in accordance with the procedure referred to in Article 22(2). The Authority shall be consulted in drawing up the list.

3. Products entered in the Register shall be subject to the provisions of this Regulation, in particular Articles 8, 9, 12, 13, 14 and 16, which without prejudice to specific conditions concerning the labelling, placing on the market and use of each substance pursuant to paragraph 1, shall apply to such products as if they had been authorised pursuant to Article 9.

4. In the case of authorisations not issued to a specific holder, any person who imports or manufactures the products referred to in this Article or any other interested party may submit the information as referred to in paragraph 1 or the application as referred to in paragraph 2 to the Commission.

5. Where the notification and accompanying particulars referred to in paragraph 1(a) are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 2 within the period specified, a Regulation shall be adopted, in accordance with the procedure referred to in Article 22(2), requiring the additives concerned to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

6. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. The Commission shall inform the applicant of this extension of the authorisation.

7. By way of derogation from Article 3, substances, microorganisms and preparations used in the Community as silage additives at the date referred to in Article 26(2), may be placed on the market and used provided that points (a) and (b) of paragraph 1 and paragraph 2 are complied with. Paragraphs 3 and 4 shall apply accordingly. For these substances, the deadline for application as referred to in paragraph 2 shall be seven years after the entry into force of this Regulation.

Article 11

Phasing out

1. With a view to a decision on the phasing out of the use of coccidiostats and histomonostats as feed additives by 31 December 2012, the Commission shall submit to the European Parliament and the Council before 1 January 2008 a report on the use of these substances as feed additives and available alternatives, accompanied, where appropriate, by legislative proposals.

2. By way of derogation from Article 10 and without prejudice to Article 13, antibiotics, other than coccidiostats and histomonostats, may be marketed and used as feed additives only until 31 December 2005; as from 1 January 2006, those substances shall be deleted from the Register.

Article 12

Supervision

1. After an additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a feedingstuff into which it has been incorporated, or any other interested party shall ensure that any conditions or restrictions which have been imposed on the placing on the market, use and handling of the additive or feedingstuffs containing it are respected.

2. Where monitoring requirements, as referred to in Article 8(4)(c), have been imposed, the holder of the authorisation shall ensure that monitoring is carried out and shall submit reports to the Commission in accordance with the authorisation. The holder of the authorisation shall forthwith communicate to the Commission any new information that might influence the evaluation of the safety in use of the feed additive, in particular health sensitivities of specific categories of consumers. The holder of the authorisation shall forthwith inform the Commission of any prohibition or restriction imposed by the competent authority of any third country in which the feed additive is placed on the market.

Article 13

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.

2. The Commission shall examine the opinion of the Authority without delay. Any appropriate measures shall be taken in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002. A decision on the modification, suspension or revocation of an authorisation shall be taken in accordance with the procedure referred to in Article 22(2) of this Regulation.

3. If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States. The Commission shall examine the opinion of the Authority without delay and decide in accordance with the procedure referred to in Article 22(2).

4. The Commission shall without delay inform the applicant of the decision taken. The Register shall be amended where appropriate.

5. Articles 7(1) and (2), 8 and 9 shall apply accordingly.

Article 14

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods. An application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

In the case of authorisations not issued to a specific holder, any person who first places the additive on the market or any other interested party may submit the application to the Commission and shall be considered as the applicant.

In the case of authorisations issued to a specific holder, the holder of the authorisation or his legal successor or successors may submit the application to the Commission and shall be deemed to be the applicant.

2. At the time of application, the applicant shall send the following particulars and documents directly to the Authority:

(a) a copy of the authorisation for placing the feed additive on the market;

(b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;

(d) where appropriate, a proposal for amending or supplementing the conditions of the original authorisation, *inter alia*, the conditions concerning future monitoring.

3. Articles 7(1), (2), (4) and (5), 8 and 9 shall apply accordingly.

4. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. Information on this extension of the authorisation shall be made available to the public in the Register referred to in Article 17.

Article 15

Urgent authorisation

In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the Commission may, in accordance with the procedure referred to in Article 22(2), provisionally authorise the use of an additive for a maximum period of five years.

CHAPTER III

LABELLING AND PACKAGING

Article 16

Labelling and packaging of feed additives and premixtures

1. No person shall place on the market a feed additive or a premixture of additives unless its packaging or container is labelled under the responsibility of a producer, packer, importer, seller or distributor established within the Community and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material:

(a) the specific name given to the additives upon authorisation, preceded by the name of the functional group as mentioned in the authorisation;

(b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this Article;

(c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;

(d) where appropriate, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of that Directive;

(e) directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the authorisation, including animal species and categories for which the additive or premixture of additives is intended;

(f) the identification number;

(g) the batch reference number and date of manufacture.

2. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed and drinking water.

3. In addition to the information specified in paragraph 1, the packaging or container of an additive belonging to a functional group specified in Annex III must bear the information, presented in a conspicuous, clearly legible and indelible manner, indicated in that Annex.

4. Moreover, in the case of premixtures, the word 'Premixture' (in capital letters) must appear clearly on the label, and the carrier substance must be declared.

5. Additives and premixtures shall be marketed only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

6. Amendments to Annex III to take technological progress and scientific development into account may be adopted in accordance with the procedure referred to in Article 22(2).

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 17

Community Register of Feed Additives

1. The Commission shall establish and keep up to date a Community Register of Feed Additives.

2. The Register shall be made available to the public.

Article 18

Confidentiality

1. The applicant may indicate which information submitted under this Regulation he wishes to be treated as confidential on the ground that its disclosure might significantly harm his competitive position. Verifiable reasons must be given in such cases.

2. The Commission shall determine, after consultation with the applicant, which information other than that specified in paragraph 3 should be kept confidential and shall inform the applicant of its decision.

3. The following information shall not be considered confidential:

(a) name and composition of the feed additive and, where appropriate, indication of the production strain;

(b) physico-chemical and biological characteristics of the feed additive;

(c) the conclusions of the study results on effects of the feed additive on human and animal health and on the environment;

(d) the conclusions of the study results on effects of the feed additive on the characteristics of animal products and its nutritional properties;

(e) methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

4. Notwithstanding paragraph 2, the Authority shall, on request, supply the Commission and Member States with all information in its possession, including any identified as confidential pursuant to paragraph 2.

5. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1] when handling applications for access to documents held by the Authority.

6. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

7. If an applicant withdraws or has withdrawn an application, the Member States, the Commission and the Authority shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Commission and the applicant disagree as to its confidentiality.

Article 19

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.

Article 20

Data protection

1. The scientific data and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used.

2. In order to stimulate efforts to obtain authorisations for minor species for additives whose use is authorised for other species, the 10-year data protection period shall be extended by one year for each minor species for which a use extension authorisation is granted.

[1] OJ L 145, 31.5.2001, p. 43.

3. The applicant and the previous applicant shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat toxicological tests on vertebrates. If, however, no such agreement is reached on sharing the information, the Commission may decide to disclose information necessary to avoid repeating toxicological tests on vertebrates, while ensuring a reasonable balance between the interests of the parties concerned.

4. On the expiry of the 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant.

Article 21

Reference laboratories

The Community Reference Laboratory and its duties and tasks shall be those laid down in the Annex II.

Applicants for the authorisation of additives shall contribute to supporting the cost of the tasks of the Community Reference Laboratory and the consortium of National Reference Laboratories mentioned in Annex II.

Detailed rules for implementing Annex II and any amendments to that Annex shall be adopted in accordance with the procedure referred to in Article 22(2).

Article 22

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established 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 23

Repeals

1. Directive 70/524/EEC shall be repealed with effect from the date of application of this Regulation. However, Article 16 of Directive 70/524/EEC shall remain in force until Directive 79/373/EEC has been revised to include rules concerning the labelling of feedingstuffs incorporating additives.

2. Points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC shall be deleted with effect from the date of application of this Regulation.

3. Directive 87/153/EEC shall be repealed with effect from the date of application of this Regulation. However, the Annex to that Directive shall remain in force until the implementing rules provided for in Article 7(4) of this Regulation are adopted.

4. References to Directive 70/524/EEC shall be construed as references to this Regulation.

Article 24

Penalties

Member States shall lay down the rules on penalties applicable to infringements 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.

Member States shall notify those rules and measures to the Commission at the latest 12 months after the date of publication of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

Article 25

Transitional measures

1. Applications submitted under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be treated as applications under Article 7 of this Regulation where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have not yet been forwarded to the Commission. Any Member State selected as rapporteur in respect of any such application shall immediately forward the dossier submitted in support of that application to the Commission. Notwithstanding Article 23(1), such applications shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have already been forwarded to the Commission.

2. The labelling requirements laid down in Chapter III shall not apply to products which have been lawfully manufactured and labelled in the Community or which have been lawfully imported into the Community and put into circulation, before the date of application of this Regulation.

Article 26

Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from 12 months after the date of publication of this Regulation.

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

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

ANNEX I

ADDITIVE GROUPS

1. In the category 'technological additives', the following functional groups are included:
   (a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;
   (b) antioxidants: substances prolonging the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by oxidation;
   (c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs;
   (d) stabilisers: substances which make it possible to maintain the physico-chemical state of feedingstuffs;
   (e) thickeners: substances which increase the viscosity of feedingstuffs;
   (f) gelling agents: substances which give a feedingstuff texture through the formation of a gel;
   (g) binders: substances which increase the tendency of particles of feedingstuffs to adhere;
   (h) substances for control of radionucleide contamination: substances that suppress absorption of radionucleides or promote their excretion;
   (i) anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere;
   (j) acidity regulators: substances which adjust the pH of feedingstuffs;
   (k) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage;
   (l) denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials.
2. In the category 'sensory additives', the following functional groups are included:
   (a) colourants:
      (i) substances that add or restore colour in feedingstuffs;
      (ii) substances which, when fed to animals, add colours to food of animal origin;
      (iii) substances which favourably affect the colour of ornamental fish or birds;
   (b) flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability.
3. In the category 'nutritional additives', the following functional groups are included:
   (a) vitamins, pro-vitamins and chemically well-defined substances having similar effect;
   (b) compounds of trace elements;
   (c) amino acids, their salts and analogues;
   (d) urea and its derivatives.
4. In the category 'zootechnical additives', the following functional groups are included:
   (a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
   (b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
   (c) substances which favourably affect the environment;
   (d) other zootechnical additives.

ANNEX II

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory referred to in Article 21 is the Joint Research Centre of the Commission (JRC).
2. For the tasks outlined in this Annex, the JRC may be assisted by a consortium of national reference laboratories.

   The JRC shall be notably responsible for:

   — the reception, preparation, storage and maintenance of the reference samples;

   — the testing and evaluation or validation of the method for detection;

   — evaluating the data provided by the applicant for authorisation to place the feed additive on the market, for the purpose of testing and evaluation or validation of the method for detection;

   — submitting full evaluation reports to the Authority.
3. The Community reference laboratory shall play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.

ANNEX III

SPECIFIC LABELLING REQUIREMENTS FOR CERTAIN FEED ADDITIVES AND FOR PREMIXTURES

(a) Zootechnical additives, coccidiostats and histomonostats:
   — the expiry date of the guarantee or the storage life from the date of manufacture,
   — the directions for use, and
   — the concentration;

(b) Enzymes, in addition to the abovementioned indications:
   — the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given,
   — the International Union of Biochemistry identification number, and
   — instead of concentration: units of activity (units of activity per gram or units of activity per millilitre);

(c) Micro-organisms:
   — the expiry date of the guarantee or the storage life from the date of manufacture,
   — the directions for use,
   — the strain identification number, and
   — the number of colony-forming units per gram;

(d) Nutritional additives:
   — the active-substance level, and
   — the expiry date of the guarantee of that level or storage life from the date of manufacture;

(e) Technological and sensory additives with the exception of flavouring compounds:
   — the active substance level;

(f) Flavouring compounds:
   — the incorporation rate in premixtures.

ANNEX IV

GENERAL CONDITIONS OF USE

1. The quantity of additives that also exists in the natural state in certain feed materials shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorisation Regulation.

2. Mixing of additives shall be permitted only in premixtures and feedingstuffs where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

3. Supplementary feedingstuffs, diluted as specified, may not contain levels of the additives which exceed those fixed for complete feedingstuffs.

4. In the case of premixtures containing silage additives the words 'of silage additives' must clearly be added on the label after 'PREMIXTURE'.

COMMISSION REGULATION (EC) No 1832/2003

of 17 October 2003

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables [1], as last amended by Regulation (EC) No 1947/2002 [2], and in particular Article 4(1) thereof,

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 18 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

[1] OJ L 337, 24.12.1994, p. 66.
[2] OJ L 299, 1.11.2002, p. 17.

ANNEX

to the Commission Regulation of 17 October 2003 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	96,9
	060	81,9
	096	66,2
	204	96,8
	999	85,5
0707 00 05	052	138,1
	999	138,1
0709 90 70	052	108,7
	999	108,7
0805 50 10	052	88,3
	388	66,6
	524	50,4
	528	56,8
	999	65,5
0806 10 10	052	106,1
	400	194,0
	624	230,3
	999	176,8
0808 10 20, 0808 10 50, 0808 10 90	060	37,8
	096	41,3
	388	75,0
	400	78,4
	512	36,1
	720	48,9
	800	170,3
	804	103,5
	999	73,9
0808 20 50	052	103,9
	060	44,5
	064	63,7
	999	70,7

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1833/2003
of 17 October 2003
fixing the export refunds on pigmeat

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2759/75 of 29 October 1975 on the common organisation of the market in pigmeat [1], as last amended by Regulation (EC) No 1365/2000 [2], and in particular the second paragraph of Article 13(3) thereof,

Whereas:

(1) Article 13 of Regulation (EEC) No 2759/75 provides that the difference between prices on the world market for the products listed in Article 1(1) of that Regulation and prices for these products within the Community may be covered by an export refund.

(2) It follows from applying these rules and criteria to the present situation on the market in pigmeat that the refund should be fixed as set out below.

(3) In the case of products falling within CN code 0210 19 81, the refund should be limited to an amount which takes account of the qualitative characteristics of each of the products falling within these codes and of the foreseeable trend of production costs on the world market. It is important that the Community should continue to take part in international trade in the case of certain typical Italian products falling within CN code 0210 19 81.

(4) Because of the conditions of competition in certain third countries, which are traditionally importers of products falling within CN codes 1601 00 and 1602, the refund for these products should be fixed so as to take this situation into account. Steps should be taken to ensure that the refund is granted only for the net weight of the edible substances, to the exclusion of the net weight of the bones possibly contained in the said preparations.

(5) Article 13 of Regulation (EEC) No 2759/75 provides that the world market situation or the specific requirements of certain markets may make it necessary to vary the refund on the products listed in Article 1(1) of Regulation (EEC) No 2759/75 according to destination.

(6) The refunds should be fixed taking account of the amendments to the refund nomenclature established by Commission Regulation (EEC) No 3846/87 [3], as last amended by Regulation (EC) No 118/2003 [4].

(7) Refunds should be granted only on products that are allowed to circulate freely within the Community. Therefore, to be eligible for a refund, products should be required to bear the health mark laid down in Council Directive 64/433/EEC [5], as last amended by Directive 95/23/EC [6], Council Directive 94/65/EC [7] and Council Directive 77/99/EEC [8], as last amended by Directive 97/76/EC [9].

(8) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Pigmeat,

HAS ADOPTED THIS REGULATION:

Article 1

The list of products on which the export refund specified in Article 13 of Regulation (EEC) No 2759/75 is granted and the amount of the refund shall be as set out in the Annex hereto.

The products concerned must comply with the relevant provisions on health marks laid down in:

— Chapter XI of Annex I to Directive 64/433/EEC,

— Chapter VI of Annex I to Directive 94/65/EC,

— Chapter VI of Annex B to Directive 77/99/EEC.

Article 2

This Regulation shall enter into force on 20 October 2003.

[1] OJ L 282, 1.11.1975, p. 1.
[2] OJ L 156, 29.6.2000, p. 5.
[3] OJ L 366, 24.12.1987, p. 1.
[4] OJ L 20, 24.1.2003, p. 3.
[5] OJ 121, 29.7.1964, p. 2012/64.
[6] OJ L 243, 11.10.1995, p. 7.
[7] OJ L 368, 31.12.1994, p. 10.
[8] OJ L 26, 31.1.1977, p. 85.
[9] OJ L 10, 16.1.1998, p. 25.

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

Done at Brussels, 17 October 2003.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

to the Commission Regulation of 17 October 2003 fixing the export refunds on pigmeat

Product code	Destination	Unit of measurement	Amount of refund
0210 11 31 9110	P05	EUR/100 kg	67,50
0210 11 31 9910	P05	EUR/100 kg	67,50
0210 19 81 9100	P05	EUR/100 kg	71,50
0210 19 81 9300	P05	EUR/100 kg	56,50
1601 00 91 9120	P05	EUR/100 kg	20,50
1601 00 99 9110	P05	EUR/100 kg	15,50
1602 41 10 9110	P05	EUR/100 kg	30,50
1602 41 10 9130	P05	EUR/100 kg	18,00
1602 42 10 9110	P05	EUR/100 kg	24,00
1602 42 10 9130	P05	EUR/100 kg	18,00
1602 49 19 9130	P05	EUR/100 kg	18,00

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 27.3.2002, p. 1) as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 1779/2002 (OJ L 269, 5.10.2002, p. 6).

The other destinations are defined as follows:

P05 All destinations except the Czech Republic, the Slovak Republic, Hungary, Poland, Bulgaria, Latvia, Estonia, Lithuania.

COMMISSION REGULATION (EC) No 1834/2003

of 17 October 2003

on import licences in respect of beef and veal products originating in Botswana, Kenya, Madagascar, Swaziland, Zimbabwe and Namibia

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2286/2002 of 10 December 2002 on the arrangements applicable to agricultural products and goods resulting from the processing of agricultural products originating in the African, Caribbean and Pacific States (ACP States) and repealing Regulation (EC) No 1706/98 ([1]), and in particular Article 5 thereof,

Having regard to Commission Regulation (EC) No 1918/98 of 9 September 1998 laying down detailed rules for the application in the beef and veal sector of Council Regulation (EC) No 1706/98 on the arrangements applicable to agricultural products and certain goods resulting from the processing of agricultural products originating in the African, Caribbean and Pacific States and repealing Regulation (EC) No 589/96 ([2]), and in particular Article 4 thereof,

Whereas:

(1) Article 1 of Regulation (EC) No 1918/98 provides for the possibility of issuing import licences for beef and veal products. However, imports must take place within the limits of the quantities specified for each of these exporting non-member countries.

(2) The applications for import licences submitted between 1 and 10 October 2003, expressed in terms of boned meat, in accordance with Regulation (EC) No 1918/98, do not exceed, in respect of products originating from Botswana, Kenya, Madagascar, Swaziland, Zimbabwe and Namibia, the quantities available from those States. It is therefore possible to issue import licences in respect of the quantities applied for.

(3) The quantities in respect of which licences may be applied for from 1 November 2003 should be fixed within the scope of the total quantity of 52 100 tonnes.

(4) This Regulation is without prejudice to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries ([3]), as last amended by Regulation (EC) No 807/2003 ([4]),

HAS ADOPTED THIS REGULATION:

Article 1

The following Member States shall issue on 21 October 2003 import licences for beef and veal products, expressed as boned meat, originating in certain African, Caribbean and Pacific States, in respect of the following quantities and countries of origin:

Germany:

— 550 tonnes in Botswana,

— 580 tonnes in Namibia;

United Kingdom:

— 90 tonnes originating in Namibia,

— 10 tonnes originating in Swaziland.

Article 2

Licence applications may be submitted, pursuant to Article 3(2) of Regulation (EC) No 1918/98, during the first 10 days of November 2003 for the following quantities of boned beef and veal:

Botswana:	11 585,5 tonnes,
Kenya:	142 tonnes,
Madagascar:	7 579 tonnes,
Swaziland:	2 748 tonnes,
Zimbabwe:	9 100 tonnes,
Namibia:	3 820 tonnes.

Article 3

This Regulation shall enter into force on 21 October 2003.

([1]) OJ L 348, 21.12.2002, p. 5.
([2]) OJ L 250, 10.9.1998, p. 16.
([3]) OJ L 302, 31.12.1972, p. 28.
([4]) OJ L 122, 16.5.2003, p. 36.

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

Done at Brussels, 17 October 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

COMMISSION REGULATION (EC) No 1835/2003

of 17 October 2003

laying down to what extent applications for issue of export licences submitted during October 2003 for beef products which may benefit from special import treatment in a third country may be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 1445/95 of 26 June 1995 on rules of application for import and export licences in the beef sector and repealing Regulation (EEC) No 2377/80 [1], as last amended by Regulation (EC) No 852/2003 [2], and in particular Article 12(8) thereof,

Whereas:

(1) Regulation (EC) No 1445/95 lays down, in Article 12, detailed rules for export licence applications for the products referred to in Article 1 of Commission Regulation (EEC) No 2973/79 [3], as last amended by Regulation (EEC) No 3434/87 [4].

(2) Regulation (EEC) No 2973/79 fixed the quantities of meat which might be exported on special terms for the fourth quarter of 2003. No applications were submitted for export licences for beef,

HAS ADOPTED THIS REGULATION:

Article 1

No applications for export licences were lodged for the beef referred to in Regulation (EEC) No 2973/79 for the fourth quarter of 2003.

Article 2

Applications for licences in respect of the meat referred to in Article 1 may be lodged in accordance with Article 12 of Regulation (EC) No 1445/95 during the first 10 days of the first quarter of 2004 the total quantity available being 1 250 t.

Article 3

This Regulation shall enter into force on 21 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

[1] OJ L 143, 27.6.1995, p. 35.
[2] OJ L 123, 17.5.2003, p. 9.
[3] OJ L 336, 29.12.1979, p. 44.
[4] OJ L 327, 18.11.1987, p. 7.

COMMISSION REGULATION (EC) No 1836/2003

of 17 October 2003

fixing the minimum selling prices for butter for the 128th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], as last amended by Regulation (EC) No 806/2003 [2], and in particular Article 10 thereof,

Whereas:

(1) The intervention agencies are, pursuant to Commission Regulation (EC) No 2571/97 of 15 December 1997 on the sale of butter at reduced prices and the granting of aid for cream, butter and concentrated butter for use in the manufacture of pastry products, ice-cream and other foodstuffs [3], as last amended by Regulation (EC) No 635/2000 [4], to sell by invitation to tender certain quantities of butter from intervention stocks that they hold and to grant aid for cream, butter and concentrated butter. Article 18 of that Regulation stipulates that in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed for butter and maximum aid shall be fixed for cream, butter and concentrated butter. It is further stipulated that the price or aid may vary according to the intended use of the butter, its fat content and the incorporation procedure, and that a decision may also be taken to make no award in response to the tenders submitted. The amount(s) of the processing securities must be fixed accordingly.

(2) The Management Committee for Milk and Milk Products has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The minimum selling prices of butter from intervention stocks and processing securities applying for the 128th individual invitation to tender, under the standing invitation to tender provided for in Regulation (EC) No 2571/97, shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 18 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ L 160, 26.6.1999, p. 48.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 350, 20.12.1997, p. 3.
[4] OJ L 76, 25.3.2000, p. 9.

ANNEX

to the Commission Regulation of 17 October 2003 fixing the minimum selling prices for butter for the 128th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

(EUR/100 kg)

Formula			A		B	
Incorporation procedure			With tracers	Without tracers	With tracers	Without tracers
Minimum selling price	Butter ≥ 82 %	Unaltered	219	217	—	217
		Concentrated	218	—	—	—
Processing security		Unaltered	126	126	—	126
		Concentrated	126	—	—	—

COMMISSION REGULATION (EC) No 1837/2003

of 17 October 2003

fixing the maximum aid for cream, butter and concentrated butter for the 128th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], as last amended by Regulation (EC) No 806/2003 [2], and in particular Article 10 thereof,

Whereas:

(1) The intervention agencies are, pursuant to Commission Regulation (EC) No 2571/97 of 15 December 1997 on the sale of butter at reduced prices and the granting of aid for cream, butter and concentrated butter for use in the manufacture of pastry products, ice-cream and other foodstuffs [3], as last amended by Regulation (EC) No 635/2000 [4], to sell by invitation to tender certain quantities of butter of intervention stocks that they hold and to grant aid for cream, butter and concentrated butter. Article 18 of that Regulation stipulates that in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed for butter and maximum aid shall be fixed for cream, butter and concentrated butter. It is further stipulated that the price or aid may vary according to the intended use of the butter, its fat content and the incorporation procedure, and that a decision may also be taken to make no award in response to the tenders submitted. The amount(s) of the processing securities must be fixed accordingly.

(2) The Management Committee for Milk and Milk Products has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The maximum aid and processing securities applying for the 128th individual invitation to tender, under the standing invitation to tender provided for in Regulation (EC) No 2571/97, shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 18 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ L 160, 26.6.1999, p. 48.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 350, 20.12.1997, p. 3.
[4] OJ L 76, 25.3.2000, p. 9.

ANNEX

to the Commission Regulation of 17 October 2003 fixing the maximum aid for cream, butter and concentrated butter for the 128th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

(EUR/100 kg)

Formula		A		B	
Incorporation procedure		With tracers	Without tracers	With tracers	Without tracers
Maximum aid	Butter ≥ 82 %	79	75	—	71
	Butter < 82 %	77	72	—	—
	Concentrated butter	98	91	97	89
	Cream	—	—	34	31
Processing security	Butter	91	—	—	—
	Concentrated butter	113	—	113	—
	Cream	—	—	39	—

COMMISSION REGULATION (EC) No 1838/2003

of 17 October 2003

fixing the maximum aid for concentrated butter for the 300th special invitation to tender opened under the standing invitation to tender provided for in Regulation (EEC) No 429/90

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], as last amended by Regulation (EC) No 806/2003 [2], and in particular Article 10 thereof,

Whereas:

(1) In accordance with Commission Regulation (EEC) No 429/90 of 20 February 1990 on the granting by invitation to tender of an aid for concentrated butter intended for direct consumption in the Community [3], as last amended by Regulation (EC) No 124/1999 [4], the intervention agencies are opening a standing invitation to tender for the granting of aid for concentrated butter; Article 6 of that Regulation provides that in the light of the tenders received in response to each special invitation to tender, a maximum amount of aid is to be fixed for concentrated butter with a minimum fat content of 96 % or a decision is to be taken to make no award; the end-use security must be fixed accordingly.

(2) In the light of the tenders received, the maximum aid should be fixed at the level specified below and the end-use security determined accordingly.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

For the 300th special invitation to tender under the standing invitation to tender opened by Regulation (EEC) No 429/90, the maximum aid and the amount of the end-use security shall be as follows:

— maximum aid: EUR 97/100 kg,

— end-use security: EUR 112/100 kg.

Article 2

This Regulation shall enter into force on 18 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 45, 21.2.1990, p. 8.
[4] OJ L 16, 21.1.1999, p. 19.

COMMISSION REGULATION (EC) No 1839/2003

of 17 October 2003

concerning the 47th special invitation to tender issued under the standing invitation to tender referred to in Regulation (EC) No 2799/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], as last amended by Commission Regulation (EC) No 806/2003 [2], and in particular Article 10 thereof,

Whereas:

(1) Pursuant to Article 26 of Commission Regulation (EC) No 2799/1999 of 17 December 1999 laying down detailed rules for applying Council Regulation (EC) No 1255/1999 as regards the grant of aid for skimmed milk and skimmed-milk powder intended for animal feed and the sale of such skimmed-milk powder [3], as last amended by Regulation (EC) No 2238/2002 [4], intervention agencies have put up for sale by standing invitation to tender certain quantities of skimmed-milk powder held by them.

(2) According to Article 30 of Regulation (EC) No 2799/1999, in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed or a decision shall be taken to make no award.

(3) On the basis of the examination of the offers received, the tendering procedure should not be proceeded with.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

For the 47th individual invitation to tender pursuant to Regulation (EC) No 2799/1999, in respect of which the time limit for the submission of tenders expired on 14 October 2003, no award shall be made.

Article 2

This Regulation shall enter into force on 18 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 340, 31.12.1999, p. 3.
[4] OJ L 341, 17.12.2002, p. 11.

COMMISSION REGULATION (EC) No 1840/2003
of 16 October 2003
prohibiting fishing for anglerfish by vessels flying the flag of Spain

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy [1], as last amended by Regulation (EC) No 806/2003 [2], and in particular Article 21(3) thereof,

Whereas:

(1) Council Regulation (EC) No 2341/2002 of 20 December 2002 fixing for 2003 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks, applicable in Community waters and, for Community vessels, in waters where catch limitations are required [3], as last amended by Regulation (EC) No 1754/2003 [4], lays down quotas for anglerfish for 2003.

(2) In order to ensure compliance with the provisions relating to the quantity limits on catches of stocks subject to quotas, the Commission must fix the date by which catches made by vessels flying the flag of a Member State are deemed to have exhausted the quota allocated.

(3) According to the information received by the Commission, catches of anglerfish in the waters of ICES divisions VIIIa,b,d,e, by vessels flying the flag of Spain or registered in Spain have exhausted the quota allocated for 2003. Spain has prohibited fishing for this stock from 8 October 2003. This date should consequently be adopted in this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Catches of anglerfish in the waters of ICES divisions VIIIa,b,d,e, by vessels flying the flag of Spain or registered in Spain are hereby deemed to have exhausted the quota allocated to Spain for 2003.

Fishing for anglerfish in the waters of ICES divisions VIIIa,b,d,e, by vessels flying the flag of Spain or registered in Spain is hereby prohibited, as are the retention on board, transhipment and landing of this stock caught by the above vessels after the date of application of this Regulation.

Article 2

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

It shall apply from 8 October 2003.

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

Done at Brussels, 16 October 2003.

For the Commission
Jörgen HOLMQUIST
Director-General for Fisheries

[1] OJ L 261, 20.10.1993, p. 1.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 356, 31.12.2002, p. 12.
[4] OJ L 252, 4.10.2003, p. 1.

COMMISSION REGULATION (EC) No 1841/2003

of 17 October 2003

amending Regulation (EC) No 1227/2000 laying down detailed rules for the application of Council Regulation (EC) No 1493/1999 on the common organisation of the market in wine, as regards production potential

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine [1], as last amended by Regulation (EC) No 806/2003 [2], and in particular Article 7(2) and Articles 15 and 23 thereof,

Whereas:

(1) Commission Regulation (EC) No 1227/2000 [3], as last amended by Regulation (EC) No 1203/2003 [4], fixed the deadline for the period referred to in Article 2(3)(b) of Regulation (EC) No 1493/1999 during which a producer may obtain replanting rights after the area concerned has been planted. Since the date for applying the procedure provided for in Article 2(3) of Regulation (EC) No 1493/1999 has been postponed, the abovementioned deadline should also be extended accordingly.

(2) So that the allocations provided for in Article 14(1) and (2) of Regulation (EC) No 1493/1999 can be determined effectively, the date by which the Member States must make their annual notifications to the Commission should be amended and the date to be used for the purposes of determining the expenditure actually incurred and expenditure validated should be fixed.

(3) The fixed format of the data and information which the Member States must send to the Commission must also be adapted as regards the classification of vine varieties.

(4) Regulation (EC) No 1227/2000 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Wine,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1227/2000 is hereby amended as follows:

1. In Article 2(5), '15 July 2002' is replaced by '30 June 2004'.

2. In Article 16(1), the first sentence and points (a) and (b) are replaced by the following:

   'The Member States shall forward to the Commission, not later than 10 July each year in respect of the restructuring and conversion system:

   (a) a statement of expenditure actually incurred at 30 June of the current financial year and the total area concerned;

   (b) a statement of expenditure validated at 30 June of the current financial year and the total area concerned;'

3. In the Annex, table 9 'Classification of wine-grape vine varieties' is replaced by the table in the Annex hereto.

Article 2

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

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ L 179, 14.7.1999, p. 1.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 143, 16.6.2000, p. 1.
[4] OJ L 168, 5.7.2003, p. 9.

ANNEX

'9. CLASSIFICATION OF WINE-GRAPE VINE VARIETIES

Member State/Region:						**Date of communication:**			
Variety		**Classification**				**Other uses**			
Name	Synonym	Recommended	Authorised	Temporary authorisation	Observations	Table grapes	Wine spirits bearing designation of origin	Grapes for drying	Stock
1.									
2.									
3.									
4.									
5.									
6.									

1. Annual communication on a date in the year decided on by the Member State with details of any changes in relation to the previous year (Article 20(4) and (9) of this Regulation).

2. Member States are to adjust the table to bring it into line with their systems for classifying varieties.'

COMMISSION REGULATION (EC) No 1842/2003

of 17 October 2003

fixing the interest rates to be used for calculating the costs of financing intervention measures comprising buying-in, storage and disposal for the EAGGF Guarantee Section for the accounting year 2004

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1883/78 of 2 August 1978 laying down general rules for the financing of interventions by the European Agricultural Guidance and Guarantee Fund (EAGGF), Guarantee Section ([1]), as last amended by Regulation (EC) No 1259/96 ([2]), and in particular the first subparagraph of Article 5 thereof,

Whereas:

(1) Article 3 of Commission Regulation (EEC) No 411/88 of 12 February 1988 on the method and the rate of interest to be used for calculating the costs of financing intervention measures comprising buying-in, storage and disposal ([3]), as last amended by Regulation (EC) No 2623/1999 ([4]), lays down that the uniform interest rate used for calculating the costs of financing intervention measures is to correspond to the three months' and 12 months' forward Euribor rates with a weighting of one third and two thirds respectively.

(2) The Commission fixes this rate before the beginning of each EAGGF Guarantee Section accounting year on the basis of the rates recorded in the six months preceding fixing.

(3) Article 4(1) of Regulation (EEC) No 411/88 lays down that if the rate of interest borne by a Member State is lower for at least six months than the uniform interest rate fixed for the Community, a specific interest rate is to be fixed for that Member State. Where a Member State has not notified the rates before the end of the accounting year, the rate to be applied is determined on the basis of the reference interest rates set out in the Annex to the said Regulation.

(4) The measures provided for in this Regulation are in accordance with the opinion of the EAGGF Committee,

HAS ADOPTED THIS REGULATION:

Article 1

For expenditure incurred during the 2004 EAGGF Guarantee Section accounting year:

1. the interest rate referred to in Article 3 of Regulation (EEC) No 411/88 shall be 2,3 %;
2. the specific interest rate referred to in Article 4 of Regulation (EEC) No 411/88 shall be 2,2 % for Italy.

Article 2

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

It shall apply from 1 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

([1]) OJ L 216, 5.8.1978, p. 1.
([2]) OJ L 163, 2.7.1996, p. 10.
([3]) OJ L 40, 13.2.1988, p. 25.
([4]) OJ L 318, 11.12.1999, p. 14.

COMMISSION REGULATION (EC) No 1843/2003

of 17 October 2003

fixing depreciation percentages to be applied when agricultural products are bought in for the 2004 financial year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1883/78 of 2 August 1978 laying down general rules for the financing of interventions by the European Agricultural Guidance and Guarantee Fund, Guarantee Section ([1]), as last amended by Regulation (EC) No 1259/96 ([2]), and in particular the second sentence of Article 8(1) thereof,

Whereas:

(1) Pursuant to Article 8 of Regulation (EEC) No 1883/78, depreciation of agricultural products stored in public intervention warehouses must take place when they are bought in. The depreciation percentage must not exceed the difference between the buying-in price and the foreseeable disposal price for each of these products.

(2) Pursuant to Article 8(3) of Regulation (EEC) No 1883/78, the Commission may restrict depreciation at the time of buying-in to a proportion of this depreciation percentage, but such proportion may not be less than 70 % of total depreciation. Coefficients should be fixed for certain products for the 2004 financial year, to be applied by the intervention agencies to the monthly buying-in values of these products, so that the agencies can establish the depreciation amounts.

(3) The measures provided for in this Regulation are in accordance with the opinion of the EAGGF Committee,

HAS ADOPTED THIS REGULATION:

Article 1

1. In respect of the products listed in the Annex, which, having been bought in by public intervention, have entered storage or been taken over by the intervention agencies between 1 October 2003 and 30 September 2004, the authorities shall depreciate their value to account for the difference between the buying-in prices and the foreseeable selling prices of the relevant products.

2. To establish the amounts of the depreciation, the intervention agencies shall apply to the values of the products bought in every month the coefficients set out in the Annex.

3. The expenditure amounts determined in this way shall be notified to the Commission under the declarations established pursuant to Commission Regulation (EC) No 296/96 ([3]).

Article 2

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

It shall apply from 1 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

([1]) OJ L 216, 5.8.1978, p. 1.
([2]) OJ L 163, 2.7.1996, p. 10.
([3]) OJ L 39, 17.2.1996, p. 5.

ANNEX

Depreciation coefficients to be applied to the monthly buying-in values

Products	Coefficients
Breadmaking common wheat	—
Barley	—
Rye	0,20
Maize	0,10
Sorghum	0,10
Paddy rice	0,40
Alcohol	0,65
Butter	0,45
Skimmed-milk powder	0,20
Beef quarters	0,25
Boneless beef	0,25

COMMISSION REGULATION (EC) No 1844/2003

of 17 October 2003

on the issue of licences for the import of garlic in the quarter from 1 December 2003 to 29 February 2004

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables [1], as last amended by Regulation (EC) No 47/2003 [2],

Having regard to Commission Regulation (EC) No 565/2002 of 2 April 2002 establishing the method for managing the tariff quotas and introducing a system of certificates of origin for garlic imported from third countries [3], and in particular Article 8(2) thereof,

Whereas:

(1) The quantities for which licence applications have been lodged by traditional importers and by new importers on 13 and 14 October 2003, under Article 5(2) of Regulation (EC) No 565/2002 exceed the quantities available for products originating in China, Argentina and in all third countries other than China and Argentina.

(2) It is now necessary to establish the extent to which the licence applications sent to the Commission on 16 October 2003 can be met and to fix, for each category of importer and product origin, the dates until which the issue of certificates must be suspended,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for import licences lodged under Article 3(1) of Regulation (EC) No 565/2002 on 13 and 14 October 2003 and sent to the Commission on 16 October 2003, shall be met at a percentage rate of the quantities applied for as set out in Annex I hereto.

Article 2

For each category of importer and the origin involved, applications for import licences under Article 3(1) of Regulation (EC) No 565/2002 relating to the quarter from 1 December 2003 to 29 February 2004 and lodged after 14 October 2003 but before the date in Annex II hereto, shall be rejected.

Article 3

This Regulation shall enter into force on 18 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

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[1] OJ L 297, 21.11.1996, p. 1.
[2] OJ L 7, 11.1.2003, p. 64.
[3] OJ L 86, 3.4.2002, p. 11.

ANNEX I

Origin of the products	Percentage allocations		
	China	Third countries other than China or Argentina	Argentina
— traditional importers (Article 2(c) of Regulation (EC) No 565/2002)	14,766 %	100,000 %	100,000 %
— new importers (Article 2(e) of Regulation (EC) No 565/2002)	0,781 %	14,219 %	5,356 %

X: No quota for this origin for the quarter in question.
—: No application for a licence has been sent to the Commission.

ANNEX II

Origin of the products	Dates		
	China	Third countries other than China or Argentina	Argentina
— traditional importers (Article 2(c) of Regulation (EC) No 565/2002)	29.2.2004	—	—
— new importers (Article 2(e) of Regulation (EC) No 565/2002)	29.2.2004	5.1.2004	5.1.2004

COMMISSION REGULATION (EC) No 1845/2003
of 17 October 2003
correcting Regulation (EC) No 1828/2003 fixing the import duties in the rice sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice [1], as last amended by Regulation (EC) No 411/2002 [2],

Having regard to Commission Regulation (EC) No 1503/96 of 29 July 1996 laying down detailed rules for the application of Council Regulation (EC) No 3072/95 as regards import duties in the rice sector [3], as last amended by Regulation (EC) No 1298/2002 [4], and in particular Article 4(1) thereof,

Whereas:

An error has been discovered in Annex I to Commission Regulation (EC) No 1828/2003 [5]. The Regulation in question should therefore be corrected,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1828/2003 is hereby replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 18 October 2003.

It shall apply from 16 October 2003.

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

Done at Brussels, 17 October 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

[1] OJ L 329, 30.12.1995, p. 18.
[2] OJ L 62, 5.3.2002, p. 27.
[3] OJ L 189, 30.7.1996, p. 71.
[4] OJ L 189, 18.7.2002, p. 8.
[5] OJ L 265, 16.10.2003, p. 31.

ANNEX I

Import duties on rice and broken rice

(EUR/t)

CN code	Duties [5]				
	Third countries (except ACP and Bangladesh) [3]	ACP [1] [2] [3]	Bangladesh [4]	Basmati India and Pakistan [6]	Egypt [8]
1006 10 21	[7]	69,51	101,16		158,25
1006 10 23	[7]	69,51	101,16		158,25
1006 10 25	[7]	69,51	101,16		158,25
1006 10 27	[7]	69,51	101,16		158,25
1006 10 92	[7]	69,51	101,16		158,25
1006 10 94	[7]	69,51	101,16		158,25
1006 10 96	[7]	69,51	101,16		158,25
1006 10 98	[7]	69,51	101,16		158,25
1006 20 11	264,00	88,06	127,66		198,00
1006 20 13	264,00	88,06	127,66		198,00
1006 20 15	264,00	88,06	127,66		198,00
1006 20 17	264,00	88,06	127,66	14,00	198,00
1006 20 92	264,00	88,06	127,66		198,00
1006 20 94	264,00	88,06	127,66		198,00
1006 20 96	264,00	88,06	127,66		198,00
1006 20 98	264,00	86,06	127,66	14,00	198,00
1006 30 21	410,76	131,37	190,47		308,07
1006 30 23	410,76	131,37	190,47		308,07
1006 30 25	410,76	131,37	190,47		308,07
1006 30 27	[7]	133,21	193,09		312,00
1006 30 42	410,76	131,37	190,47		308,07
1006 30 44	410,76	131,37	190,47		308,07
1006 30 46	410,76	131,37	190,47		308,07
1006 30 48	[7]	133,21	193,09		312,00
1006 30 61	410,76	131,37	190,47		308,07
1006 30 63	410,76	131,37	190,47		308,07
1006 30 65	410,76	131,37	190,47		308,07
1006 30 67	[7]	133,21	193,09		312,00
1006 30 92	410,76	131,37	190,47		308,07
1006 30 94	410,76	131,37	190,47		308,07
1006 30 96	410,76	131,37	190,47		308,07
1006 30 98	[7]	133,21	193,09		312,00
1006 40 00	[7]	41,18	[7]		96,00

[1] The duty on imports of rice originating in the ACP States is applicable, under the arrangements laid down in Council Regulation (EC) No 2286/2002 (OJ L 345, 10.12.2002, p. 5) and amended Commission Regulation (EC) No 638/2003 (OJ L 93, 9.4.2003, p. 3).

[2] In accordance with Regulation (EC) No 1706/98, the duties are not applied to products originating in the African, Caribbean and Pacific States and imported directly into the overseas department of Réunion.

[3] The import levy on rice entering the overseas department of Réunion is specified in Article 11(3) of Regulation (EC) No 3072/95.

[4] The duty on imports of rice not including broken rice (CN code 1006 40 00), originating in Bangladesh is applicable under the arrangements laid down in Council Regulation (EEC) No 3491/90 (OJ L 337, 4.12.1990, p. 1) and amended Commission Regulation (EEC) No 862/91 (OJ L 88, 9.4.1991, p. 7).

[5] No import duty applies to products originating in the OCT pursuant to Article 101(1) of amended Council Decision 91/482/EEC (OJ L 263, 19.9.1991, p. 1).

[6] For husked rice of the Basmati variety originating in India and Pakistan, a reduction of EUR/t 250 applies (Article 4a of amended Regulation (EC) No 1503/96).

[7] Duties fixed in the Common Customs Tariff.

[8] The duty on imports of rice originating in and coming from Egypt is applicable under the arrangements laid down in Council Regulation (EC) No 2184/96 (OJ L 292, 15.11.1996, p. 1) and Commission Regulation (EC) No 196/97 (OJ L 31, 1.2.1997, p. 53).

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 7 October 2003

concerning the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Croatia concerning the system of ecopoints to be applied to Croatian transit traffic through Austria as from 1 January 2003

(2003/740/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71(1) in conjunction with Article 300(2), first subparagraph, first sentence and Article 300(3), first subparagraph thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) The Interim Agreement on trade and trade-related matters between the European Community, of the one part, and the Republic of Croatia, of the other part [2], and in particular Article 2(2)(b) of Protocol 6 on road transit traffic, establishes that a system of ecopoints equivalent to that laid down by Article 11 of Protocol 9 to the 1994 Act of Accession is to apply.

(2) The Commission has negotiated on behalf of the Community an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Croatia establishing the method of calculation and the detailed rules and procedures for the management and control of the ecopoints.

(3) This Agreement was signed on behalf of the Community on 23 July 2003, subject to its possible conclusion at a later date, in accordance with Council Decision 2003/440/EC [3].

(4) This Agreement should be approved,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement in the form of an Exchange of Letters between the European Community and the Republic of Croatia concerning the system of ecopoints to be applied to Croatian transit traffic through Austria as from 1 January 2003 is hereby approved on behalf of the Community.

The text of the Agreement in the form of an Exchange of Letters is attached to this Decision [4].

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

Done at Luxembourg, 7 October 2003.

For the Council

The President

G. TREMONTI

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[1] Opinion delivered on 15 May 2003 (not yet published in the Official Journal).

[2] OJ L 330, 14.12.2001, p. 3.

[3] OJ L 150, 18.6.2003, p. 32.

[4] For text of Agreement, see OJ L 150, 18.6.2003, p. 33. The Agreement was signed on behalf of Croatia on 1 August 2003.

Information relating to the entry into force of the Agreement amending the Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part, on conformity assessment and acceptance of industrial products (PECA)

The Agreement amending the Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part, on conformity assessment and acceptance of industrial products (PECA), which the Council decided to conclude on 22 September 2003 [1], enters into force on 1 November 2003, the procedures provided for in Article 2 of the Agreement having been completed on 29 September 2003.

[1] OJ L 256, 9.10.2003, p. 20.

COMMISSION

COMMISSION DECISION
of 13 August 2003
relating to a proceeding under Article 82 of the EC Treaty
(Case COMP D3/38.044 — NDC Health/IMS Health: Interim measures)

(notified under document number C(2003) 2920)

(Only the English text is authentic)

(2003/741/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation No 17 of 6 February 1962, First Regulation implementing Articles 85 and 86 of the Treaty [1], as last amended by Regulation (EC) No 1/2003 [2], and in particular Articles 3 and 16 thereof,

Having regard to the Commission Decision of 8 March 2001 to initiate proceedings in this case,

Having regard to the Commission Decision 2002/165/EC [3] based on Regulation No 17, and particularly on the Commission's powers under Article 3 thereof to adopt interim measures, addressed and notified to IMS Health in this case,

Having regard to the application for withdrawal of the decision by IMS Health on 31 October 2002,

Having given IMS Health, NDC Health and AzyX the opportunity to make known their views on whether or not the Commission should withdraw the interim measures decision on grounds of lack of urgency,

Having regard to the final report of the Hearing Officer in this case [4],

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas:

(1) IMS Health (IMS) has created, in collaboration with the pharmaceutical industry over a long period of time, a brick structure for the presentation of regional pharmaceutical prescription and sales data services in Germany. The Commission found in its Decision 2002/165/EC that this constituted a de facto industry standard and it was acknowledged to be so by the pharmaceutical companies. The need for comparable and compatible data, the possible loss of relationship between sales representatives and the doctors, the modification of the working contracts of sales representatives and the costs incurred to modify software and applications based on the 1860 brick structure if pharmaceutical companies were to switch to another brick structure, were considered as creating a very significant obstacle for them to do so. Moreover, technical and other constraints such as the necessary use of administrative boundaries, the data-protection law and the uncertainty concerning the permissibility under copyright law of selling data in another structure based on postal districts, gravely limited the possibilities to create other marketable brick structures. In particular, the Landgericht Frankfurt am Main (Frankfurt District Court) had granted, between October and December 2000, separate injunctions prohibiting NDC Health (NDC) (an American multinational company), AzyX (a much smaller Belgian company) and Pharma Intranet Information (PI, now a subsidiary of NDC), competitors of IMS on the regional pharmaceutical sales data services market, from using structures derived from the 1 860 brick structure on the basis that IMS enjoyed copyright protection.

[1] OJ 13, 21.2.1962, p. 204/62.
[2] OJ L 1, 4.1.2003, p. 1.
[3] OJ L 59, 28.2.2002, p. 18.
[4] OJ C 250, 18.10.2003.

(2) The Commission also found that IMS had no objective justification for refusing to grant a licence for the 1860 brick structure to, NDC and AzyX. The Commission considered that there was a prima facie case of behaviour constituting an abuse under Article 82. The Commission considered that there were 'exceptional circumstances' within the meaning of the phrase used by the European Court of Justice in *Magill* ([1]) read in conjunction with the *Ladbroke* ([2]) and *Bronner* ([3]) cases. The use of the 1 860 brick structure was considered as being indispensable to carrying on business on the relevant market because there was no actual or potential substitute for it.

(3) The Commission found that the refusal by IMS to license the 1 860 brick structure created a risk of serious and irreparable harm to the complainant, NDC, and of intolerable damage to the public interest which established the urgent need to grant protective interim measures. First, the Commission considered, on the basis of the evidence before it, that unless NDC was granted a licence to the 1 860 brick structure its German operation would go out of business. In the Commission's view, without interim measures, NDC would lose current customers, had no prospect of attracting new customers for the coming years and would probably cease trading in Germany. Second, apart from the serious risk of irreparable harm to NDC, there was also a risk of intolerable damage to the public interest within the meaning of the *La Cinq* judgment ([4]). Since without the 1 860 brick structure it was not possible to compete on the market at that time or in the foreseeable future, there would be, in the absence of interim measures, a serious risk to the continued presence on the market of the other competitor then active, AzyX. Finally, rejecting IMS's contention that it would suffer irreparable harm, the Commission concluded that the balance of interests in this case favoured both NDC and the public interest.

(4) The Commission therefore adopted Decision 2002/165/EC, which ordered IMS, by way of interim measures, to license the 1 860 brick structure to its then competitors on the market for German regional pharmaceutical sales data services, in return for royalties to be agreed by the parties within a two-week period of the date of the request for a licence failing which appropriate royalties would be determined by independent experts.

(5) By application lodged at the Registry of the Court of First Instance on 6 August 2001 under the reference T-184/01, IMS Health brought an action seeking the annulment of the decision or alternatively annulment of its decision concerning the requirement to license the 1 860 brick structure in circumstances where the licence terms would be conducted and approved by the Commission and the suspension of the operation of the Commission's Decision.

(6) By an Order of 26 October 2001 in case T-184/01R, the President of the Court of First Instance (CFI) suspended the execution of Commission Decision 2002/165/EC until such time as the Court of First Instance has given judgment in the main action.

(7) By application lodged at the Court Registry on 12 December 2001 under the reference C-481/01 P(R), NDC Health Corporation appealed against the abovementioned order of the President of the CFI.

(8) By an Order of 11 April 2002 in case C-481/01P(R), the President of the Court of Justice (ECJ) dismissed the appeal of NDC.

(9) Reference has been made on 12 July 2001 to the ECJ by the Landgericht Frankfurt am Main (Frankfurt District Court) for a preliminary ruling on related questions regarding the interpretation of Article 82 of the Treaty. The reference arises in the context of a copyright infringment action before the German courts between IMS Health and NDC Health. This case was registered under the reference C-418/01 and is still pending and proceedings in the main action concerning Decision 2002/165/EC have been stayed until judgment has been given in that preliminary ruling.

(10) In a judgment of 17 September 2002, the Oberlandesgericht Frankfurt am Main (Frankfurt Higher Regional Court) dismissed an appeal brought by PI against the abovementioned judgment of the Frankfurt District Court enjoining PI and its co-founder from using the 1 860 brick structure or any derivative thereof. While recognising that the 1 860 brick structure was protected by national copyright (the relevant right being held by, *inter alia*, certain IMS employees rather than by IMS itself) and that direct reproduction of that structure by a competitor of IMS constituted a breach of the Gesetz gegen den unlauteren Wettbewerb (Law on Unfair Competition), the Higher Regional Court held that 'der Beklagten oder Dritten die freie, selbständige Entwicklung einer Segmentstruktur, die ebenfalls auf der Einteilung nach Landkreisen, kreisfreien Städten und Postleitzahlbezirken beruht und deshalb ggfs. aus einer annähernd gleichen Anzahl von Segmenten besteht, nicht ohne weiteres untersagt werden könnte. (…) Insbesondere könnte es der Beklagten oder Dritten nicht zugemutet werden, eine den praktischen Anforderungen nur unzulänglich gerecht werdende Datenstruktur zu erstellen, nur um einen möglichst weiten Abstand von dem Produkt der Klägerin zu halten. Vielmehr können

([1]) Joined cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP)* v *Commission*, [1995] ECR p. I-0743.
([2]) Case T-504/93 *Tiercé Ladbroke SA* v *Commission*, [1997] ECR p. II-923.
([3]) Case C-7/97 *Oscar Bronner GmbH & Co KG* v *Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co KG*, [1998] ECR p. I-7791.
([4]) Case T-44/90 *La Cinq*, [1992] ECR p. II-1.

Abweichungen nicht verlangt werden, wo die Übereinstimmungen auf sachlich — technischen Anforderungen beruhen und unter Berücksichtigung des Freihaltebedürfnisses der Wettbewerber in diesen Merkmalen die angemessene Verwirklichung der Technischen Aufgabe liegt.' (The defendant or third parties could not simply be prohibited from developing freely and independently a brick structure that is similarly based on a breakdown by district, urban district and post-code district and for that reason comprise more or less the same number of bricks. (…) In particular, the defendant or third parties could not be expected to produce a data structure that does not sufficiently satisfy the practical requirements simply in order to keep as much distance as possible from the plaintiff's product. Instead, variations cannot be demanded where the overlaps are based on material technical requirements and, in the light taking into account 'the need of availability' for competitors, the appropriate performance of the technical task depends on these features).

(11) On 16 April 2003, the Frankfurt District Court forbade AzyX to use the 1 860 brick structure and any derivative of it. This judgment was not appealed before the Frankfurt Higher Regional Court.

(12) In its observations of 12 May 2003 on whether or not the Commission should withdraw the interim measures decision, IMS considered that the interpretation of the 17 September 2002 raises legal and factual questions that remain sub judice before the German Courts and that it is for them to determine the precise scope of that judgment. As to the withdrawal of the interim measures decision, IMS suggested that the appropriate course of action would be to withdraw that decision since none of the conditions for interim measures are satisfied, including, but not limited to the lack of urgency. As for the current situation in the market, in 2002, IMS had a market share of between […] (*) and […] % in value and […] contracts. In the first quarter of 2003, this market share increased by […] points in value and to […] contracts taking into account the situation of AzyX.

(13) In its observations of 12 May 2003, NDC considered that there is still considerable uncertainty as to what could be regarded as a derivative of the 1 860 brick structure, in particular what is substantially similar to the 1 860 brick structure and consequently prohibited under German copyright law. NDC is currently offering data in a structure consisting in around 4 000 bricks. This structure is consistent with the structures used by the German postal services. Nevertheless NDC has signed a certain number of new contracts since the 17 September judgment was rendered and there is now apparently greater scope for competitors of IMS to stay on the market as NDC represented between […] and […] % in value of the market in 2002 and increased its market share by […] points in the first quarter with a large amount of contracts. Moreover, NDC has been able to conclude contracts with some bigger pharmaceutical undertakings in its view since the judgement, whereas it previously had no contracts with the top 20 firms.

(*) The square brackets denote confidential information.

(14) AzyX stopped its activities in Germany on 12 March 2003. AzyX had some contracts and represented between […] and […] % in value of the market for German regional pharmaceutical sales data services at the end of 2002. According to AzyX, the losses were caused by its difficulties, driven in its view by the legal uncertainty, in achieving a sustainable level of penetration of the German market and were no longer bearable.

(15) As regards AzyX, its withdrawal from the German market for regional pharmaceutical sales data services constitutes a material change in circumstances. To the extent that the Commission's decision sought to preserve the public interest in viable competition on that market until a final decision could be adopted in this case, that objective can no longer be realised by requiring the grant of a licence to AzyX. The grant of such a licence to AzyX therefore is not possible and is no longer urgent.

(16) As regards NDC's own interests and the public interest in the maintenance of the sole surviving source of competition, it is not necessary for the Commission to take a position on the likely outcome of the pending proceedings for breach of copyright and unfair competition between IMS and NDC. The Commission notes that the Frankfurt Higher Regional Court's judgment of 17 September 2002 coincides with an improvement in the market position of NDC, based on use of the abovementioned structure. In particular, NDC has, for the first time, succeeded in concluding contracts with some larger pharmaceutical companies in the period subsequent to the judgment and its projections for 2003 indicate a general improvement relative to previous years. Therefore, without prejudice to the question whether the judgment of 17 September 2002 has caused this improvement in the commercial position of NDC, there has been a material change in circumstances. The threat of extinction of NDC, posed to NDC and to the public interest in competition, no longer has the urgency to require the grant of a licence to NDC which was identified by the Commission at the time of adoption of its Decision and which is necessary to justify the maintenance of interim measures.

(17) It is therefore necessary to withdraw Decision 2002/165/EC notified to IMS Health on the ground that there is no longer proven urgency requiring the prevention of irreparable damage to NDC and to the public interest in competition before the Commission adopts the decision concluding the present administrative proceeding,

HAS ADOPTED THIS DECISION:

Article 1

Commission Decision 2002/165/EC of 3 July 2001, relating to a proceeding pursuant to Article 82 of the EC Treaty (COMP/D3/38.044 NDC Health/IMS Health: Interim measures) is hereby withdrawn.

Article 2

This Decision is addressed to:

IMS Health
Harewood Avenue
London NW1
United Kingdom.

Done at Brussels, 13 August 2003.

For the Commission
Mario MONTI
Member of the Commission

COMMISSION DECISION

of 13 October 2003

amending Decision 98/371/EC as regards the import of fresh pigmeat from Slovakia

(notified under document number C(2003) 3579)

(Text with EEA relevance)

(2003/742/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries [1], as last amended by Regulation (EC) No 807/2003 [2], and in particular Articles 14, 15 and 16 thereof,

Whereas:

(1) Commission Decision 98/371/EC [3], as last amended by Decision 2003/533/EC [4], governs animal health conditions and veterinary certification for imports of fresh meat from certain European countries.

(2) Slovakia has reported a case of classical swine fever in wild boar in the district of Trnava, which is outside the restricted and infected wild boar areas.

(3) Slovakia has taken measures for the control of classical swine fever concerning wild boars and, in particular, prohibited any imports into the Community of pigmeat originating from this area.

(4) Therefore the district of Trnava should be excluded from the areas authorised for the importation of pigmeat into the Community as laid down in Annex I to Decision 98/371/EC.

(5) Decision 98/371/EC should be amended accordingly.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Annexes I and II to Decision 98/371/EC are replaced by the text in the Annexes to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 October 2003.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 302, 31.12.1972, p. 28.
[2] OJ L 122, 16.5.2003, p. 36.
[3] OJ L 170, 16.6.1998, p. 16.
[4] OJ L 184, 23.7.2003, p. 33.

ANNEX I

'ANNEX I

Description of territories of certain European countries established for animal health certification purposes

Country	Code of territory	Version	Description of territory
Albania	AL	1/1998	Whole country
Bosnia-Herzegovina	BA	1/1998	Whole country
Bulgaria	BG	1/1998	Whole country
	BG-1	1/1998	The provinces of Varna, Dobrich, Solistra, Choumen, Targovichte, Razgrad, Rousse, V.Tarnovo, Gabrovo, Pleven, Lovetch, Plovdiv, Smolian, Pasardjik, Sofia district, Sofia city, Pernik, Kustendil, Blagoevgrad, Vratza, Montana and Vidin
	BG-2	1/1999	The provinces of Bourgas, Jambol, Sliven, Starazagora, Hasskovo and Kardjali, except the 20 km-wide corridor on the border with Turkey
	BG-3	1/1999	The 20 km-wide corridor to the border with Turkey
Belarus	BY	1/1998	Whole country
Czech Republic	CZ	1/1998	Whole country
	CZ-1	1/1999	Whole country excluding the provinces of Kroměříž, Vyškov, Hodonín, Uherské Hradiště, Zlín and Vsetín
	CZ-2	1/1999	The provinces of Kroměříž, Vyškov, Hodonín, Uherské Hradiště, Zlín and Vsetín
Estonia	EE	1/1998	Whole country
Federal Republic of Yugoslavia	YU	1/1998	Whole country
	YU-1	1/1998	The Federal Republic of Yugoslavia excluding the region of Kosovo and Metohija
	YU-2	1/1998	The region of Kosovo and Metohija
Croatia	HR	1/1998	Whole country
Hungary	HU	1/1998	Whole country
Lithuania	LI	1/1998	Whole country
Latvia	LV	1/1998	Whole country

Country	Code of territory	Version	Description of territory
Poland	PL	1/1998	Whole country
Romania	RO	1/1998	Whole country
Russia	RU	1/1998	Whole country
Slovenia	SI	1/1998	Whole country
Slovak Republic	SK	1/1998	Whole country
	SK-1	1/2003	The District Veterinary and Food Administrations (DVFA) of Trnava (comprising Piešťany, Hlohovec and Trnava districts); Levice (comprising Levice district); Nitra (comprising Nitra and Zlaté Moravce districts); Topoľčany (comprising Topoľčany district); Nové Mesto nad Váhom (comprising Nové Mesto nad Váhom district); Trenčín (comprising Trenčín and Bánovce nad Bebravou districts); Prievidza (comprising Prievidza and Partizánske districts); Púchov (comprising Púchov and Ilava districts); Žiar nad Hronom (comprising Žiar nad Hronom, Žarnovica and Banská Štiavnica districts); Zvolen (comprising Zvolen and Detva districts); Banská Bystrica (comprising Banská Bystrica and Brezno districts).
	SK-2	1/2003	The District Veterinary and Food Administrations (DVFA) of Bratislava mesto (comprising Bratislava I, II, III, IV and V districts); Senec (comprising Senec, Pezinok and Malacky districts); Dunajská Streda (comprising Dunajská Streda district); Galanta (comprising Galanta district); Senica (comprising Senica and Skalica districts); Nové Mesto nad Váhom (comprising Myjava district); Púchov (comprising Považská Bystrica district); Nové Zámky (comprising Nové Zámky district); Komárno (comprising Komárno district); Šaľa (comprising Šaľa district); Žilina (comprising Žilina and Bytča district); Dolný Kubín (comprising Dolný Kubín, Tvrdošín and Námestovo districts); Martin (comprising Martin and Turčianske Teplice districts); Liptovský Mikuláš (comprising Liptovský Mikuláš and Ružomberok districts); Lučenec (comprising Lučenec and Poltár districts); Veľký Krtíš (comprising Veľký Krtíš district); Rimavská Sobota (comprising Rimavská Sobota and Revúca districts); Zvolen (comprising Krupina district); Poprad (comprising Poprad, Kežmarok and Levoča districts); Prešov (comprising Prešov and Sabinov districts); Bardejov (comprising Bardejov district); Vranov nad Topľou (comprising Vranov nad Topľou district); Svidník (comprising Svidník and Stropkov districts); Humenné (comprising Humenné, Medzilaborce and Snina districts); Stará Ľubovňa (comprising Stará Ľubovňa district); Košice - mesto (comprising Košice I, II, III and IV districts); Košice - okolie (comprising Košice - okolie district); Michalovce (comprising Michalovce and Sobrance districts); Rožňava (comprising Rožňava district); Spišská Nová Ves (comprising Spišská Nová Ves and Gelnica districts) and Trebišov (comprising Trebišov district).’

ANNEX II

'ANNEX II

Animal health guarantees to be requested on certification of fresh meat

Country	Code	Fresh meat for human comsumption								Fresh meat intended for purposes other than human consumption
		Bovine		Swine		Ovine/caprine		Solipeds		
		MC [1]	SG [2]	MC [1]	SG [2]	MC [1]	SG [2]	MC [1]	SG [2]	MC
Albania	AL	—		—		—		—	—	—
Bosnia-Herzegovina	BA	—		—		—		—	—	—
Bulgaria	BG	—		—		—		D	—	E
	BG-1	A		—		C		D	—	E
	BG-2	—		—		—		D	—	E
Belarus	BY	—		—		—		—	—	E
Czech Republic	CZ	A		B		C		D	—	E
	CZ-1	A		B		C		D	—	E
	CZ-2	A		B		C		D	—	E
Estonia	EE	—		B	a	—		—	—	E
Federal Republic of Yugoslavia	FY	—		—		—		D	—	E
	FY-1	A		—		C		D	—	E
	FY-2	—		—		—		D	—	E
Croatia	HR	A		—		C		D	—	E
Hungary	HU	A		B		C		D	—	E
Lithuania	LT	A		B	a	C		D	—	E
Latvia	LV	—		—		—		—	—	E
Former Yugoslav Republic of Macedonia [3]	MK	—		—		C		D	—	E
Poland	PL	A		B	a	C		D	—	E
Romania	RO	A		—		C		D	—	E
Russia	RU	—		—		—		—	—	E
Slovenia	SI	A		—		C		D	—	E
Slovakia	SK	A		—		C		D	—	E
	SK-1	A		—		C		D	—	E
	SK-2	A		B	a	C		D	—	E

NB: Imports of fresh meat for human consumption are not allowed unless a programme of control of residues in the exporting third country has been approved by the Commission.

[1] MC: Model of certificate to be completed. The letters (A, B, C, D...) appearing in the tables refer to the models of animal health guarantees, as described in Annex III to Decision 98/371/EC, to be applied for each product and origin in accordance with Article 2 of this Decision. A dash "—" indicates that imports are not authorised.

[2] SG: Supplementary guarantees. The letters (a, b, c, d...) appearing on the tables refer to the supplementary guarantees to be provided by the exporting country as described in Annex IV. These supplementary guarantees must be inserted by the exporting country in the section V of each model of certificate laid down in Annex III.

[3] Provisional code that does not affect the definitive denomination of the country to be attributed after the conclusion of the negotiations currently taking place in the United Nations.'

COMMISSION DECISION

of 14 October 2003

on the lists of programmes for the eradication and monitoring of animal diseases and of checks aimed at the prevention of zoonoses qualifying for a financial contribution from the Community in 2004

(notified under document number C(2003) 3708)

(2003/743/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], as last amended by Regulation (EC) No 806/2003 [2], and in particular Articles 24(5) and 32 thereof,

Whereas:

(1) Certain Member States and acceding Member States have submitted programmes to the Commission for the eradication and monitoring of animal diseases for which they wish to receive a financial contribution from the Community.

(2) Under Council Regulation (EC) No 1258/1999 of 17 May 1999 on the financing of the common agricultural policy [3], programmes for the eradication and monitoring of animal diseases are to be financed under the Guarantee Section of the European Agricultural Guidance and Guarantee Fund. For financial control purposes, Articles 8 and 9 of that Regulation are to apply.

(3) In drawing up the list of programmes for the eradication and monitoring of animal diseases qualifying for a financial contribution from the Community in 2004, and the proposed rate and amount of the contribution for each programme, both the interest of each programme for the Community and the volume of available appropriations must be taken into account.

(4) In drawing up the list of programmes of checks aimed at the prevention of zoonoses qualifying for a financial contribution from the Community in 2004, and the proposed rate and amount of the contribution for each programme, the interest of each programme for the Community, its compliance with the technical provisions of relevant Community veterinary legislation and the volume of available appropriations must be taken into account.

(5) Article 32 of the Act of Accession of 2003 lays down that the new Member States are to receive the same treatment as the present Member States as regards expenditure under veterinary funds.

(6) However, no financial commitment under the 2004 budget for any programme concerned may be made before the accession of the concerned acceding Member State has taken place. Furthermore, the eradication of certain diseases in the acceding Member States can also be co-financed under other Community instruments.

(7) The Commission has considered each of the programmes submitted from both the veterinary and the financial point of view and is satisfied that those programmes should be included in the lists of programmes qualifying for a financial contribution from the Community in 2004.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

1. The programmes for the eradication and monitoring of animal diseases listed in Annex I shall qualify for a financial contribution from the Community in 2004.

2. For each programme referred to in paragraph 1, the proposed rate and amount of the financial contribution from the Community shall be as set out in Annex I.

Article 2

1. The programmes of checks aimed at the prevention of zoonoses listed in Annex II shall qualify for a financial contribution from the Community in 2004.

2. For each programme referred to in paragraph 1, the proposed rate and amount of the financial contribution from the Community shall be as set out in Annex II.

[1] OJ L 224, 18.8.1990, p. 19.
[2] OJ L 122, 16.5.2003, p. 1.
[3] OJ L 160, 26.6.1999, p. 103.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 14 October 2003.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

List of programmes for the eradication and monitoring of animal diseases (Article 1(1))

Proposed rate and amount of the Community financial contribution

(in EUR)

Disease	Member State or acceding Member State	Rate	Proposed amount
African/Classical swine fever	Italy (Sardinia)	50 %	250 000
Aujeszkys disease	Belgium	50 %	700 000
	Spain	50 %	75 000
	Hungary	50 %	100 000
	Ireland	50 %	50 000
	Lithuania	50 %	50 000
	Malta	50 %	5 000
	Portugal	50 %	50 000
	Slovakia	50 %	60 000
Bluetongue	Spain	50 %	150 000
	France	50 %	225 000
	Italy	50 %	700 000
Bovine brucellosis	Cyprus	50 %	85 000
	Greece	50 %	300 000
	Spain	50 %	4 000 000
	Ireland	50 %	5 000 000
	Italy	50 %	1 500 000
	Lithuania	50 %	50 000
	Poland	50 %	150 000
	Portugal	50 %	1 800 000
	Slovenia	50 %	110 000
	United Kingdom (Northern Ireland)	50 %	2 000 000
Bovine tuberculosis	Greece	50 %	300 000
	Spain	50 %	5 000 000
	Ireland	50 %	4 500 000
	Italy	50 %	1 200 000
	Lithuania	50 %	70 000
	Poland	50 %	150 000
	Portugal	50 %	400 000
	Slovenia	50 %	40 000
	United Kingdom (Northern Ireland)	50 %	2 000 000
Classical swine fever	Belgium	50 %	175 000
	Czech Republic	50 %	75 000
	Germany	50 %	800 000
	Lithuania	50 %	20 000
	Luxembourg	50 %	90 000
	Slovenia	50 %	30 000
	Slovakia	50 %	125 000

(in EUR)

Disease	Member State or acceding Member State	Rate	Proposed amount
Enzootic bovine leucosis	Italy	50 %	100 000
	Lithuania	50 %	100 000
	Portugal	50 %	100 000
	Slovakia	50 %	40 000
	United Kingdom (Northern Ireland)	50 %	5 000
Ovine and caprine brucellosis (B melitensis)	Cyprus	50 %	725 000
	Greece	50 %	1 000 000
	Spain	50 %	6 500 000
	France	50 %	300 000
	Italy	50 %	3 500 000
	Lithuania	50 %	17 000
	Portugal	50 %	2 000 000
	Slovenia	50 %	70 000
Poseidom (1)	France	50 %	250 000
Rabies	Austria	50 %	200 000
	Czech Republic	50 %	650 000
	Germany	50 %	800 000
	Finland	50 %	70 000
	Latvia	50 %	370 000
	Poland	50 %	1 800 000
	Slovenia	50 %	110 000
	Slovakia	50 %	400 000
Swine vesicular disease Classical swine fever	Italy	50 %	400 000
Total			51 892 000

(1) Heartwater, babesiosis and anaplasmosis transmitted by vector insects in the French overseas departments.

ANNEX II

List of programmes of checks aimed at the prevention of zoonoses (Article 2(1))

Proposed rate and amount of the Community financial contribution

(in EUR)

Zoonosis	Member State or acceding Member State	Rate	Proposed amount
Salmonella	Austria	50 %	150 000
	Denmark	50 %	260 000
	France	50 %	700 000
	Ireland	50 %	90 000
	Lithuania	50 %	400 000
	Netherlands	50 %	400 000
	Slovakia	50 %	400 000
Total			2 400 000