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EN

[1] Text with EEA relevance

I

(Information)

COUNCIL

COMMON POSITION (EC) No 20/2003

adopted by the Council on 17 March 2003

with a view to adopting Regulation (EC) No .../2003 of the European Parliament and of the Council of ... on additives for use in animal nutrition

(2003/C 113 E/01)

(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],

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty [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 wellbeing 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) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.

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

(7) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [4] 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.

(8) 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.

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

(10) 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.

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[1] OJ C 203 E, 27.8.2002, p. 10.

[2] Opinion delivered on 18 September 2002 (not yet published in the Official Journal).

[3] Opinion of the European Parliament of 21 November 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 and Decision of the European Parliament of ... (not yet published in the Official Journal).

[4] 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).

(11) 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 [1], should be included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation.

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

(13) 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 of the European Parliament and of the Council [2]. Applications should be supplemented by residue studies in order to assess the establishment of maximum residues limits (MRLs).

(14) 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.

(15) 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 [3].

(16) 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.

(17) 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 year's data protection for all species for which the additive is authorised.

(18) 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.

(19) 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.

(20) 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.

(21) 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.

(22) 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 in so far 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.

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[1] 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).

[2] 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).

[3] 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).

(23) 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.

(24) 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'.

(25) 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.

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

(27) 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.

(28) Regulation (EC) No .../2003 of the European Parliament and of the Council of ..., on genetically modified food and feed (*) 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.

(29) 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.

(30) 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].

(31) 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.

(32) 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 [2] is completed.

(33) 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 [3]. 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.

(*) See p. 31 of this Official Journal.

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

[2] OJ L 86, 6.4.1979, p. 30. Directive as last amended by Directive 2002/2/EC of the European Parliament and of the Council (OJ L 63, 6.3.2002, p. 23).

[3] 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).

(34) 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.

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 Directive 1999/29/EC;

(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;

[1] OJ L 311, 28.11.2001, p. 1.

[2] OJ L 125, 23.5.1996, p. 35. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

(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 21(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 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.

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 21(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,

[1] Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediairies 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 Council Directive 1999/29/EC (OJ L 115, 4.5.1999, p. 32).

(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 21(2).

Article 7

Application for authorisation

1. An application for an authorisation as provided for in Article 4 shall be sent to the Commission. The Commisison 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 point (h) of paragraph 3 available to the public, subject to the confidentiality requirements laid down in Article 17(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 20, 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 21(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 21(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 21(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 17(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 21(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 21(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 .../2003 ... of the European Parliament and of the Council of ... 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 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 16 (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 analoguous 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 61/2003 (OJ L 11, 16.1.2003, p. 12).

[2] See p. 21 of this Official Journal.

(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. For substances belonging to the category of coccidiostats and histomonostats, an application shall be submitted within a maximum of four years after the entry into force of this Regulation. Before 1 January 2008, the Commission shall submit a report on the use of these substances as feed additives together, where appropriate, with a legislative proposal concerning further use.

3. Products entered in the Register shall be subject to the provisions of this Regulation, in particular Articles 8, 9, 12, 13, 14 and 15, 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 21(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, micro-organisms and preparations used in the Community as silage additives at the date referred to in Article 25(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

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.

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 21(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 21(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 and the efficacy 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 16.

CHAPTER III

LABELLING AND PACKAGING

Article 15

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. 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.

3. 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.

4. 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.

5. 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 21(2).

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 16

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 17

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 18

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.

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

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 19

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.

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 20

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 21(2).

Article 21

Committee

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 22

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 23

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 24

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 22(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 25

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, . . .

For the European Parliament

The President

For the Council

The President

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) colorants:

      (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 20 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:

— the active-substance level.

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 exeed 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'.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 22 March 2002 the Commission presented a proposal for a Regulation of the European Parliament and of the Council, based on Articles 37 and 152(4)(b) of the Treaty, on additives for use in animal nutrition.

The European Parliament delivered its opinion at first reading on 21 November 2002. The Economic and Social Committee delivered its opinions on 18 September 2002.

The Council adopted its common position on 17 March 2003, in accordance with the procedure laid down in Article 251 of the Treaty.

II. OBJECTIVES

The proposal is intended to:

1. simplify the existing rules regarding the authorisation procedure of additives in feedingstuffs,

2. distinguish clearly between the risk evaluation (European Food Safety Authority (EFSA)) and the risk management (Commission and Member States),

3. lay down provisions for the phasing out of antibiotics used as growth promoters,

4. maintain the use of coccidiostats as feed additives and to consolidate EU provisions on additives for use in animal nutrition.

III. ANALYSIS OF THE COMMON POSITION

A. General observations

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

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

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

In particular, the Council has retained the legal form of a Regulation with a view to consolidating existing provisions on the regulation of additives for use in animal nutrition which stem from a variety of Directives. The basic legislation (Directive 70/524/EEC) which it is intended to replace has undergone five major amendments and numerous modifications of the annexes, making its application increasingly difficult for operators and authorities.

The Council also felt that it was appropriate to introduce a number of amendments, many of them at the suggestion of the Parliament, either to define the scope of some provisions, or to make the wording of the Regulation more explicit and guarantee legal certainty, or to increase its consistency with other Community instruments and the transparency of some of the arrangements for its operation.

B. **Specific comments**

1. Main amendments to the Commission proposal

(a) *Status of coccidiostats — Inclusion of histomonostats — Report of use of coccidiostats and histomonostats*

At the suggestion of the Parliament, the Council included histomonostats in the same category of feed additives as coccidiostats, as listed in Article 6(1), thus maintaining these two groups within the framework of the feed additives legislation. While not prejudging the future use of these substances at the present time, the Council also followed Parliament in asking the Commission to present a report on the use of coccidiostats and histomonostats as feed additives before 1 January 2008, where appropriate together with a legislative proposal concerning further use.

(b) *Authorisation procedure*

Following a series of Parliament amendments, several provisions were adapted to clarify the Commission proposal regarding the authorisation procedure, in particular concerning the steps and delays to be followed by the applicant, the Commission and the EFSA (Articles 1, 2, 3, 5, 7, 10, 11, 12, 13 and 14). Part of these modifications aims at ensuring a strict separation of risk evaluation and risk management.

Further, a new paragraph in Article 20 specifies that applicants for authorisation of additives shall contribute to support the implied cost of the the tasks carried out by the Community reference laboratory and the consortium of national reference laboratories.

(c) *Improvement of transparency and traceability — Administrative review*

At the suggestion of Parliament, amendments were made to a few provisions in order to improve the traceability of additives and facilitate communication during the authorisation procedure and the availability of information to the public, in particular through modification of Article 15 on labelling and packaging and Article 17 on confidentiality.

In the interest of animal welfare, a new paragraph was included in Article 19 on data protection, providing rules for the sharing of information in order to avoid repeating toxicological tests on vertebrates.

Further, a new Article 18 was added regarding the administrative review of decisions or failures to act by the EFSA.

(d) *Minor species — Animal categories*

In line with several Parliament amendments, more flexibility in the authorisation procedure was provided for, in particular regarding minor species and the extension to further categories of animals (Article 7(5) and Recitals 14, 15 and 17). Specific conditions suggested by Parliament were added to Article 19 regarding data protection when applying for authorisations for minor species.

The Council also followed Parliament suggestions in allowing for specific guidelines for each category of additive, where necessary (Article 7(5)).

(e) *Specific requirements for pets*

At the suggestion of Parliament, Article 7(5) and corresponding Recital 4 indicate that specific provisions for additives in pet food are appropriate. Taking into account that pets do not enter the human food chain, such exclusive rules may be adopted for pets.

(f) *Definitions and general conditions*

The Council considered it appropriate in the interest of legal clarity to include several additional definitions in Article 2, in particular one of 'feed additives', and to render others more precise, as suggested by Parliament. Various clarifications proposed by Parliament regarding mixtures of additives have been included in Articles 1, 2 and 3 as well as in Recital 8. Likewise, the additive groups in Annex I have been completed, taking into account a series of Parliament amendments. A new Annex IV gives room for establishing general conditions of use.

(g) *Silage agents*

Following a suggestion by Parliament, an extension for silage agents was added in Article 10. This extension, accompanied by a transitional arrangement for silage agents which are currently marketed and used in the Community without an authorisation pursuant to Directive 70/524/EEC, was considered necessary because the scope of said Directive is vague and therefore there is no uniform application in the Member States concerning silage agents.

(h) *Phasing out of antibiotics used as growth promoters*

At the suggestion of Parliament, Article 11 clarifies that any antibiotic, other than coccidiostats and histomonostats, shall be deleted from the Register as from the phase-out date specified in that Article. In setting this date at the 1 January 2006, the Council followed the Commission proposal.

2. Council's position on the European Parliament's amendments

The Council has incorporated the following amendments in its common position:

— 1, 4, 6, 8, 16, 17, 18, 19, 21, 24, 25, 28, 29, 30, 34, 43 and 45;

and incorporated part of, or retained the principle of amendments

— 3, 5, 12, 13, 20, 26, 31, 32, 33, 36, 38, 40, 41, 44 and 47.

The Council followed the Commission and did not incorporate amendments

— 2, 7, 9, 10, 15, 22, 27, 35 (partially), 37, 42, 46 and 48.

COMMON POSITION (EC) No 21/2003

adopted by the Council on 17 March 2003

with a view to adopting Regulation (EC) No .../2003 of the European Parliament and of the Council of ... 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

(2003/C 113 E/02)

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 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 .../2003 of the European Parliament and of the Council of ... 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 .../2003.

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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 and Decision of the European Parliament of ... (not yet published in the Official Journal).

[5] OJ L 106, 17.4.2001, p. 1.

[6] OJ L ...

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

(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 .../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) 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].

(12) 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.

(13) 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.

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

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 alpha-numeric 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;

[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 amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

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 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.

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[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).

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 .../2003, provided that these traces of GMOs are adventitious or technically unavoidable.

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 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 .../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 pre-packaged 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 re-packaging of a product.

Article 7

Amendment of Directive 2001/18/EC

Directive 2001/18/EC is hereby amended as follows:

1) Article 4(6) shall be deleted.

2) The following paragraph shall be 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 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 .../2003.

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 . . . (*) and shall notify it without delay of any subsequent amendment affecting them.

Article 12

Review clause

No later than . . . (**), 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 twentieth 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 ninetieth 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, . . .

For the European Parliament

The President

For the Council

The President

(*) 180 days following the date of publication of this Regulation.

(**) Two years from the date of publication of this Regulation.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. The Commission submitted to the Council on 21 August 2001 a **proposal** for a Regulation of the European Parliament and of the Council 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. The Economic and Social Committee adopted its **opinion** on 21 March 2002.

3. The Committee of the Regions adopted its **opinion** on 16 May 2002.

4. The European Parliament adopted its **opinion** on 3 July 2002.

5. The Commission submitted to the Council on 16 September 2002 an **amended proposal** on the above subject.

6. On 17 March 2003, the Council adopted its common position in accordance with Article 251(2) of the Treaty.

II. OBJECTIVE

The Regulation aims at the establishment of a traceability and labelling system for genetically modified organisms (GMOs) as or in products and of a traceability system for food and feed derived from GMOs. Such a system shall apply at all stages of the placing on the market, and it will facilitate:

— targeted monitoring of potential effects,

— control and verification of labelling claims,

— withdrawal of products, should an unforeseen risk to human health or the environment be established.

The traceability system involves the following elements:

— the establishment by the Commission (through a comitology procedure) of a system to specify the identity of GMOs by the assignment of a 'unique identifier', allowing the retrieval of information concerning its traits, characteristics and authorised transformation events,

— systems and procedures to identify the operators to whom and from whom products are made available,

— the transmission by operators of information concerning the identity of a product, i.e.

  (i) whether it contains GMOs as well as the 'unique identifiers' for the individual GMOs that the product contains, or

  (ii) that the product is 'produced from GMOs' in case of GMO-derived food and feed products,

— retention by operators of specified information for a period of five years, to be made available to competent authorities upon request,

— Commission guidance on sampling and testing methodology to facilitate a coordinated approach to inspections and controls.

Labelling requirements are foreseen for products consisting of or containing GMOs, complementary to the existing ones in Directive 2001/18/EC (on the deliberate release of GMOs) and to those foreseen by the Commission in its proposed Regulation on genetically modified food and feed.

III. ANALYSIS OF THE COMMON POSITION

1. General

The main issues of the Regulation are requirements for traceability and labelling of products that consist of or contain GMOs (Article 4), and provisions for traceability of products that are produced from GMOs but do not contain GMOs themselves (Article 5). In this respect, as well as with regard to the scope of the Regulation, the Council fully accepts the Commission proposal.

Exemptions from the traceability and labelling scheme shall be allowed for the adventitious or technically unavoidable presence of traces of GMOs (Articles 4(7), 4(8) and 5(4)). The thresholds for these exemptions are introduced in this Regulation by way of reference to the respective Articles of the Regulation on genetically modified food and feed (as discussed in parallel with this Regulation), where the threshold level has been set at 0,9 % and can be lowered via a regulatory committee procedure, as well as by way of reference to Directive 2001/18/EC. While the exemptions generally cover only GMOs that have been authorised in the EU, the adventitious or technically unavoidable presence of such GMOs that have not been authorised but have benefited from a favourable risk evaluation will be permitted below a threshold level of 0,5 %, or lower as set by a regulatory committee procedure, for a transitional period of three years.

The Council has tightened the Commission proposal with regard to the information that has to accompany bulk shipments of products containing mixtures of GMOs (Article 4(3)) by allowing only for '. . . a list of the unique identifiers for all those GMOs that **have been used to constitute the mixture**', instead of '. . . unique codes for the GMOs that the product **may contain**' as originally proposed by the Commission.

Complementary to this provision, the Council has introduced a review clause (Article 12) in order to call on the Commission

— to present a report after the first experiences with the provision of Article 4(3) have been gained in practice, and

— where appropriate, to make proposals for changes to the Regulation.

While the Regulation generally covers all stages of placing on the market of the products, the Council has filled a gap by introducing that inspection and control measures can also target the holding of a product.

The Commission has accepted the common position agreed by the Council.

2. European Parliament amendments

In its plenary vote on 3 July 2002, the EP adopted 30 amendments to the proposal. While 15 of these amendments could not be accepted by the Council, another 15 have been incorporated either verbatim, in part or in spirit into the common position.

(a) *The 15 amendments that have been incorporated can be grouped as follows:*

Five amendments accepted verbatim:

Amendment 9 has been incorporated in the definition of 'Genetically modified organism' in Article 3.

Amendment 10 has been incorporated in the definition of 'Operator' in Article 3.

Amendment 11 has been taken on board in the definition of 'Food' in Article 3.

Amendment 13: 'to the ultimate user' has been deleted from the definition of 'Pre-packaged' in Article 3.

Amendment 14: an improved provision for labelling as proposed in this amendment has been incorporated in Article 4(6).

10 amendments accepted in part or in spirit:

Amendment 2: the reference to the precautionary principle has been incorporated in Recital 3, and Article 1 now refers to appropriate risk management measures.

Amendment 6: several aspects of this long amendment have been taken up in Article 1 (reference to health) and Recital 3 (references to the precautionary principle, to the protection of human and animal health, and to the protection of ecosystems).

Other issues mentioned in the amendment are not regarded as appropriate for consideration in the Regulation.

Amendment 12 has been, in principle, incorporated in the definition of 'Placing on the market' in Article 3 by way of referring to Article 2(4) of Directive 2001/18/EC. However, for reasons of consistency, the Council gives priority to definitions, in the event that they exist, in the specific Community legislation under which the relevant product has been authorised.

Amendment 24: the spirit of this amendment has been taken on board by clarifying the exemption in Article 6 through the addition of the sentence *'This Article does not apply to the first stage of placing on the market of a product or to primary manufacture or re-packing of a product.'*, as contained in the amended Commission proposal.

Amendment 27: with regard to 'good segregation practice', the Council has agreed upon a declaration in connection with the Regulation on genetically modified food and feed. The declaration was added to the minutes of the Agriculture/Fisheries Council of 28/29 November 2002 and reads as follows:

'The Council invites the Member States to encourage and contribute to the drawing up of ***guides in particular on good segregation practice*** *to be applied by food and feed operators in order to minimise the adventitious or technically unavoidable presence of genetically modified material in food and feed.'*

Amendment 29: the reference to 'sample checks and testing (quantitative and qualitative)' has been incorporated in Article 9(1). Mentioning 'risk assessment' is not deemed appropriate in this respect, as inspection and control rather constitute risk management measures.

Amendment 30 has been taken into account in part in Article 9(2). The regulatory committee procedure, however, has been replaced by an advisory committee procedure and the Council prefers not to include an explicit provision for publishing the technical guidance to be developed by the Commission.

Amendment 31: a reference to existing and future registers containing information on GMOs has been included in Recital 8.

Amendment 35: the spirit of this amendment has been integrated into Recital 4: *'. . . so as to ensure that accurate information is available to operators and consumers . . .'*.

Amendment 47 has been completely incorporated in Article 9(2) with the only exception that reference is made to the work rather than to the rules of the Community Reference Laboratory.

(b) *The 15 amendments that have not been incorporated can be grouped as follows:*

Information accompanying mixtures of GMOs **('may contain', Amendment 16**): instead of deleting this provision, which would have costly and non-practicable consequences, the Council has considerably tightened the conditions by allowing a list of identifiers only for those GMOs that **have been used to constitute the mixture** (Article 4(3)).

Holding of all information relevant for traceability of GMOs and derived products for a period of ten years instead of five **(Amendments 17 and 22)**: the Council is of the opinion that the proposed doubling of the time period is of no added practical value, but also puts additional burden on operators and inspection authorities.

Amendment 20 has not been taken on board because additional labelling of products produced from GMOs (derived products) is not necessary to meet the objectives of the proposal.

Amendment 21: the transmission of information on the unique code of GMOs from which a product is made is not deemed necessary by the Council, as the products in question do not contain any GMOs. For the purpose of labelling products produced from GMOs (under the Regulation on genetically modified food and feed), it is sufficient to transmit the information that they are produced from GMOs, but it is not necessary to establish a detailed history and documentation of the origin of each product.

Thresholds for the adventitious or technically unavoidable presence of GMOs or of traces of materials produced from GMOs **(Amendments 26, 52 and 55)**: the provisions of these amendments are not appropriate in the framework of the traceability and labelling scheme that was proposed by the Commission and that has been in general accepted by the Council. Also, they cannot be accepted in order to keep consistency with Directive 2001/18/EC and the Regulation on genetically modified food and feed. Furthermore, the Council agrees with the arguments as outlined by the Commission in its amended proposal of 13 September 2002.

Deletion of Article 4(6) of Directive 2001/18/EC **(Amendments 28 and 51)**: Article 4(6) of Directive 2001/18/EC has to be deleted in order to avoid a dual system of national and Community systems for traceability. It is the firm intention of the Council to provide for a harmonised framework for all measures related to traceability of GMOs, as expressed also in Recital 2.

Entry into force **(Amendments 32 and 33)**: as the Council does not intend to delete Article 7, this Article may not be excluded from the provisions for entry into force.

Furthermore, the Council does not agree to link the authorisation procedure for GMOs with the establishment of the system of unique identifiers by the Commission, as contained in Article 8 of the Regulation.

Definition of 'Produced from GMOs' **(Amendment 39)**: the Council cannot accept this amendment for reasons of consistency with other legislation (Novel Foods Regulation (EC) No 258/97 and the proposed Regulation on genetically modified food and feed).

Reference to comitology **(Amendment 48)**: with regard to the scope of this Regulation, the Council deems most appropriate the committee established under horizontal Directive 2001/18/EC.

Standardisation of the procedures for the identification of transactions **(Amendment 50)**: the Council does not share the opinion of the EP that the procedures referred to in Article 4(4) need to be standardised at Community level. The choice of the procedure should be left to the Member States in order to allow them to apply existing systems.

3. **Important innovations introduced by the Council**

Apart from the innovations already described under III.1:

— thresholds for exemptions from traceability and labelling,

— information accompanying mixtures of GMOs,

— review clause,

— control and inspection also for the holding of products

and described under III.2 (EP amendments), the Council has introduced the following main innovations in the text of the Regulation:

— new recital 7, addressing feed for animals not destined for food production (pets),

— further detailing of recital 10, addressing the need for thresholds for the exemption of the adventitious or technically unavoidable presence of GMOs from the traceability and labelling rules,

— revision of the definitions (Article 3): elimination of the definitions of food/feed additives, (compound) feedingstuff, flavourings and feed materials and the inclusion of the definitions of 'Final consumer' and 'Ingredient',

— re-structuring of the Articles 4 to 6 that describe the traceability and labelling rules and the exemptions thereof,

— amendment of Directive 2001/18/EC by way of inclusion of a new Article 21(3), which provides for an exemption from labelling for GMOs intended for direct processing.

IV. **CONCLUSION**

Despite the fact that the Council is not able to accept all amendments adopted by the European Parliament, it considers that the common position coincides to a large extent with the concerns of the Parliament and it is in almost complete agreement with the Commission's amended proposal.

The common position represents a balanced approach between practicability and the concerns for the protection of health and environment, without compromising biosafety.

After the entry into force of Directive 2001/18/EC, this Regulation is another milestone in the legislation for the safe management of products originating from modern biotechnology.

With regard to the political relevance of this Regulation and also in the light of the de-facto moratorium on the authorisation of new GMOs being linked to its entry into force, the Council expresses its firm hopes that it will be possible to achieve an agreement soon.

COMMON POSITION (EC) No 22/2003

adopted by the Council on 17 March 2003

with a view to adopting Regulation (EC) No .../2003 of the European Parliament and of the Council of ... on genetically modified food and feed

(2003/C 113 E/03)

(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 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 wellbeing 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 and Decision of the European Parliament of ... (not yet published in the Official Journal).

[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) The making available of genetically modified micro-organisms for activities regulated under Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [2], including culture collections, the making available of GMOs to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment, and the making available of GMOs to be used exclusively for deliberate releases complying with the requirements referred to in part B of Directive 2001/18/EC, are not considered as forms of marketing under the latter Directive. Those operations are therefore exempted from the need to obtain a Community authorisation under Part C of Directive 2001/18/EC. It is appropriate to apply the same exceptions in this Regulation. It is, however, appropriate to maintain the need for an authorisation for genetically modified food and feed, including food and feed produced from GMOs or genetically modified micro-organisms in contained use.

(11) 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.

(12) 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.

(13) 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 [3] 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.

(14) 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 [4] 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.

(15) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition [5] 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.

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

[2] OJ L 117, 8.5.1990, p. 1. Directive as last amended by Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32).

[3] 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).

[4] 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).

[5] 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).

(16) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [1], 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.

(17) 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, 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.

(18) In accordance with Article 153 of the Treaty, the Community is to contribute to the promotion of 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.

(19) 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 [2] 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.

(20) 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 [3] 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 [4].

(21) 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.

(22) 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 the potential misleading of consumers as regards methods of manufacture or production.

(23) 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.

(24) Regulation (EC) No . . ./2003 of the European Parliament and of the Council of . . . concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms [5] 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.

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[1] 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).

[2] OJ L 109, 6.3.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

[3] 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).

[4] OJ L 6, 11.1.2000, p. 15.

[5] OJ L . . .

(25) 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 its 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.

(26) It is appropriate to provide that, when the combined level of the 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.

(27) It is vital 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 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.

(28) 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.

(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 . . ./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 competent national 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.

(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 [11].

(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.

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[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 Commission Decision 2002/111/EC (OJ L 41, 13.2.2002, p. 43).

[7] OJ L 157, 10.6.1992, p. 10. Directive as last amended by Commission Decision 2002/112/EC (OJ L 41, 13.2.2002, p. 44).

[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 Directive 2002/68/EC (OJ L 195, 24.7.2002, p. 32).

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

(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;

(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', 'risk', 'final consumer', 'food business' and 'feed business' given in Regulation (EC) No 178/2002 shall apply;

2. '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;

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

4. '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;

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

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

7. '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;

8. '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;

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

10. '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);

11. '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;

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

13. '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. The following operations shall not be regarded as placing on the market:

— making available genetically modified micro-organisms for activities regulated under Directive 90/219/EEC, including culture collections,

— making available GMOs, other than micro-organisms referred to in the first indent, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment; the measures should be based on the same principles of containment as those referred to in Directive 90/219/EEC,

— making available GMOs to be used exclusively for deliberate releases complying with the requirements referred to in Part B of Directive 2001/18/EC;

14. '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.

15. '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) present an unacceptable risk for human 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 competent national authority of a Member State.

(a) The competent national 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. This 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 competent national authority through the Authority may, where appropriate, ask 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 competent national 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 competent national 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 to 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 . . ./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 ten 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.

(*) Note for the Official Journal (GMO Traceability Regulation).

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 ten-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 safety in the 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 % 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 that of 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) present an unacceptable risk for animal health, human 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 Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition [1], 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 [2];

(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 a 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.

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[1] 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).

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

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 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. This time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided in paragraph 2.

2. The Authority or a competent national 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 competent national 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 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 competent national 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 to 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 . . ./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 ten 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.

(*) Note for the Official Journal (GMO Traceability Regulation).

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 wishes 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 safety in the 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 ten-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry 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 safety in the 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, 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 % 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 that of 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 that of 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) the name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, an indication of the substrate and the micro-organism;

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

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

(d) the 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) the 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) the 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 ten years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used.

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

On the expiry of this ten-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 the cost of the tasks of the Community reference laboratory and the European Network of GMO laboratories mentioned in the Annex.

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 . . ./2003 of the European Parliament and of the Council of . . . on genetically modified food and feed (*).

(*) OJ L . . .'

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 . . ./2003 of the European Parliament and of the Council of . . . on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L . . .'

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 . . ./2003 of the European Parliament and of the Council of . . . on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L . . .'

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 . . ./2003 of the European Parliament and of the Council of . . . 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 ...
(**) OJ L 31, 1.2.2002, p. 1.'

Article 43

Amendment to Directive 2001/18/EC

The following Article shall be inserted in Directive 2001/18/EC with effect from the date of entry into force of this Regulation:

'*Article 12a*

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

1. The 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 .../2003 of the European Parliament and of the Council of ... 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 .../2003.

(*) OJ L ...'

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 at the latest six months after the date of entry into force of this Regulation 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 . . . (*) 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 put forward proposals at the earliest possible date.

Article 49

Entry into force

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

For the European Parliament
The President

For the Council
The President

(*) Two years from the date of entry into force of this Regulation.

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 purposes of 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:

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

   — the 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.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 25 July 2001 the Council adopted a proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed, based on Articles 37, 95, and 152(4)(b) of the EC Treaty.

The European Parliament delivered its opinion at first reading on 3 July 2002; the Committee of the Regions and the Economic and Social Committee delivered their opinions on 16 and 30 May 2002 respectively.

On 8 October 2002 the Commission adopted an amended proposal for a Regulation of the European Parliament and of the Council in accordance with Article 250(2) of the EC Treaty.

The Council adopted its common position on 17 March 2003, in accordance with the procedure laid down in Article 251 of the EC Treaty.

II. OBJECTIVE

In accordance with the White Paper on food safety, the aim of this proposal is to:

(a) guarantee a high level of protection for human life and health, animal health, the environment and consumers' interests as regards genetically modified food and feed, while ensuring that the internal market functions properly;

(b) establish clear and transparent Community procedures to assess, authorise and monitor genetically modified food and feed;

(c) establish as complete a system as possible for the labelling of genetically modified food and feed.

III. ANALYSIS OF THE COMMON POSITION

A. General comments

The common position is substantially in accordance with the positions taken by the Commission and the Parliament, insofar as it

— confirms all the objectives and essential elements of the Commission's proposal which were also supported by the European Parliament;

— takes the greatest possible account of the opinion of the European Parliament by taking on, in letter or in spirit, a great number of its amendments.

On its own initiative, the Council also felt it appropriate to introduce a range of amendments to its common position, either to clarify the scope of certain provisions, or to make the wording of the Regulation more explicit and thus ensure legal certainty, or to increase its consistency with other Community acts.

B. Specific comments

1. Main provisions of the common position

(a) Authorisation procedure established for genetically modified food and feed (Articles 5, 6, 7, 17, 18 and 19)

The Council has followed entirely the solutions proposed on this subject by the Commission and supported by the Parliament.

The new authorisation procedures for genetically modified food will reproduce the new principles introduced in Directive 2001/18/EC and will make use of the new framework for the food safety risk assessment set by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002.

The placing on the market of genetically modified food and feed will therefore only be authorised after an independent and rigorous assessment of the risks which they might carry for human and animal health and, where appropriate, the environment. This assessment, which will be carried out under the responsibility of the European Food Safety Authority, will be followed by a risk management decision taken by the Community, within the framework of a regulatory procedure which will ensure close cooperation between the Commission and the Member States.

However, two significant amendments have been introduced to this procedure by the Council:

— the request for authorisation must be addressed to the Authority not directly, but through the intermediary of a Member State,

— regarding environmental risk assessment, when the request relates to GMOs to be used as seed or other plant propagating material, the Authority will ask a competent national authority to carry out the assessment itself.

(b) Transitional measures in respect of the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation (Article 47)

To ensure that the Regulation is applicable and feasible, the Council felt it appropriate to consider that below a certain threshold the presence of such traces in a food or feedingstuff should not be considered as a violation of the obligation to hold a marketing authorisation, if strict conditions were otherwise met.

The Council has therefore set a threshold which it has fixed at 0,5 %, subject to compliance with the following strict conditions:

— the GMOs concerned must have received a favourable opinion from a Community scientific authority before the date of application of the Regulation,

— this tolerance will apply only during the three years following the entry into force of this Regulation,

— the threshold may if necessary be lowered in accordance with the committee procedure.

The Council also noted that, in the context of the review clause in Article 48 of the Regulation, the Commission undertook to monitor whether the application of the measures was giving rise to any difficulties.

It should be noted that the Council here chose a much stricter and more consistent approach than that initially proposed by the Commission (since the threshold has been significantly lowered, and the measures provided for are now only temporary), and that it has therefore come considerably closer to the position expressed by the European Parliament.

(c) Labelling threshold concerning the adventitious presence of GMOs (Articles 12 and 24)

The Council took into account the fact that, despite operators' wishes to the contrary, GMO material might nonetheless be present in the form of traces in the food or feed which they produced, as a result of its adventitious or technically unavoidable presence during the production of seed, cultivation, transport or processing. It therefore judged, like the Commission, that in such cases the food or feed should not be subject to the obligation to indicate the presence of GMOs on the labelling, if that presence was below a certain threshold.

The Council set the proportion of adventitious or technically unavoidable presence of GMOs at a maximum of 0,9 % for each ingredient.

However, it will also be possible to set lower thresholds under the committee procedure, particularly as regards food and feed containing GMOs or consisting of such organisms or to take account of progress in science and technology.

It should be noted that the threshold was fixed following a careful examination of all points raised by this issue, and that the Council considers that it represents a good balance enabling the objectives pursued to be attained, while ensuring the applicability of the future Regulation.

(d) Status of existing products (Articles 8 and 20)

The common position extends the scope of the rules applicable to existing products, not limiting these only to GMO products which have already been authorised on the basis of existing legislation but also including GMO products put legally onto the Community market before the Regulation was applied.

Thus the Council intends to establish improved monitoring of all existing genetically modified food and feed on the Community market.

2. Council's position on the European Parliament's amendments

(a) The following amendments have been either accepted or taken into account in the common position:

— Authorisation procedure

37, 39, 81, 84, 87, 93 and 165 (see Article 5(2), Articles 6(3)(c) and 6(4), Article 17(2), Articles 18(3)(c) and 18(4), and recitals 33 and 34).

— Transparency and public information

30, 38, 45, 47, 52, 55, 56, 57, 77, 82, 90, 92, 98, 101, 102, and 103 (see Article 5(3)(j), Articles 6(5)(f) and 6(6), Article 17(3)(j), Articles 18(5)(f) and 18(6), and more particularly Article 29 which lists the documents and information to be made accessible to the public).

— Community reference laboratory

41, 44, 86 and 89 (see Articles 6(3)(d) and 5(f), 18(3)(d) and 5(f)).

— Labelling

70, 71, 110, 112, 123, 145, 146, 147, 162, 163, 164 (see Articles 12, 13, 24, 25 and 46(2)).

— Precautionary principle

1 and 13 (see Article 1 which refers to the general principles laid down in Regulation (EC) No 178/2002).

— Concept of risk

23 (see Articles 4(1)(a) and 16(1)(a) which introduce the concept of an unacceptable risk for health).

— Emergency measures

117 and 118 (see Article 34).

(b) Various editorial amendments

Many of the editorial improvements which have been made to the text of the common position on points of detail are consistent with the spirit of many of the amendments proposed by the European Parliament.

(c) However, the Council has aligned itself with the Commission's position by not taking into account the following amendments:

8, 14, 22, 25, 26, 29, 33, 35, 43, 46, 48, 49, 50, 51, 53, 54, 58, 59, 60, 61, 72, 73, 74, 76, 79, 83, 88, 91, 95, 96, 97, 99, 100, 104, 105, 109, 111, 113, 116, 120, 122, 142, 156, 159, 161, 167.

COMMON POSITION (EC) No 23/2003

adopted by the Council on 17 March 2003

with a view to adopting a directive 2003/. . ./EC of the European Parliament and of the Council of . . . amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

(2003/C 113 E/04)

(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 Article 95 thereof,

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

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

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

Whereas:

(1) On 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes [4] (hereinafter referred to as the Convention).

(2) Council Directive 86/609/EEC [5] is the implementing tool of the Convention incorporating the same objectives as the Convention.

(3) Annex II to Directive 86/609/EEC containing guidelines for accommodation and care of animals takes over Appendix A to the Convention. The provisions contained in Appendix A to the Convention and the Annexes to the said Directive are of a technical nature.

(4) It is necessary to ensure the consistency of the Annexes to Directive 86/609/EEC with the latest scientific and technical developments and results of research within the fields covered. Currently, changes to the Annexes can only be adopted by the long-drawn-out co-decision procedure with the consequence that their content is lagging behind the latest developments in the field.

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

(6) Therefore Directive 86/609/EEC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Directive 86/609/EEC the following Articles shall be inserted:

'*Article 24a*

The measures necessary for the implementation of this Directive relating to the subject matters referred to below shall be adopted in accordance with the regulatory procedure set out in Article 24b(2):

— Annexes to this Directive.

Article 24b

1. The Commission shall be assisted by a 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 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before . . . (*). They shall forthwith inform the Commission thereof.

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[1] OJ C 25 E, 29.1.2002, p. 536.

[2] OJ C 94, 18.4.2002, p. 5.

[3] Opinion of the European Parliament of 2 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 and Decision of the European Parliament of . . . (not yet published in the Official Journal).

[4] OJ L 222, 24.8.1999, p. 29.

[5] OJ L 358, 18.12.1986, p. 1.

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

(*) One year after the date of entry into force of this Directive.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, . . .

For the European Parliament
The President

For the Council
The President

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 28 November 2001, the Commission submitted to the Council a proposal for a Directive of the European Parliament and of the Council amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.

2. The Economic and Social Committee submitted its opinion on 19 March 2002.

The European Parliament adopted its opinion at first reading on 19 June 2002.

3. On 17 March 2003, the Council adopted its common position in accordance with Article 251(2) of the Treaty.

II. OBJECTIVE

Directive 86/609/EEC (on the protection of animals used for experimental and other scientific purposes) is the implementing tool for Council of Europe Convention ETS 123 (on the protection of vertebrate animals used for experimental and other scientific purposes), of which the Community is a Party. Annex 2 of the Directive takes up Appendix A of the convention, containing guidelines for the housing and care of laboratory animals.

The Council of Europe has opened for signature and ratification a 'Protocol of Amendment' to the Convention. It provides for amending the Appendices by a simplified procedure rather than by the usual procedure that involves ratification by all parties. This would allow the Convention to keep up-to-date with the latest scientific knowledge and research on the welfare of the laboratory animals quicker and much more flexibly than today. The Commission has proposed a Council decision on the conclusion of that Protocol of Amendment on behalf of the European Community.

In order to have the implementing legislation in line with the Protocol of Amendment, the Commission has proposed the present Directive amending Council Directive 86/609/EEC. This amendment is aimed at providing for a regulatory committee procedure instead of the full co-decision process for a more flexible introduction of changes to the Annexes of Directive 86/609/EEC.

III. ANALYSIS OF THE COMMON POSITION

1. *European Parliament amendments*

As the European Parliament adopted the Commission proposal unchanged, there are no amendments to be taken into account.

2. *Innovations introduced by the Council*

— In Article 1, the Council has introduced the standard wording for the reference to the comitology procedure.

— In Article 2, the Council has specified the time limit for compliance with the Directive by setting it to one year following the publication of the Directive in the *Official Journal of the European Union*.

— Recitals 3 and 5 have been slightly rephrased without changing the substance.

IV. **CONCLUSION**

The Council welcomes and supports the Commission proposal as useful and appropriate.

However, in contrast to the European Parliament, the Council is not able to accept the Commission proposal unchanged, as it insists on the standard wording for the reference to the comitology procedure.