Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed

(2001/C 304 E/15)

(Text with EEA relevance)

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(Submitted by the Commission on 30 July 2001)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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

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

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

Whereas:

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

(2) A high level of protection of human life and health should be assured 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 (hereunder called '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 on novel foods and novel food ingredients [1]. 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 safety assessment process 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) have so far been authorised in accordance with Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [2]; 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 new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [3]. They should further make use of the new framework for risk assessment in matters of food safety set up by Regulation (EC) No . . ./. . . laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety. 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 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.

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 117, 8.5.1990, p. 15.

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

(9) 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.

(10) Under this Regulation, authorisation may be granted either to a GMO 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 do not need an authorisation under this Regulation, but are subject to the requirements laid down in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation are 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 laid down 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.

(11) Council Directive 89/107/EEC of 21 December 1988 concerning food additives authorised for use in foodstuffs intended for human consumption ([1]), as last amended by Directive 94/34/EC of 30 June 1994 ([2]), provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also under the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure laid down in Directive 89/107/EEC.

(12) Flavourings falling under the scope of Council Directive 88/388/EEC of 22 June 1988 relating to flavourings for use in foodstuffs, which contain, consist of or are produced from GMOs should fall also under the scope of this Regulation for the safety assessment of the genetic modification.

(13) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([3]), as last amended by Council Directive 1999/20/EC ([4]), provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment; these feed materials containing, consisting of or produced from GMOs should fall instead under the scope of this Regulation.

(14) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([5]), as last amended by Council Directive 1999/20/EC ([6]), 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 under the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure laid down in Directive 70/524/EEC.

(15) This Regulation covers 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 starting material is present in the food or in the feed. Processing aids as defined in Council Directive 89/107/EEC, 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. Thus, food produced with a genetically modified enzyme that does not remain in the final product and products obtained from animals fed with genetically modified feed or treated with genetically modifed medicinal products will be subject neither to the authorisation requirements, nor to the labelling requirements laid down in this Regulation.

(16) In accordance with Article 153 of the Treaty, the Community shall contribute to promote the right of consumers to information. Additional to other types of information to the public established in this Regulation, labelling of products is a means that enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

(17) Article 2 of Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([7]) requires that the labelling must not mislead the purchaser, as to the characteristics of the foodstuff and among others, in particular, as to its nature, identity, properties, composition, method of manufacture or production.

([1]) OJ L 40, 11.2.1989, p. 27.
([2]) OJ L 237, 10.9.1994, p. 1.
([3]) OJ L 213, 21.7.1982, p. 8.
([4]) OJ L 80, 25.3.1999, p. 20.
([5]) OJ L 270, 14.12.1970, p. 1.
([6]) OJ L 80, 25.3.1999, p. 20.
([7]) OJ L 109, 6.3.2000, p. 29.

(18) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97 on novel foods and novel foods ingredients, in Regulation (EC) No 1139/98 [1] 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, as amended by Regulation (EC) No 49/2000 [2] and in Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings [3].

(19) 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, which enable the user to make an informed choice.

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

(21) Additionally, the labelling should inform about any characteristic or property which renders a food or feed not equivalent to its conventional counterpart in respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications on certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

(22) Regulation (EC) No .../... 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 ensures that the specific information concerning the genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced thereof and should thereby facilitate accurate labelling.

(23) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable contamination during cultivation, harvest, transport and 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, it is necessary to establish thresholds for the adventitious or technically unavoidable presence of genetically modified material in foods or feed.

(24) 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.

(25) In order to ensure the practicability and feasibility of this Regulation, a threshold of 1 %, with the possibility of establishing lower levels, should be established for minute traces in food or feed of genetically modified material not authorised under Community legislation, where the presence of such material is adventitious or technically unavoidable; Directive 2001/18/EC should be amended accordingly.

(26) 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.

(27) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the European Food Authority.

(28) 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 legitimate factors relevant to the matter under consideration may be taken into account.

(29) Risks to the environment may be associated with foods and feed which contain or consist of GMOs. Part C of Directive 2001/18/EC provides that no product consisting of or containing a GMO may be placed on the market without *inter alia* a risk assessment having been carried out in accordance with that part of the Directive. However, that requirement is waived in respect of any product covered by sectoral Community legislation that provides for a specific environmental risk assessment at least equivalent to the environmental risk assessment carried out in accordance with Annexes II and III to that Directive. This Regulation should satisfy the conditions for the waiver to apply the requirements of that Directive. It is therefore also necessary that its provisions in regard to risk management, labelling, monitoring, information to the public and safeguard clause, must be at least equivalent to those laid down in Directive 2001/18/EC.

[1] OJ L 159, 3.6.1998, p. 4.

[2] OJ L 6, 11.1.2000, p. 13.

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

(30) It is necessary to introduce, where appropriate and based on the conclusions of the risk assessment, post-market monitoring requirements for the use of the genetically modified foods for human consumption and for the use of the genetically modified feed for animal consumption. In the case of genetically modified organisms, a monitoring plan concerning environment effects is compulsory in accordance with Directive 2001/18/EC.

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

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

(33) Existing authorisations and notifications for placing on the market genetically modified foods under Regulation (EC) No 258/97 on novel foods and novel food ingredients and existing authorisations of genetically modified food and feed, granted under Directives 90/220/EEC and 2001/18/EC, Directive 82/471/EEC or Directive 70/524/EEC, should continue to remain in force, subject to that the European Food Authority is provided with information concerning the risk assessment, methods for sampling and detection as appropriate, including samples of the food and feed and their control samples within six months of the entry into force of this Regulation.

(34) A register of genetically modified food and feed authorised under this Regulation shall be established, including product specific information, studies which demonstrate the safety of the product, and sampling and detection methods; non-confidential data should be made available to the public.

(35) In order to stimulate research and development into genetically modified organisms 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 should be against the public interest.

(36) The measures necessary for the implementation of this Regulation are to 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]. The Commission shall be assisted by the Committee referred to in Article 57 (1) of Regulation (EC) No . . ./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety.

(37) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Decision of 16 December 1997 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.

(38) 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.

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVE AND DEFINITIONS

Article 1

Objective

The objective of this Regulation is:

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

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

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

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

Article 2

Definitions

For the purposes of this Regulation:

1. the definitions of 'food', 'feed', 'placing on the market' and 'traceability', laid down in Regulation (EC) No .../2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety shall apply;

2. the definitions of 'organism', 'genetically modified organism' ('GMO'), 'deliberate release' and 'environmental risk assessment' laid down in Directive 2001/18/EC shall apply;

3. 'genetically modified food or feed' means food or feed containing, consisting of or produced from genetically modified organisms;

4. 'genetically modified organism for food use' means a genetically modified organism which is not exempted from the application of Directive 2001/18/EC and that may be used as food or as a source material for the production of food;

5. 'genetically modified organism for feed use' means a genetically modified organism which is not exempted from the application of Directive 2001/18/EC and that may be used as feed or as a source material for the production of feed;

6. 'produced from genetically modified organisms' means derived, in whole or in part, from genetically modified organisms, but not containing or consisting of genetically modified organisms;

7. 'control sample' means the genetically modified organism or its genetic material (positive sample) or the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample).

CHAPTER II

GENETICALLY MODIFIED FOOD

Section 1

Authorisation and Monitoring

Article 3

Scope

1. This Section shall apply to:

(a) genetically modified organisms for food use,

(b) food containing or consisting of genetically modified organisms,

(c) food produced from or containing ingredients produced from genetically modified organisms.

2. Where necessary, it may be determined in accordance with the procedure laid down in Article 36 (2) whether a type of food falls within the scope of this Section.

Article 4

Requirements

1. Food falling within the scope of this Section must not:

— present a risk for human health or the environment,

— mislead the consumer,

— 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 genetically modified organism for food use or food falling within the scope of this Section unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are adhered to.

3. No genetically modified organism for food use or food falling within the scope of this Section shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1.

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

— a genetically modified organism and foods containing or consisting of that genetically modified organism as well as foods produced from or containing ingredients produced from that genetically modified organism, or

— a food produced from or containing an ingredient produced from a genetically modified organism as well as foods produced from or containing that food.

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, shall be established in the Community.

7. Authorisation under this Regulation is without prejudice to Directive 70/457/EEC and Directive 70/458/EEC.

Article 5

Adventitious or technically unavoidable presence of genetically modified material

The presence in food of material which contains, consists of or is produced from genetically modified organisms in a proportion no higher than 1 % or lower thresholds established in accordance with the procedure laid down in Article 36 (2), shall not be considered to be in breach of Article 4 (2), provided that this presence is adventitious or technically unavoidable and that the genetically modified material has been subject to a scientific risk assessment made by the relevant Scientific Committee(s) or the European Food Authority, which concludes that this material does not present a risk for human health or the environment.

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 organisms (or produce thereof).

Article 6

Application for authorisation

1. To obtain the authorisation referred to in Article 4 (2), an application shall be submitted to the European Food Authority, hereinafter referred to as 'the Authority'.

2. The Authority shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.

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

(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 appropriate, the information for the purpose of complying with Annex II of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

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

(e) a copy of the studies which have been carried out and any other material which is available to demonstrate that the food complies with the criteria laid down in Article 4 (1);

(f) either an analysis, supported by appropriate information and data, demonstrating that the food is not different to a conventional food, having regard to the criteria specified in Article 14 (2) (a), or a proposal for labelling the food in accordance with Article 14 (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 14 (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) a 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 and/or in foods produced from it;

(j) samples of the food and their control samples;

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

(l) a summary of the dossier.

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 genetically modified organisms or foods containing or consisting of genetically modified organisms, 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 genetically modified organism has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects according to Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period 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, may establish, in accordance with the procedure laid down in Article 36 (2), implementing rules for the application of this Article.

8. The Authority shall publish detailed guidance concerning the preparation and the presentation of the application.

Article 7

Opinion of the Authority

1. Save in exceptionally complex cases, the Authority shall give an opinion within 6 months of the receipt of a valid application.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that this information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.

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 6, and examine whether the food complies with the criteria laid down in Article 4 (1);

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

(c) shall make the summary of the dossier mentioned in Article 6 (3) (l) available to the public;

(d) may ask the appropriate food assessment body of a Member State to carry out a safety assessment of the food;

(e) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment;

(f) shall forward to the Community reference laboratory referred to in Article 33 the particulars referred to in Article 6 (3) (h) and (i) and shall ask it to test and validate the method of detection and identification proposed by the applicant;

(g) shall, in verifying the application of Article 14 (2) (a), examine the information and data submitted by the applicant showing that the characteristics of the food are not different in comparison with the conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of genetically modified organisms or food containing or consisting of genetically modified organisms falling within the scope of this Section, the evaluation shall respect the environmental safety requirements laid down in Directive 2001/18/EC to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the Authority with the bodies set up by the Community and/or the Member States in accordance with Directive 2001/18/EC.

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 appropriate, the information required under Annex II of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

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

(e) where appropriate, any conditions or restrictions which should be imposed on the supply or use of the food and/or foods produced from it, including post-market monitoring requirements based on the outcome of the risk assessment;

(f) a 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 and/or in foods produced from it;

(g) where appropriate, the monitoring plan referred to in Article 6 (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.

7. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 31. The public may make comments to the Commission within 30 days from this publication.

8. Before the entry into application of this Regulation, the Commission shall publish a recommendation on the nature of the risk assessment to be undertaken by the Authority for the purpose of preparing its opinion.

Article 8

Authorisation by the Community

1. Save in exceptionally complex cases, within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account 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 of the reasons for the differences.

2. In the event of a draft decision which envisages the granting of authorisation, the draft decision shall include the particulars mentioned in Article 7 (5), the name of the authorisation-holder and, where appropriate, the unique code attributed to the genetically modified organism as referred to in the Regulation (EC) No . . ./. . . 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.

3. A final decision on the application shall be adopted in accordance with the procedure laid down in Article 36 (2).

4. The Commission shall without delay inform the applicant of the decision taken. The decision shall be published in the *Official Journal of the European Communities*.

5. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 12. The authorised food shall be entered in the Register referred to in Article 30. 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 subject to their inclusion in a list of substances registered or authorised to the exclusion of others.

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

Article 9

Status of existing products

1. By derogation to Article 4 (2), a product falling within the scope of this Section which has been 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 laid down in Regulation (EC) No 258/97 may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) within six months of the entry into force of this Regulation, the person responsible for placing on the market the concerned product shall notify the Authority of the date at which it was first placed on the market in the Community. This notification shall be accompanied by the particulars mentioned in Article 6 (3) and (5), as appropriate, which the Authority shall forward to the Commission and the Member States. The Authority shall forward to the Community reference laboratory referred to in Article 33 the particulars referred to in Article 6 (3) (i) and (j) and shall ask it to test and validate the method of detection and identification proposed by the applicant;

(b) within one year of the entry into force of this Regulation, 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 product concerned shall be entered in the Register. Each entry in the Register shall mention the date at which the concerned product was first placed on the market and shall include the particulars referred to in Article 8 (2) as appropriate.

2. Within nine years from the date at which the concerned product was first placed on the market, the person responsible for placing it on the market shall submit an application in accordance with Article 12, which shall apply in a like manner.

3. Products referred to in paragraph 1 and foods containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 10, 11 and 35, which shall apply in a like manner.

4. 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 specifed, the Commission, acting in accordance with the procedure laid down in Article 36 (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.

5. Detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 36 (2).

Article 10

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder shall comply with any conditions or restrictions which have been imposed in the authorisation. Where post-market monitoring as referred to in Article 6 (3) (k) and Article 6 (5) (b) has been imposed on the authorisation-holder, he shall ensure that it is carried out and shall submit reports to the Authority in accordance with the authorisation.

2. If the authorisation-holder proposes to modify the terms of the authorisation, he shall submit an application to the Authority.

3. The authorisation-holder shall forthwith inform the Authority 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 Authority of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

Article 11

Modification, suspension and revocation of authorisations

1. Where, on its own initiative or following a request from a Member State or from the Commission, the Authority is of the opinion that an authorisation granted in accordance with this Regulation should be modified, suspended or revoked, it shall forthwith transmit this opinion to the Commission.

2. The Commission shall examine the opinion of the Authority as soon as possible and prepare a draft of the decision to be taken.

3. In the event of a draft decision which envisages the modification of the authorisation, the draft decision shall include any amendment needed to the particulars mentioned in Article 8 (2).

4. A final decision on the modification, the suspension or the revocation of the authorisation shall be adopted in accordance with the procedure laid down in Article 36 (2).

5. The Commission shall without delay inform the authorisation-holder of the decision taken. The decision shall be published in the *Official Journal of the European Communities*. The Register shall be amended as appropriate.

Article 12

Renewal of authorisations

1. Without prejudice to the right of a third party to submit an application for authorisation for a food essentially similar to a food for which an authorisation has already been granted, authorisations under this Regulation shall be renewable for ten-years periods, on application to the Authority by the authorisation-holder at the latest one year before the expiry date of the authorisation.

The Authority shall acknowledge receipt of the application, in writing, to the authorisation-holder within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.

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

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

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

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

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

3. Article 7 and Article 8 shall apply in a like manner.

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 the Commission takes a decision.

5. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure laid down in Article 36 (2).

6. The Authority shall publish detailed guidance concerning the preparation and the presentation of the application.

Section 2

Labelling

Article 13

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:

— contain or consist of genetically modified organisms, or

— are produced from or contain ingredients produced from genetically modified organisms.

2. This Section shall not apply to foods containing material which contains, consists of or is produced from genetically modified organisms in a proportion no higher than the thresholds established in accordance with the procedure laid down in Article 36 (2), provided that this presence is adventitious or technically unavoidable.

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 the genetically modified organisms (or produce thereof).

Article 14

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 organism] but not containing a genetically modified organism' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned. Alternatively, these words may appear in a footnote to the list of ingredients. It shall be printed in a font of at least the same size as the list of ingredients.

(b) Where the ingredient is designated by the name of a category, the words 'contains [name of ingredient] produced from genetically modified [name of organism] but not containing a genetically modified 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] but not containing a genetically modified organism' shall appear clearly on the labelling.

(d) Where the food is offered for sale to the ultimate consumer or to mass caterers without pre-packaging, the information required under this paragraph must be displayed on or in connection with the display of the food.

2. In addition to the labelling requirements laid down 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 not equivalent to its conventional counterpart as regards:

— composition,

— nutritional value or nutritional effects,

— intended use of the food,

— 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 laid down 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 15

Implementing measures

Detailed rules for implementing this Section may be adopted in accordance with the procedure laid down in Article 36 (2).

CHAPTER III

GENETICALLY MODIFIED FEED

Section 1

Authorisation and Monitoring

Article 16

Scope

1. This Section shall apply to:

(a) genetically modified organisms for feed use;

(b) feed containing or consisting of genetically modified organisms;

(c) feed produced from genetically modified organisms.

2. Where necessary, it may be determined in accordance with the procedure laid down in Article 36 (2) whether a type of feed falls within the scope of this Section.

Article 17

Requirements

1. Feed referred to in Article 16 (1) must not:

(a) present a risk for animal health, human health or the environment;

(b) mislead the user;

(c) harm 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 16 (1) for feed use or feed falling within the scope of this Section unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are adhered to.

3. No product referred to in Article 16 (1) for feed use or feed falling within the scope of this Section shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1.

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

— a genetically modified organism and feed containing or consisting of that genetically modified organism as well as feed produced from that genetically modified organism, or

— a feed produced from a genetically modified organism as well as feed 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, shall be established in the Community.

7. Authorisation under this Regulation is without prejudice to Directive 70/457/EEC and Directive 70/458/EEC.

Article 18

Adventitious or technically unavoidable presence of genetically modified material

The presence in feed of material which contains, consists of or is produced from genetically modified organisms in a proportion no higher than 1 % or lower thresholds established in accordance with the procedure laid down in Article 36 (2), shall not be considered to be in breach of Article 17 (2), provided that this presence is adventitious or technically unavoidable and that the genetically modified material has been subject to a scientific risk assessment made by the relevant Scientific Committee(s) or the European Food Authority, which concludes that this material does not present a risk for human health, animal health or the environment.

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 organisms (or produce thereof).

Article 19

Application for authorisation

1. To obtain the authorisation referred to in Article 17 (2), an application shall be submitted to the Authority.

2. The Authority shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.

3. The application shall be accompanied by the following:

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

(b) the designation of the feed referred to in Article 16 (1), and its specification, including the transformation event(s) used;

(c) where appropriate, the information for the purpose of complying with Annex II of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

(d) where appropriate, a detailed description of the method of production, manufacturing and intended uses of the feed referred to in Article 16 (1);

(e) a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed referred to in Article 16 (1) complies with the criteria laid down in Article 17 (1), and in particular for feed falling within the scope of Directive 82/471/EEC, the information required under Directive 83/228/EEC on the fixing of guidelines for the assessment of certain products used in animal nutrition;

(f) either an analysis, supported by appropriate information and data, demonstrating that the feed referred to in Article 16 (1) is not different to a conventional feed, having regard to the criteria specified in Article 27 (3) (c), or a proposal for labelling the feed referred to in Article 16 (1) in accordance with Article 27 (3) (c) and (4);

(g) either a reasoned statement that the feed referred to in Article 16 (1) does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 27 (3) (d);

(h) where appropriate, the conditions for placing the feed referred to in Article 16 (1) on the market, including specific conditions for use and handling;

(i) a 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 feed referred to in Article 16 (1);

(j) samples of the feed referred to in Article 16 (1) and their control samples;

(k) where appropriate, a proposal for post-market monitoring for the use of the feed referred to in Article 16 (1) for animal consumption;

(l) a summary of the dossier.

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. For genetically modified organisms and feed referred to respectively in Article 16 (1) (a) and (b), 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 genetically modified organisms has been authorised under Part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects according to Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period 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 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, may establish, in accordance with the procedure laid down in Article 36 (2), implementing rules for the application of this Article.

8. The Authority shall publish detailed guidance concerning the preparation and the presentation of the application.

Article 20

Opinion of the Authority

1. Save in exceptionally complex cases, the Authority shall give an opinion within 6 months of the receipt of a valid application.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that this information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.

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 19, and examine whether the feed referred to in Article 16 (1) complies with the criteria laid down in Article 17 (1);

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

(c) shall make the summary of the dossier mentioned in Article 19 (3) (l) available to the public;

(d) may ask the appropriate feed assessment body of a Member State to carry out a safety assessment of the feed referred to in Article 16 (1);

(e) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment;

(f) shall forward to the Community reference laboratory referred to in Article 33 the particulars referred to in Article 19 (3) (i) and (j) and shall ask it to test and validate the method of detection and identification proposed by the applicant;

(g) shall, in verifying the application of Article 27 (3) (c), examine the information and data submitted by the applicant showing that the characteristics of the feed referred to in Article 16 (1) are not different in comparison with the conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of genetically modified organisms and feed referred to respectively in Article 16 (1) (a) and (b), the evaluation shall respect the environmental safety requirements laid down in Directive 2001/18/EC 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 genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the Authority with the bodies set up by the Community and/or the Member States in accordance with Directive 2001/18/EC.

5. In the event of an opinion in favour of authorising the feed referred to in Article 16 (1), the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the feed referred to in Article 16 (1), and its specification;

(c) where appropriate, the information required under Annex II of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

(d) the proposal for the labelling of the feed referred to in Article 16 (1);

(e) where appropriate, any conditions or restrictions which should be imposed on the placing on the market, including specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment;

(f) a 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 feed referred to in Article 16 (1);

(g) where appropriate, the monitoring plan as referred to in Article 19 (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 referred to in Article 16 (1) and stating the reasons for its opinion.

7. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 31. The public may make comments to the Commission within 30 days from this publication.

8. Before the entry into application of this Regulation, the Commission shall publish a recommendation on the nature of the risk assessment to be undertaken by the Authority for the purpose of preparing its opinion.

Article 21

Authorisation by the Community

1. Save in exceptionally complex cases, within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account 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 of the reasons for the differences.

2. In the event of a draft decision which envisages the granting of authorisation, the draft decision shall include the particulars mentioned in Article 20 (5), the name of the authorisation-holder, and, where appropriate, the unique code attributed to the genetically modified organism as referred to in the Regulation (EC) No . . ./. . . 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.

3. A final decision on the application shall be adopted in accordance with the procedure laid down in Article 36 (2).

4. The Commission shall without delay inform the applicant of the decision taken. The decision shall be published in the *Official Journal of the European Communities*.

5. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 25. The authorised feed shall be entered in the Register referred to in Article 30. 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 subject to their inclusion in a list of substances authorised to the exclusion of others.

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

Article 22

Status of existing products

1. By derogation to Article 17 (2), products as referred to in Article 16 (1) which have been authorised before the date of application of this Regulation

— 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,

may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) within six months of the entry into force of this Regulation, the person responsible for placing on the market the concerned products shall notify the Authority of the date at which they were first placed on the market in the Community. This notification shall be accompanied by the particulars mentioned in Article 19 (3) and (5), as appropriate, which the Authority shall forward to the Commission and the Member States. The Authority shall forward to the Community reference laboratory referred to in Article 33 the particulars referred to in Article 19 (3) (i) and (j) and shall ask it to test and validate the method of detection and identification proposed by the applicant;

(b) within one year of the entry into force of this Regulation, 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 at which the concerned products were first placed on the market and shall include the particulars referred to in Article 21 (2) as appropriate.

2. Within nine years from the date at which the concerned products were first placed on the market, the person responsible for placing them on the market shall submit an application in accordance with Article 25, which shall apply in a like manner.

3. 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 23, 24 and 35, which shall apply in a like manner.

4. 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, the Commission, acting in accordance with the procedure laid down in Article 36 (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.

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

6. Detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 36 (2).

Article 23

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder shall comply with any conditions or restrictions which have been imposed in the authorisation. Where post-market monitoring as referred to in Article 19 (3) (k) and Article 19 (5) (b) has been imposed on the authorisation-holder, he shall ensure that it is carried out and shall submit reports to the Authority in accordance with the authorisation.

2. If the authorisation-holder proposes to modify the terms of the authorisation, he shall submit an application to the Authority.

3. The authorisation-holder shall forthwith inform the Authority of any new scientific or technical information which might influence the evaluation of the safety in use of the feed referred to in Article 16 (1). In particular, the authorisation-holder shall forthwith inform the Authority of any prohibition or restriction imposed by the competent authority of any third country in which the feed referred to in Article 16 (1) is placed on the market.

Article 24

Modification, suspension and revocation of authorisations

1. Where, on its own initiative or following a request from a Member State or from the Commission, the Authority is of the opinion that an authorisation granted in accordance with this Regulation should be modified, suspended or revoked, it shall forthwith transmit this opinion to the Commission.

2. The Commission shall examine the opinion of the Authority as soon as possible and prepare a draft of the decision to be taken.

3. In the event of a draft decision which envisages the modification of the authorisation, the draft decision shall include any amendment needed to the particulars mentioned in Article 21 (2).

4. A final decision on the modification, the suspension or the revocation of the authorisation shall be adopted in accordance with Article 36 (2).

5. The Commission shall without delay inform the authorisation-holder of the decision taken. The decision shall be published in the *Official Journal of the European Communities*. The Register shall be amended as appropriate.

Article 25

Renewal of authorisations

1. Without prejudice to the right of a third party to submit an application for authorisation for a feed essentially similar to a feed for which an authorisation has already been granted, authorisations under this Regulation shall be renewable for ten-years periods, on application to the Authority by the authorisation-holder at the latest one year before the expiry date of the authorisation.

The Authority shall acknowledge receipt of the application, in writing, to the authorisation-holder within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.

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

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

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

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

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

3. Article 20 and Article 21 shall apply in a like manner.

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 the Commission takes a decision.

5. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure laid down in Article 36 (2).

6. The Authority shall publish detailed guidance concerning the preparation and the presentation of the application.

Section 2

Labelling

Article 26

Scope

1. This Section shall apply to feed referred to in Article 16 (1).

2. This Section shall not apply to feed containing, consisting of or produced from genetically modified organisms in a proportion no higher than the thresholds established in accordance with the procedure laid down in Article 36 (2), provided that this presence is adventitious or technically unavoidable.

In order to establish that the presence of this feed 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 the genetically modified organisms (or produce thereof).

Article 27

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 16 (1) shall be subject to additional specific labelling requirements laid down in this Article.

2. By way of derogation from the previous paragraph the exemptions for labelling requirements provided for in Article 6 (3) to Directive 96/25/EC shall not be applicable for feed referred to in Article 16 (1).

3. No person shall place a feed referred to in Article 16 (1) on the market unless he ensures that 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:

(a) the name of the feed:

— for genetically modified feed the name shall be: 'genetically modified [name of the feed]';

— for feed produced from genetically modified organisms: 'produced from genetically modified [name of the feed from which the feed is produced] but not containing a genetically modified organism';

(b) for feed referred to in Article 16 (1) (b) the name of the feed shall be accompanied by the relevant unique code as established in Regulation (EC) .../... 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;

(c) as specified in the authorisation, any characteristic of the feed referred to in Article 16 (1) such as those indicated hereunder, which is not equivalent to its conventional counterpart:

— composition,

— nutritional properties,

— intended use,

— 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.

4. In addition to the requirements laid down in paragraph 3 (a) and (b) and as specified in the authorisation, the labelling or accompanying documents of feed 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 feed concerned.

Article 28

Implementing measures

Detailed rules for implementing this Section may be adopted in accordance with the procedure laid down in Article 36 (2).

CHAPTER IV

COMMON PROVISIONS

Article 29

Products likely to be used as food and feed

1. Where a product is likely to be used both as food and feed, a single application under Articles 6 and 19 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision.

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

Article 30

Community Register

1. The Commission shall establish and maintain a Community Register of Genetically Modified Food and Feed, referred to in this Regulation as 'the Register'.

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

Article 31

Confidentiality

1. The applicant may indicate which information submitted under the present Regulation he wishes to be treated as confidential because its disclosure may significantly harm its competitive position. Verifiable justification must be given in such cases.

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

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

(a) name and composition of the genetically modified organism, food or feed referred to in Articles 3 (1) and 16 (1) and, where appropriate, indication of the substrate and the micro-organism;

(b) general description of the genetically modified organism and the name and address of the authorisation-holder;

(c) physico-chemical and biological characteristics of the genetically modified organism, food or feed referred to in Articles 3 (1) and 16 (1);

(d) effects of the genetically modified organism, food or feed referred to in Articles 3 (1) and 16 (1) on human and animal health and on the environment;

(e) effects of the genetically modified organism, food or feed referred to in Articles 3 (1) and 16 (1) on the characteristics of animal products and its nutritional properties;

(f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3 (1) and 16 (1) and, where applicable, monitoring requirements and a summary of the results of the monitoring;

(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 Commission, the Authority and the Member States shall keep confidential all the information identified as confidential under paragraph 2 except for information which must be made public if circumstances so require, in order to protect human health, animal health or the environment.

6. 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 on which the Authority and the applicant disagree as to its confidentiality.

Article 32

Data protection

The scientific data and other information in the application dossier required under Article 6 (3) and (5) and Article 19 (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. On expiry of this ten-years 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 he can demonstrate that the food or feed for which he is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

Article 33

Community reference laboratory

The Community reference laboratory and its duties and tasks shall be those laid down in the Annex.

National reference laboratories may be established in accordance with the procedure laid down in Article 36 (2).

Detailed rules for implementing this Annex and any changes to it may be adopted in accordance with the procedure laid down in Article 36 (2).

Article 34

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 established by Commission Decision of 16 December 1997, with a view to obtaining its opinion on ethical issues.

2. The Commission shall make available to the public the opinions of the European Group on Ethics in Science and New Technologies.

Article 35

Emergency measures

1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or feed authorised in accordance with this Regulation endangers human health, animal health or the environment, it shall immediately inform the Authority and the Commission.

2. If the Commission, following information received from a Member State pursuant to paragraph 1 or on its own initiative, considers that emergency measures are necessary, it may adopt them in accordance with Article 36 (3). These emergency measures may remain in place until a final decision is taken in accordance with Article 11 or Article 24, as appropriate.

Article 36

Implementing powers of the Commission

1. The Commission shall be assisted by the Committee referred to in Article 57 (1) of Regulation (EC) No . . ./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety.

2. When reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof. The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.

3. When reference is made to this paragraph, the safeguard procedure laid down in Article 6 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof. Any Member State may refer the Commission's decision to the Council within 15 days from the receipt of the notification of this decision, in which case the Council, acting by a qualified majority, may take a different decision within one month from the date of referral to the Council.

Article 37

Repeals

The following Regulations are 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 amended with effect from the date of application of this Regulation as follows:

1. The following provisions are deleted:

— Article 1 (2) (a) and (b),

— Article 3 (2) second paragraph and (3),

— Article 8 (1) (d),

— Article 9,

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

'By way of derogation from paragraph 2, the procedure laid down 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.'

3. In Article 12 (1), the words 'or the environment' are deleted.

Article 39

Amendments to Directive 82/471/EEC

Directive 82/471/EEC is amended with effect from the date of application of this Regulation as follows:

The following paragraph is added to Article 1:

'3. This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation . . ./. . ./EC on genetically modified food and feed'.

Article 40

Amendments to Directive 70/457/EEC

Directive 70/457/EEC is amended with effect from the date of application of this Regulation as follows:

1. Article 4 (5) is 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 feed falling within the scope of Article 16 of Regulation . . ./. . ./EC on genetically modified food and feed, the variety shall only be accepted if it has been approved in accordance with that Regulation.'

2. Article 7 (5) is 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 . . ./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety, is accepted only if it has been authorised pursuant to Regulation (EC) No 258/97 for food or under Directive 90/220/EEC or Directive 2001/18/EC for feed or Regulation . . ./. . ./EC on genetically modified food and feed.'

Article 41

Amendments to Directive 70/458/EEC

Directive 70/458/EEC is amended with effect from the date of application of this Regulation as follows:

1. Article 4 (3) is 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 feed falling within the scope of Article 16 of Regulation . . ./. . ./EC on genetically modified food and feed, the variety shall only be accepted if it has been approved in accordance with that Regulation.'

2. Article 7 (5) is 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 . . ./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety, is accepted only if it has been authorised pursuant to Regulation (EC) No 258/97 for food or Directive 90/220/EEC or Directive 2001/18/EC for feed or Regulation . . ./. . ./EC on genetically modified food and feed.'

Article 42

Amendments to Directive 2001/18/EC

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

The following Article 12a is inserted:

'Article 12a

Adventitious presence of GMOs in products

Articles 13 to 21 shall not apply to 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, in a proportion no higher than 1 % or lower thresholds established in accordance with the procedure laid down in Article 30 (2), provided that these traces of GMOs are adventitious or technically unavoidable and that the GMOs have been subject to a scientific risk assessment made by the relevant Scientific Committee(s) or the European Food Authority, which concludes that the GMOs do not present a risk for human health or the environment.

In order to establish that traces of GMOs are adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid them'.

Article 43

Information to be provided in accordance with the Cartagena Protocol on Biosafety

1. Any authorisation, renewal, modification, suspension or revocation of authorisation of a genetically modified organism, food or feed referred to in Articles 3 (1) (b) and 16 (1) (b) shall be notified by the Commission to the Parties to the Cartagena Protocol on Biosafety through the Biosafety Clearing-House in accordance with Article 11 (1) or Article 12 (1) of the Cartagena Protocol on Biosafety, 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) and will provide copies of the laws, regulations and guidelines in accordance with Article 11 (5) of the Cartagena Protocol on Biosafety.

Article 44

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 by [six months after the date of publication of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 45

Transitional measures

1. Requests submitted under Article 4 of Regulation (EC) No 258/97 before the entry into force 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.

2. The labelling requirements laid down in this Regulation 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.

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

4. Requests submitted for products referred to in Article 16 (1) (c) under Article 7 of Directive 82/471/EEC before the entry into force 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 16 (1) under Article 4 of Directive 70/524/EEC before the entry into force of this Regulation shall be complemented by applications under Chapter III, Section 1 of this Regulation.

Article 46

Review

1. No later than two years from the date of entry into force of this Regulation 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 accompanied, where appropriate, by any suitable proposal.

2. Notwithstanding the review provided for in paragraph 1, the Commission shall monitor the application of this Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 47

Entry into force

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

It shall apply from [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.

ANNEX

Duties and Tasks of the Community reference laboratory

1. The Community reference laboratory referred to in Article 33 is the Commission's Joint Research Centre.

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

3. The Community reference laboratory shall be notably responsible for:

   — reception, preparation, storage and maintenance of the appropriate positive and negative control samples;

   — testing and validation of the method for detection, including sampling and identification of the transformation event and, where applicable, 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 disputes settlements between Member States concerning the results of the tasks outlined in this Annex.