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COMMISSION OF THE EUROPEAN COMMUNITIES

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Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON GENETICALLY MODIFIED FOOD AND FEED

(presented by the Commission pursuant to Article 250 (2) of the EC-Treaty)

EXPLANATORY MEMORANDUM

AMENDED PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED

1. BACKGROUND

- Adoption of the proposal by the Commission on 25 July 2001 and transmission to the Parliament and the Council on 30 July 2001 (COM(2001) 425 final – 2001/0173(COD)), on the basis of Articles 37, 95 and 152 (4) (b) of the EC-Treaty.
- Opinion of the Committee of the Regions adopted on 16 May 2002.
- Opinion of the Economic and Social Committee adopted on 30 May 2002.
- Opinion of the European Parliament at first reading adopted on 3 July 2002.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The objective of the proposal is to provide the basis for ensuring a high level of protection of human life and health, animal health, environment and consumers' interest in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market.

The proposal lays down centralised Community procedures for the assessment, authorisation and supervision of genetically modified food and feed, as well as labelling requirements for these products.

3. COMMISSION POSITION ON THE 111 AMENDMENTS ADOPTED BY THE PARLIAMENT

3.1. Amendments accepted by the Commission

The Commission can accept amendments 13, 16, 17, 18, 19, 31, 70, 78, 110, 115, 119, 123, 124, 145, 146 and 147, as these amendments improve or bring clarification to the Commission's initial proposal.

Amendment 13 makes explicit reference in Article 1 of the proposal to the precautionary principle, which is taken into account by the regime provided for by the proposal.

Amendment 16 aims at splitting the definition of "genetically modified food" from "genetically modified feed", which is consistent with the structure of the text of the proposal.

Amendments 17 and 18 refer to the definition of "genetically modified organisms for food and feed use" and suppress the reference to the exemption of genetically modified organisms not covered by the scope of Directive 2001/18/EC. This is accepted by the Commission because such exemption should rather be included in the definition of "genetically modified organism" (see also amendment 9 on the "Traceability and Labelling" proposal). For the sake of legal consistency, the exclusion provided for in Article 3 (1) of Directive 2001/18/EC, which refers to specific techniques of genetic modification, has to be taken into account in the present proposal.

Amendment 19 clarifies the wording of the definition of “control sample” in order to make a clear distinction between positive and negative control samples.

Amendments 31 and 78 require that the summary of the dossier submitted by the applicant be presented in a standardised form, which will make the handling and the access to the application easier. This is also in line with Directive 2001/18/EC.

Amendment 70 clarifies how the labelling of genetically modified food without pre-packaging has to be made in order to offer a better information to the consumer. It also adds reference to small pre-packagings, as the particularity of these items should be taken into account.

Amendments 110, 145, 146 and 147 suppress the mention of “but not containing a genetically modified organism” within the labelling requirements of food and feed produced from genetically modified organisms. This brings clarification to the labelling and suppresses unnecessary and possibly misleading information on the label.

Amendment 115 makes legally clear in Article 29 of the proposal that the Authority has the obligation - and not only the possibility - to examine whether the application for authorisation should be submitted both as food and feed.

Amendment 119 aims at deleting the proposed amendment to Article 12 (1) of Regulation (EC) No 258/97, in order to maintain the possible application of the emergency clause of this Regulation to non-genetically modified novel foods in case of danger to the environment. It cannot be excluded indeed that new production processes could have effects on the environment.

Amendment 123 imposes a time limit of twelve months from the date of application of the proposed Regulation to the transitional measure laid down in Article 45 (2) of the proposal, so that the labelling requirements would fully apply to all genetically modified food and feed after this time limit.

Amendment 124 provides for the publication of the report on the implementation of the proposed Regulation and of any accompanying proposal. It is appropriate to refer explicitly to the public availability of these documents in Article 46 (1) of the proposal.

3.2. Amendments accepted in principle, in part and/or subject to re-wording

The Commission can accept amendments 10, 36, 64 and 144 in principle.

Amendments 10 and 36 refer to the contribution by the Member States to the drawing up of guides to good segregation practice to be applied by food operators in order to avoid adventitious contamination by genetically modified organisms. The Commission can accept the principle laid down in these amendments and would refer to its Communication on life sciences and biotechnology adopted in January 2002, where an action concerning the issue of co-existence has been put forward. However, this specific issue is basically not the subject of the proposal and should therefore not be expressly mentioned in the proposed Regulation. The Commission accepts to make reference to this issue in another appropriate document in relation to the proposed Regulation.

Amendments 64 and 144 explicitly mention in Article 13 of the proposal the exclusion of processing aids (amendment 64) and of foods produced from animals fed with genetically modified organisms or products thereof (amendment 144) from the scope of the labelling

section for genetically modified food. The Commission agrees with the principle of these exclusions, but these should not be explicitly mentioned in the enacting terms of the proposed Regulation as Article 13 of the proposal already defines the scope in a positive way and includes “food produced from genetically modified organisms” and not “foods produced with genetically modified organisms”. The Commission accepts however that mention of the exclusion of these specific products from the scope of the labelling but also the authorisation sections be explicitly made in the recitals of the proposal, which is the purpose of recital 15.

The Commission can accept the following amendments subject to re-wording: 1, 3, 12, 20, 23, 28, 30, 34, 38, 45, 55, 56, 71, 75, 77, 82, 89, 90, 101, 112, 114, 117, 118 and 121. The following amendments can be accepted in part: 37, 41, 44, 57, 81, 86, 102, 103, 165 and 166.

Amendment 1 adds reference to the precautionary principle in the recitals of the proposal. This reference should be included in recital 3 of the proposal related to safety assessment and should be re-worded in order to be in line with the wording of Directive 2001/18/EC and to mention that the precautionary principle has also been taken into account in the drafting of the proposed Regulation.

Amendments 3 and 114 mention that the Community requirements for food and feed should apply similarly to imported products to avoid the creation of unfair conditions of competition. This is a general principle already laid down in Regulation (EC) No 178/2002 and which can be reminded in a recital of the proposal, but not in the enacting terms as it is not a new specific requirement laid down by the proposal. It is proposed to include mention of this principle in recital 38, related to international trade, with a reference to the basic objectives of the proposal.

Amendments 12, 28 and 75 add reference to independent and peer-reviewed studies on the safety of the product to be included in the Register and the application dossier. As these independent studies may not always exist, it is proposed to specify that this applies “where available”.

Amendment 20 adds a definition of “final consumer”. The Commission proposes to refer to the definition included in Regulation (EC) No 178/2002. It should be noted that the concept of “final consumer” is not used in the feed sector. The wording of Article 14 (1) (d) (“ultimate consumer”) should be adapted accordingly.

Amendment 23 refers to Article 4 (1) of the proposal laying down the basic requirements for genetically modified food and replaces the concept of “risk” with “danger”. The Commission agrees that a zero risk level can generally not be guaranteed and, taking into account the definitions of “risk” and “danger” included in Regulation (EC) No 178/2002, would rather propose to qualify the risk as “unacceptable”. Risk management requires a risk analysis on the basis of the results of the scientific risk assessment and other factors legitimate to the matter under consideration, in order to decide whether the risk is “acceptable” with regard to the achievement of the general objectives of the proposed Regulation. This amendment should also apply to genetically modified feed in Article 17 (1) (a) of the proposal.

In addition to amendment 124 supra, the Commission can accept a series of amendments which aim at strengthening information requirements and public involvement within the authorisation and supervision process of genetically modified food and feed. All provisions on public access should however be without prejudice to the protection of intellectual property rights relating to the data concerned. Also, account should be taken of the provisions

of Regulation (EC) No 178/2002 on transparency, confidentiality and access to documents related to the activities of the European Food Safety Authority, and of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. The Commission proposes therefore to refer to these general provisions in a new first paragraph of Article 31 of the proposal, which would be re-titled “Disclosure and confidentiality”. Specific information requirements would still be stated in the relevant provisions of the proposal, “in accordance with Article 31”. Amendments accepted (subject to re-wording) are the following:

- amendments 30, 45, 77 and 90 provide for mention of the place where the reference material can be accessed. This can be necessary information for example for authorities for inspection purpose or for operators for self-check of supplies;
- amendments 38 and 82 provide that the publication of the summary of the dossier shall refer to the possibility for the public to have access to the entire application on request;
- amendments 55 and 101 require the public accessibility of the monitoring reports. This public access requirement implies an adaptation of Article 31 (3) (f) accordingly. It should be noted that these amendments also provide that all parties concerned, and not only the authorisation-holder, have to comply with the conditions and restrictions imposed in the authorisation. This is in line with Articles 4 (2) and 17 (2) of the proposal, which refer to “relevant” conditions and restrictions;
- amendments 56 and 102 refer to new information forwarded by the authorisation-holder in the frame of the supervision of the genetically modified food and feed, and require that this information be notified to the Commission and the Member States and be made available to the public. The Commission believes that this information should first be validated by the European Food Safety Authority and then be made available to the Commission, the Member States and the public. Amendment 102 (for supervision of genetically modified feed) also requires that the local authorities be informed, but this cannot be accepted by the Commission because these entities are not involved as such within the centralised procedures laid down by the proposed Regulation;
- amendments 57 and 103 provide that the opinion of the European Food Safety Authority be transmitted to the authorisation-holder, the Member States and be made publicly available, which is in line with the basic authorisation procedure. However, this opinion should not be transmitted to local authorities (see amendment 102 supra).

Amendments 34, 165 and 166 relate to the role of the competent authorities under Directive 2001/18/EC. The Commission can accept to consult these authorities for the adoption of implementing rules on the submission of application dossiers, but only for matters falling within their remit. Local authorities should not be consulted in this process (see amendment 102 supra). The Commission accepts also that the adoption of implementing rules on the application dossiers be mandatory in order to avoid a risk of legal vacuum. The Commission can accept to bring minor editorial amendments to Article 7 (4) of the proposal as regards the application of the environmental safety requirements laid down in Directive 2001/18/EC (which should also be taken into account under the Feed chapter). However, involvement of

the Commission, national and local authorities in the evaluation process cannot be accepted as such: the evaluation is to be undertaken under the responsibility of the European Food Safety Authority, who shall consult with the bodies set up under Directive 2001/18/EC, as provided for by Article 12 (4) of this Directive.

Amendments 37 and 81 provide for more involvement of the authorities of the Member States in the evaluation of the application dossiers. The Commission can accept that the Member States and the Commission be informed without delay of new applications and any supplementary information received from the applicant. However, the Commission cannot accept to give such an active role to the national authorities in this process so that it would suppress the centralised risk assessment procedure.

Amendments 41, 44, 86 and 89 make clear that the Community reference laboratory should in all cases test and validate the method of detection and identification proposed by the applicant before the European Food Safety Authority gives an opinion. However, the validated method should not be published by the laboratory at this stage: in the context of the centralised procedure, the European Food Safety Authority should receive reports from the laboratory and then include the validated method in its opinion, which should be published. Reference to “access to appropriate reference material” and to “the sequence of” the transformation event in Article 7 (5) (f) are not necessary to make as these elements are already covered by the text of the proposal (in particular, see amendment 45 supra). The last part of amendment 44 (“or with it”) is not acceptable because foods produced *with* genetically modified organisms are not included in the scope of the proposal.

Amendment 71 brings editorial improvement to Article 14 (2) of the proposal on the labelling of characteristics not equivalent to the conventional counterpart.

Amendment 112 refers to the labelling of genetically modified feed and takes into account the case of feed consisting of more than one ingredient. It proposes a wording similar to the corresponding labelling requirements of genetically modified food. The Commission agrees that the proposal should make clearer that genetically modified feed components have to be labelled, in consideration of the definition of “feed” provided for in Regulation (EC) No 178/2002, which covers also additives. The concept of “ingredient” in the Community feed legislation does however not refer to additives and therefore the Commission proposes to re-word Article 27 (3) (a) in specifying that “each feed material or additive of which a particular feed is composed of” has to be labelled. The Commission can accept that the wording related to the form of the labelling (place on the label, font) be consistent with the corresponding labelling rules of genetically modified food. Reference to Directive 79/373/EEC is however not necessary as Article 27 (1) of the proposal already states that these rules are without prejudice to the other requirements of Community law concerning the labelling of feed.

Amendments 117 and 118 relate to the provision on emergency measures. The Commission can accept to amend Article 35 of the proposal, subject to the application of the general “emergency measures” clause laid down in Regulation (EC) No 178/2002, for consistency purpose in matters of food and feed safety. The Commission proposes therefore to refer to the application of Articles 53 and 54 of Regulation (EC) No 178/2002, including where the need of emergency measures arises further to an opinion of the European Food Safety Authority. This amendment makes paragraph 3 of Article 36 of the proposal (implementing powers of the Commission in case of emergency) useless.

The Commission can accept amendment 121 referring to the adaptation of Article 7 (5) of Directive 70/457/EEC, in order to simplify its wording and make reference to “relevant legislation” instead of enumerating relevant acts.

3.3. Amendments not accepted by the Commission

The Commission cannot accept the following amendments: 8, 14, 22, 25, 26, 29, 33, 35, 39, 43, 46, 47, 48, 49, 50, 51, 52, 53, 54, 58, 59, 60, 61, 72, 73, 74, 76, 79, 83, 84, 87, 88, 91, 92, 93, 95, 96, 97, 98, 99, 100, 104, 105, 109, 111, 113, 116, 120, 122, 142, 156, 159, 161, 162, 163, 164 and 167. The Commission considers that many of these amendments would undermine the attempts to sustain the overall Community regime as proportionate and efficient.

- ***Status of sectoral legislation and application of centralised procedure***

Amendments 33, 39, 49, 73, 79, 83, 84, 87, 95 and 120 deny the future Regulation the status of sectoral legislation, implying that the non-centralised assessment procedure and the authorisation procedure laid down in Directive 2001/18/EC should apply before getting an authorisation under the proposed Regulation (no “one door-one key” procedure). The Commission considers that the proposed Regulation will have the status of sectoral legislation in accordance with the conditions of Article 12 of Directive 2001/18/EC: the proposal makes explicit reference to the relevant requirements laid down in this Directive as regards genetically modified organisms as or in products to be approved under the proposed Regulation. Environmental risk assessment, risk management, labelling, monitoring, information to the public and safeguard clause provisions are at least equivalent and even stricter to those laid down in Directive 2001/18/EC. Furthermore, the proposal consists of a Regulation of the European Parliament and of the Council, as referred to in Article 12 (3) of Directive 2001/18/EC, which is the same legislator in both cases.

Authorisations of genetically modified food and feed should be granted under the proposed Regulation subject to a single risk assessment process under the central responsibility of the European Food Safety Authority, who shall apply the relevant above-mentioned conditions and consult the bodies set up under Directive 2001/18/EC, in accordance with Article 12 (4) of this Directive. It should also be noted that the Authority may ask a food or feed assessment body of a Member State to carry out a safety assessment or ask a competent authority under Directive 2001/18/EC to perform an environmental risk assessment of the genetically modified food or feed. This is also in line with Article 36 of Regulation (EC) No 178/2002 regarding co-operation of the Authority with national bodies.

- ***Information requirements and public involvement***

Amendments 47, 48, 50, 52, 53, 58, 59, 92, 96, 98, 99, 104, 105, 116 and 167 require more information or involvement of the public or local bodies in the assessment and authorisation procedure. However, the proposed Regulation is already to be considered as providing a very transparent system, taking also into account other amendments accepted by the Commission in order to strengthen public information and involvement (see under points 3.1 and 3.2 above). Amendments considered as not reasonable or going too far with regard to usual Community rules cannot be accepted: period of three months for public consultation (this is far more than provided for by Directive 2001/18/EC and would undermine the adoption of a decision within a reasonable time limit), publication of draft Commission decision, public access to the issues discussed in connection with the risk management decision and the result of the vote. Comitology rules should not be amended through the proposed Regulation and the institution’s decision-making process should not be undermined. Also, amendments

requiring specific involvement of local authorities cannot be accepted as the European Food Safety Authority already takes into account the consultation requirements of Directive 2001/18/EC. Amendment 116 requires that detection methods used by the national reference laboratories be also included in the Register, but this would not be useful as the method validated by the Community reference laboratory, which will be assisted by the national reference laboratories, will be already included in the Register for the genetically modified product concerned.

- ***Derogation in case of adventitious presence of genetically modified organisms***

- Amendments 25, 74 and 122 aim at suppressing the derogation for adventitious presence of *unauthorised* genetically modified organisms in food and feed and thus refuse to amend Directive 2001/18/EC in this regard, which is not acceptable by the Commission. More than 50 million hectares of genetically modified crops are grown in the world and adventitious or technically unavoidable presence of traces of genetically modified organisms or materials in conventional food and feed is inevitable. The proposed Regulation would not be feasible if it does not provide for any tolerance, under certain conditions, of traces of genetically modified materials which are not authorised in the Community. The Commission believes that the objective of protection of health and the environment is safeguarded by the proposal on the basis of the strict conditions laid down therein: only adventitious or technically unavoidable presence of genetically modified organisms which were positively assessed by a European scientific committee would be tolerated under a threshold of maximum 1%, which can be lowered by comitology in order to take into account scientific developments and products particularities.
- Amendments 162, 163 and 164 relate to the derogation to the *labelling* requirements in case of adventitious presence of material produced from genetically modified organisms and provide for a threshold of maximum 0,5 %. The Commission believes that the derogation should also apply to material containing or consisting of genetically modified organisms and that the threshold should be established by comitology, as also laid down in Article 21 (2) of Directive 2001/18/EC. Explicit reference to “appropriate measures to avoid contamination” is not necessary as Articles 15 and 28 of the proposal already provide for the adoption of implementing rules for the labelling requirements. In addition, these measures should not be mixed with the adoption of actions to prevent the unintended presence of genetically modified material in non-genetically modified products, which are not the subject of the proposed Regulation (see below). Amendment 8 is not acceptable as operators should be *in a position to* demonstrate to authorities that they have taken appropriate steps, i.e. on request and not automatically at each operation of placing on the market.

- ***Objectives and scope of the proposal***

Amendments 14, 43 and 88 include the objective of prevention of the unintended presence of genetically modified material in food and feed. Reference to this objective and to measures to this effect cannot be accepted as it is basically not the subject nor the objective of the proposal. This is related to the issue of co-existence between genetically modified and non-genetically modified production, which has been addressed in the Communication on life sciences and biotechnology adopted in January 2002.

Amendments 22 and 72 refer to Articles 3 (2) and 16 (2) of the proposal and provide that “further types” of food and feed may be determined as falling within the scope of the Authorisation sections of the proposal. The Commission cannot accept these amendments, as the intention is to possibly implement the provisions of paragraph 1 of Articles 3 and 16 of the proposal, and not to add new categories of products in the scope of the section.

- ***Specific issues related to the assessment and authorisation procedure***

Amendment 26 provides for the acknowledgement of receipt of the application within 15 *working* days of its receipt. The Commission believes that a period of 15 “days” (including public holidays, Sundays and Saturdays – cfr. Regulation (EEC, Euratom) No 1182/71) is a reasonable time limit for this matter. In addition, “days” periods should be referred to with consistency: all references within the proposal, but also in Directive 2001/18/EC, in Regulation (EC) No 258/97 and in the Cartagena Biosafety Protocol are made in “days” and not “working days”.

Amendments 29 and 76 require that the application include a proposal for the labelling of the product concerned in accordance with Article 14 (1) for genetically modified food and Article 27 (3) (a) for genetically modified feed. This is not acceptable as these provisions lay down general mandatory labelling requirements which apply in all cases, irrespective of the risk assessment and of the conditions of the authorisation.

Amendment 35 provides that guidance on the presentation of applications should be published by the European Food Safety Authority “before the entry into force” of the proposed Regulation. This cannot be accepted because there would be no legal basis for such action at this time and because such guidance should be flexible and adapted regularly.

Amendment 93 deletes the provision related to the adoption of a recommendation by the Commission on the nature of the risk assessment of genetically modified feed. The Commission believes that this provision should be maintained, as it is for genetically modified food and as also laid down in Regulation (EC) No 258/97, in order to give orientations on the risk assessment, such as the basic elements to be included in the risk assessment reports.

Amendments 46 and 91 require the transmission of the opinion of the European Food Safety Authority to national food/feed safety and environmental risk assessment bodies, but the Commission considers that this is not necessary as the opinion is already published and forwarded to the Commission, the Member States and the applicant.

Amendments 51 and 97 require the notification of the authorisation decision to the European Parliament, the Member States and various national bodies, but the Commission would refer to the application of usual Community (including comitology) rules as regards the adoption, notification and publication of Community acts.

Amendments 54, 100 and 156 delete the possibility, in case of withdrawal of an existing product, to provide for a limited period of time within which existing stocks would be allowed to be used up. The Commission would point out that this rule, which exists also in other Community legislation, applies where there is no safety concern. In this case, the principle of proportionality should be respected and flexibility should be left to the risk manager as regards the using up of existing stocks of the product concerned, on a case-by-case basis.

Amendment 60, related to the renewal of authorisations, cannot be accepted as it restricts the scope of the reports to be submitted to “post-market” monitoring. Monitoring reports within the meaning of Directive 2001/18/EC should also be covered.

Amendments 159 and 161 stipulate that where no renewal decision is adopted before the authorisation expiry date, the authorisation is extended “once by one year” or until the Commission takes a decision “within that year”. The Commission believes that it is not necessary to inflict injury on the authorisation-holder in case of delay in the authorisation renewal which is not due to the authorisation-holder’s fault. This is also in line with Directive 2001/18/EC. Articles 11 or 35 of the proposal may always apply if necessary.

Amendments 52 (1st part), 98 (1st part) and 61 bring editorial amendments which are not considered appropriate with regard to legislative drafting and considering that the text of the proposal should be read as a whole.

Amendment 142 includes new transitional measures for pending applications submitted under Directive 2001/18/EC and Regulation (EC) No 258/97 before the entry into force of the proposed Regulation. However, Article 45 of the proposal already provides in a precise and comprehensive way the transitional measures applicable to the products concerned.

- ***Labelling***

Amendments 109, 111 and 113 relate to the labelling of genetically modified feed and are not acceptable because they do not take into account the wording of Community legislation on the labelling of feed, in particular Directive 96/25/EC. Unlike the provisions on food labelling, feed labelling rules cover each stage of the placing on the market and not only the final stage, justifying that information for the users is in many cases made through the documents (such as invoices or waybills) accompanying bulk consignments, where there is no packaging, container or label. Amendment 111 should not repeat what is already mentioned in the introductory part of paragraph 3 of Article 27 of the proposal.

Taking into account the above-mentioned positions, the Commission amends its proposal pursuant to Article 250 (2) of the EC-Treaty.

Formal adaptations to the wording of the proposal have also been included in order to take into account the adoption of Regulation (EC) No 178/2002 and a new amendment to Directive 70/524/EEC.

The modifications to the initial proposal of the Commission are highlighted as follows: underlining of additions and/or modifications and strikethrough of the deletions.

Amended proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON GENETICALLY MODIFIED FOOD AND FEED**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

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. **The precautionary principle has been taken into account in the drafting of this Regulation and must be taken into account when implementing it.**
- (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.

¹ OJ C **304 E**, **30.10.2001**, p. **221**.

² OJ C [x], [x], p. [x]

³ OJ C [x], [x], p. [x]

- (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 ingredients⁴. 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 organisms⁵; 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/EEC⁶. They should further make use of the new framework for risk assessment in matters of food safety set up by **European Parliament and Council** Regulation (EC) No ~~178/2002~~ **178/2002** laying down the general principles and requirements of food law, establishing the European Food **Safety** Authority, and laying down procedures in matters of food safety⁷. 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, 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 co-operation between the Commission and the Member States.
- (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

⁴ OJ L 43, 14.2.1997, p. 1.

⁵ OJ L 117, 8.5.1990, p. 15.

⁶ OJ L 106, 17.4.2001, p. 1.

⁷ OJ L **31**, **1.2.2002**, p. **1**.

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 consumption⁸, as last amended by Directive 94/34/EC of 30 June 1994⁹, 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 nutrition¹⁰, as last amended by Council Directive 1999/20/EC¹¹, 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 feedingstuffs¹², as last amended by ~~Council Directive 1999/20/EC~~ **Regulation (EC) No 2205/2001**¹³, 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

⁸ OJ L 40, 11.2.1989, p. 27.

⁹ OJ L 237, 10.9.1994, p. 1.

¹⁰ OJ L 213, 21.7.1982, p. 8.

¹¹ OJ L 80, 25.3.1999, p. 20.

¹² OJ L 270, 14.12.1970, p. 1.

¹³ OJ L ~~80, 25.3.1999, p. 20.~~ **297, 15.11.2001, p. 3.**

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 **and feed** 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 modified 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 foodstuffs¹⁴ 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.
- (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 1139/98¹⁵ 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 49/2000¹⁶ and in Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings¹⁷.
- (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.

¹⁴ OJ L 109, 6.3.2000, p. 29

¹⁵ OJ L 159, 3.6.1998, p. 4.

¹⁶ OJ L 6, 11.1.2000, p. 13.

¹⁷ OJ L 6, 11.1.2000, p. 15.

- (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 organisms¹⁸ 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 **Safety** 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

¹⁸ OJ L [x], [x], p. [x]

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.

- (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 **Safety** 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 **Safety** 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, **including, where available, reference to independent and peer reviewed studies,** 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 Commission¹⁹. The Commission shall be assisted by the Committee referred to in Article 57 ~~58~~ (1) of Regulation (EC) No ~~.../2001~~ **178/2002** ~~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) **In order to provide 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, it is necessary that requirements arising from this Regulation apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles laid down 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.
- (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:

¹⁹ OJ L 184, 17.7.1999, p. 23.

CHAPTER I

OBJECTIVE AND DEFINITIONS

Article 1 *Objective*

The objective of this Regulation, **in accordance with the precautionary principle**, 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.

Article 2 *Definitions*

For the purposes of this Regulation:

- (1) the definitions of 'food', 'feed', 'placing on the market', **'final consumer'** and 'traceability', laid down in Regulation (EC) No ~~1831/2003~~ **178/2002** ~~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 organism' ('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 I B of Directive 2001/18/EC;**
- ~~(4)~~ 'genetically modified food ~~or feed~~' means food ~~or feed~~ containing, consisting of or produced from genetically modified organisms;
- (5) 'genetically modified feed' means feed containing, consisting of or produced from genetically modified organisms;**
- ~~(6)~~ '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;

- (75) ‘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;
- (86) ‘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;
- (97) ‘control sample’ means the genetically modified organism or its genetic material (positive sample) ~~or~~ **and** 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 an **unacceptable** 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 **Safety** 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 **Safety** 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, **including, where available, reference to independent and peer-reviewed 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, **as well as information as to the place where the reference material can be accessed in accordance with Article 31;**
 - (k) where appropriate, a proposal for post-market monitoring for the 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 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 and, in matters falling within their remit, the national competent authorities established under Article 4 (4) of Directive 2001/18/EC**, ~~may~~**shall** 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 **inform without delay the Member States and the Commission of the application and shall** make the application and any supplementary

information supplied by the applicant available to ~~the Member States and to the Commission~~them;

- (c) shall make the summary of the dossier mentioned in Article 6 (3) (l) available to the public. **The publication of the summary shall refer to the possibility for the public to have access to the application on request, in accordance with Article 31;**
 - (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 (j) with a view to testing and validating** 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 **shall apply to the evaluation** 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~~ **shall consult** with the bodies set up by the Community and/or the Member States **under Directive 2001/18/EC**, in accordance with **Article 12 (4) of that** 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) thea method, validated by the Community reference laboratory, 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) information as to the place where the reference material can be accessed in accordance with Article 31;

(hg) 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 organisms²⁰.
3. A final decision on the application shall be adopted in accordance with the procedure laid down in Article 36 (2).

²⁰ OJ L [x], [x], p. [x]

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 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. 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 **and parties concerned** shall comply with **the relevant** 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. **The monitoring reports shall be made accessible to the public in accordance with Article 31.**
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. **The Authority shall examine the information forwarded and, if validated, shall make it available to the Commission, the Member States and the public in accordance with Article 31.**

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, **the Member States and the authorisation-holder. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 31.**

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~~ **final** consumer or to mass caterers without pre-packaging, **or in small pre-packaged containers**, the information required under this paragraph must be **permanently and visibly** displayed **either** on **the food display** or **right next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read** ~~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 **the following characteristics or properties**:
- 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 **an unacceptable** 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)~~ **genetically modified organism** 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)~~ **genetically modified organism** 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 **Safety** 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, **including, where available, reference to independent and peer-reviewed 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, **as well as information as to the place where the reference material can be accessed in accordance with Article 31**;
 - (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 **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. 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 **and, in matters falling within their remit, the national competent authorities established under Article 4 (4) of Directive 2001/18/EC**, may **shall** 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 **inform without delay the Member States and the Commission of the application and shall** make the application and any supplementary information supplied by the applicant available to ~~the Member States and to the Commission~~**them**;
 - (c) shall make the summary of the dossier mentioned in Article 19 (3) (1) available to the public. **The publication of the summary shall refer to the possibility for the public to have access to the application on request, in accordance with Article 31;**

- (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) **with a view** ~~and shall ask it to testing~~ 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 **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 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~~ **shall consult** with the bodies set up by the Community and/or the Member States **under Directive 2001/18/EC**, in accordance with **Article 12 (4) of that** 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) ~~the~~ **method, validated by the Community reference laboratory**, 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) information as to the place where the reference material can be accessed in accordance with Article 31;**

(hg) 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 organisms²¹.
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.

²¹ OJ L [x], [x], p. [x]

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 **and parties concerned** shall comply with ~~any~~ **the relevant** 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. **The monitoring reports shall be made accessible to the public in accordance with Article 31.**
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. **The Authority shall examine the information forwarded and, if validated, shall make it available to the Commission, the Member States and the public in accordance with Article 31.**

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, **the Member States and the authorisation-holder. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 31.**
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:~~ **each feed material or additive of which a particular feed is composed of shall be subject to the following specific labelling requirements:**
 - for **those referred to in Article 16 (1) (a) and (b), the words** ~~genetically modified feed~~ ~~the name shall be:~~ “genetically modified [*name of the feed***organism**]” **shall appear in parentheses immediately following the name of the feed material or additive concerned;**
 - for **those referred to in Article 16 (1) (c), the words** ~~feed produced from genetically modified organisms:~~ “produced from genetically modified [*name of* **organism**~~the feed from which the feed is produced~~] but not containing a genetically modified organism” **shall appear in parentheses immediately following the name of the feed material or additive concerned;**

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

- (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~~ **shall** 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

Disclosure and cConfidentiality

- 1.** **Without prejudice to Articles 38, 39 and 41 of Regulation (EC) No 178/2002 and to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents²², the Authority, the Commission and the Member States shall not divulge to third parties confidential information received under this Regulation and shall protect intellectual property rights relating to the data received.**
- 2.** 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.
- 3**~~2~~. Without prejudice to paragraph ~~4~~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**~~4~~. 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;

²²

OJ L **145**, **31.5.2001**, p. **43**.

- (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.

54. Notwithstanding paragraph ~~32~~, the Authority shall on request supply the Commission and Member States with all information in its possession.

65. The Commission, the Authority and the Member States shall keep confidential all the information identified as confidential under paragraph ~~32~~ except for information which must be made public if circumstances so require, in order to protect human health, animal health or the environment.

76. 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

Where it is evident that food or feed placed on the market in accordance with this Regulation is 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 in pursuance to Article 11 or 24, 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.

- ~~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 ~~58~~ (1) of Regulation (EC) No ~~178~~ ~~....~~/2002~~1~~ 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 Articles 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 ~~178~~.../2002~~1~~ 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 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 **under the relevant legislation**.”

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 ~~....~~/2001/178/2002 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 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 **under the relevant legislation.**”

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 **Safety** 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. **For a period of not more than twelve months from the date of its application,** ~~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 **aforementioned** ~~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. **The report and, where appropriate, any suitable proposal shall be made available to the public.**
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.

Done at Brussels, [...]

For the European Parliament
The President
[...]

For the Council
The President
[...]

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.