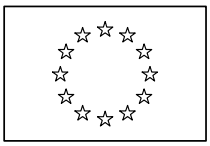

COMMISSION OF THE EUROPEAN COMMUNITIES

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2001/aaa (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on genetically modified food and feed

(presented by the Commission)

EXPLANATORY MEMORANDUM

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

1. INTRODUCTION

As part of the framework to improve and bring coherence to Community legislation from "farm to table" the Commission announced in the White Paper on Food Safety:

- To propose legislation for the evaluation, authorisation and labelling of novel feed, in particular of genetically modified organisms and feeding stuffs derived therefrom (Action 6 in the White Paper).

- To clarify and make the procedure for authorising the placing on the market of novel foods (i.e. foods and food ingredients which have not yet been used for human consumption, in particular those containing or derived from genetically modified organisms) more transparent and review exemptions from these provisions (Action 50 in the White Paper).

- To review Regulation (EC) 258/97 on novel foods and novel food ingredients[1], including the introduction of new requirements at least equivalent to those in the revised regulatory framework for the deliberate release of GMOs under Directive 90/220/EEC (now 2001/18/EC) (Action 51 in the White Paper).

- To introduce a general requirement for a new safety evaluation for permitted additives made from new sources or with new methods (Action 41 in the White Paper).

- To complete and harmonise the labelling provisions (Action 52 in the White Paper).

In the context of the adoption of Directive 2001/18/EC[2] the Commission reaffirmed its intention to supplement the Community labelling regime in accordance with the White Paper on Food Safety.

In accordance with these commitments, this proposal provides

- an improved, harmonised, uniform and transparent procedure for safety assessment of genetically modified food

- a safety assessment and an authorisation procedure for genetically modified feed, based on the same improved and transparent authorisation procedure as for genetically modified food

- that authorisation should not be granted for a single use either as food and feed in cases where such products are likely to be used both as food and feed

- harmonised and comprehensive labelling requirements for genetically modified foods with the aim of providing the consumer with a real choice

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1 OJ L 43 of 14.2.1997, p. 1.
2 OJ L 106 of 17.4.2001, p. 1.

- harmonised and comprehensive labelling requirements for genetically modified feed in order to provide users with accurate information about composition and properties.

2. GENERAL OBJECTIVES

The objectives of this proposal are:

a) to provide the basis for ensuring 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 assessment, authorisation and supervision of genetically modified food and feed;

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

In order to ensure a high level of human and animal health and protection of the environment, this proposal contains the following authorisation criteria for genetically modified food and feed:

- must not present a risk for human health, animal health or the environment,

- must not mislead the consumer or the user,

- must not differ from foods or feed which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for consumers or animals,

- and, for feed, must not harm the consumer by impairing the distinctive features of the animal products.

These criteria do not differ from the criteria laid down in the Novel Foods Regulation, Directive 90/220/EEC (now 2001/18/EC) and the general criteria for placing on the market of feed materials and authorisation of feed additives.

Based on recent experiences and in order to ensure a high level of protection, this proposal provides that authorisation should not be granted for a single use, when a product is likely to be used both for food and feed purposes. Such products would therefore have to fulfil the authorisation criteria for both food and feed before being placed on the market.

Furthermore, in accordance with Article 12 of Directive 2001/18/EC, Articles 13 to 24 of that Directive shall not apply to any GMO or products in so far as they are authorised by other Community legislation. This legislation provides already for specific environmental risk assessment carried out in Annex II and on the basis of information specified in Annex III of that Directive and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in that Directive. This proposal aims at introducing requirements which are at least equivalent to those of Directive 2001/18/EC and stipulates that the environmental risk assessment, where appropriate, shall be conducted on the basis of the requirements laid down in that Directive.

3. SCOPE

The proposal covers food and feed containing, consisting of, or produced from genetically modified organisms (hereunder called genetically modified food or feed).

In order to ensure a high level of consumer and animal health protection, this proposal extends the scope of current Community legislation on GMOs to also cover feed produced from GMOs and a specific evaluation of the genetic modification relating to substances such as food additives, flavourings or feed additives, where they have been produced from GMOs.

Authorisation in accordance with this Regulation may be granted:

- for a GMO and food and/or feed containing or consisting of that GMO as well as food and/or feed produced from or containing ingredients produced from that GMO, or

- for a food produced from or containing an ingredient produced from a GMO, as well as food produced from or containing that food,

- for a feed produced from a GMO, as well as feed produced from or containing that feed.

Thus, under the proposed Regulation an applicant shall be able to obtain authorisation of a specific GMO and/or products produced from a GMO for all possible uses in food and/or feed.

Other food or feed business operators wishing to use the authorised GMO or use the authorised products produced from a GMO as ingredients will not have to submit a new application for authorisation, provided that they respect the terms of the authorisation granted. This situation is similar to the one resulting from Article 3 (3) of the Novel Foods Regulation, except that the latter does not apply to food additives and food flavourings.

The proposed Regulation would cover products “produced from a GMO”, but not products “produced with a GMO”. The former implies that a proportion of the end product, whether it is the food or feed itself or one of its ingredients, has been derived from the original genetically modified material. The latter is produced with the assistance of a genetically modified organism, but no material derived from the genetically modified organism is present in the end product. Thus, cheese 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 would be subject neither to the authorisation requirements, nor to the labelling requirements laid down in the proposed Regulation. This is in line with the current provisions of the Novel Foods Regulation which covers foods and food ingredients produced “from” genetically modified organisms, but not foods and food ingredients produced “with” genetically modified organisms.

For reasons of practicability and legal clarity this proposal does not include the evaluation and authorisation of:

- novel foods which are not genetically modified,

- aspects not related to the genetic modification of substances which are subject to an assessment and a regulatory approval process prior to their inclusion in a positive list or register (such as additives, flavourings, food supplements, etc.).

Where the authorisation granted under the proposed Regulation will relate to the GM counterpart of a conventional substance already authorised for use as additive, flavouring, food supplement etc., these authorised uses will cover the substance authorised under the proposed Regulation.

However, where the authorisation granted under the proposed Regulation will relate to a GM substance whose conventional counterpart is not yet authorised for use as additive, flavouring, food supplement, etc., a specific approval for each specific use will still be required under the relevant legislation. This is not different from the situation that is applicable to conventional (non-GM) food ingredients or feed, where separate applications must be made under the relevant legislation, such as:

- Directive 89/107/EEC concerning food additives,
- Directive 88/388/EEC relating to flavourings for use in foodstuffs,
- Directive 91/321/EEC on infant formulae,
- Directive 96/5/EC on baby foods,
- Directive 2001/15/EC on substances for particular nutritional use,
- COM(2001) 159 on food supplements,
- Directive 70/524/EEC concerning additives in feedingstuffs.

The proposed Regulation is based on the "one door – one key" principle. Thus, it will be possible, under the proposed Regulation, to file a single application for obtaining both:

- the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18/EC;
- and the authorisation for the use of this GMO in food and/or feed under the criteria laid down in the proposed Regulation.

This authorisation, valid throughout the Community, will be granted subject to:

- a single risk assessment process (covering both the environmental risk and risks to human and animal health), under the responsibility of the European Food Authority,
- a single risk management process, involving the Commission and the Member States through a regulatory committee procedure.

However, the use of the same GMO as seed will not be included in this process, as the conventional variety acceptance criteria do not fall within the remit of the European Food Authority. Moreover, the procedure for accepting conventional varieties under the seeds legislation differs significantly from that for authorisation of genetically modified food and feed under the proposed Regulation. Therefore, it is not foreseen that the inscription into the Common Catalogues of genetically modified varieties should be obtained through this proposal. In a future amendment of Directive 98/95/EC on seeds, the possibility of granting authorisation of genetically modified foods through the seeds legislation will be repealed.

Feed falling within the scope of Directive 82/471/EEC concerning certain products used in animal nutrition[3] shall be authorised under the procedure laid down in this proposal where it contains or consists of GMOs or is produced from GMOs, instead of the procedure laid down in Directive 82/471/EEC. However, applications related to such products should still be accompanied by the information required under Directive 83/228/EEC[4]on the fixing of guidelines for the assessment of certain products used in animal nutrition.

The proposal also covers genetically modified food and feed already on the market which have been approved in accordance with the procedures provided for in Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, in Regulation (EC) 258/97 on novel foods and novel food ingredients, in Directive 70/524/EEC concerning additives in feedingstuffs[5] and in Directive 82/471/EEC concerning certain products used in animal nutrition.

The provisions in the Novel Foods Regulation concerning genetically modified food will be repealed by this Regulation. The Novel Foods Regulation will remain in place for novel foods, which are not genetically modified, and will be reviewed later this year. Where it will be proposed to apply a (non-GM) production process not currently used, in the sense of Article 1 (2) (f) of the Novel Foods Regulation, to a food authorised under the proposed Regulation, a specific authorisation will still be required, for that specific process, under the Novel Foods Regulation.

4. PRINCIPLES OF THE AUTHORISATION PROCEDURE

The proposed Regulation (COM(2000) 716 final – 2000/0286(COD)) laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety establishes the principles and procedures on which European food law will be based. It specifies that food law has as one of its objectives the high level of protection of human health and life and that, where appropriate to the circumstances, food law should be based on risk analysis. When adopted, it is foreseen that the European Food Authority should carry out the role of the Scientific Committees established respectively by Commission Decision N° 97/404/EC of 10 June 1997[6] and Commission Decision N° 97/579/EC of 23 July 1997[7] and conduct risk assessments where requested to do so by Community legislation.

In order to streamline and improve the efficiency of the current authorisation procedure for genetically modified foods, this proposal requires that the European Food Authority should carry out risk assessments. As envisaged in the proposal for a European Food Authority, the Authority should also carry out risk assessment for genetically modified feed. This will also ensure a harmonised approach to scientific assessment of genetically modified foods and feed.

This proposal foresees that Community authorisation shall be issued in a transparent and centralised way on the basis of the scientific opinion of the European Food Authority provided that the criteria for authorisation are fulfilled.

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3 OJ L 213 of 21.7.1982, p. 8.
4 OJ L 126 of 13.5.1983, p. 23.
5 OJ L 270 of 14.12.1970, p. 1.
6 OJ L 169 of 27.6.1997, p. 85.
7 OJ L 237 of 28.8.1997, p. 18.

In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this proposal does not include a notification (simplified) procedure as laid down in Regulation EC No 258/97 on novel foods and novel food ingredients for genetically modified foods which are substantially equivalent to existing foods. The use of this regulatory short-cut for so-called "substantially equivalent" GM foods has been very controversial in the Community in recent years[8] and there is consensus at the international level[9] that whilst substantial equivalence is a key step in the safety assessment process of genetically modified foods, it is not a safety assessment in itself. When reaching a decision on granting a Community authorisation under the proposed Regulation, other legitimate factors relevant to the matter under consideration shall be taken into account. Thus, when initiating the decision-making process, the Commission may well, as a risk manager, propose a Decision which would be different from the outcome of the risk assessment carried out under the responsibility of the European Food Authority. As the case may be, the Commission would have to explain its reasons for such a departure. This is in line with the *Codex Alimentarius* General Principles on Risk Analysis.

Products authorised under the proposed Regulation shall be entered into a register of genetically modified food and feed, including product specific information, studies which demonstrate the safety of the product and detection methods which have to be provided by the applicant in order to facilitate control. All non-confidential data should be made available to the public.

The initial authorisation should be granted for a period of 10 years subject, where appropriate, to a post-market monitoring plan for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. The need for post-market monitoring for use as food or feed is to be assessed on a case by case basis during the risk assessment. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory in accordance with Directive 2001/18/EC.

Authorisations are renewable for ten-year periods upon application to the Authority at least one year before the expiry date.

The proposal provides that the authorisation-holder shall submit any new information related to the conditions of authorisation of the product and any reports as specified in the authorisation to the European Food Authority. If the authorisation-holder proposes to modify the terms of the authorisation, an application shall be submitted to the European Food Authority.

To improve transparency of the decision-making process and the involvement of the public in the authorisation process, a summary of the application for approval of genetically modified food and feed and the opinion of the European Food Authority shall be made available to the public. The public may make comments to the Commission within 30 days after the publication of the opinion.

In accordance with Directive 2001/18/EC, this proposal provides for the opportunity to consult the Commission's European Group on Ethics in Science and New Technologies, established by Decision of 16 December 1997.

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[8] See, in particular, minutes of the 79th meeting of the Standing Committee on Foodstuffs.

[9] See, in particular, the "Proposed Draft Principles for the Risk Analysis of Foods Derived From Modern Biotechnology" at Step 5 of the Elaboration Procedure, Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology.

After an authorisation has been issued in accordance with this proposal, the authorisation-holder has to ensure that any conditions or restrictions, which have been imposed on the supply or use of the food or feed are respected. However, as a general principle no person should place a genetically modified food or feed on the market, use or process it unless it is covered by an authorisation granted in accordance with this proposal and the relevant conditions of the authorisation are adhered to, which are available to the public via the register of genetically modified food and feed.

It is proposed that 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, provided that additional information concerning the risk assessment, methods for sampling and detection, including samples of the food and feed, are submitted to the European Food Authority within six months of the entry into force of this proposal. The consequence of not meeting this requirement is that the food or feed shall no longer be considered approved for placing on the market in the Community.

If on the basis of new information or a reassessment of existing information, Member States or the Commission have detailed grounds for considering that the use of a food or feed authorised in accordance with this proposal endangers human health, animal health or the environment, safeguard measures to be adopted by the Commission are foreseen.

5. LABELLING

The labelling of genetically modified foods is currently regulated by several pieces of Community legislation: a) Regulation (EC) No 258/97 on novel foods and novel food ingredients, b) Regulation (EC) No 1139/98[10] concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC, as amended by Regulation (EC) No 49/2000[11] and c) Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings[12].
The labelling is triggered by the presence of DNA or protein resulting from genetic modification.

Genetically modified feed has to be labelled in accordance with Directive 90/220/EEC (now 2001/18/EC), which applies only to live GMOs. Thus, no labelling requirements are in place for feed produced from GMOs, but no longer containing GMOs. In addition, until the second revision of Directive 90/220/EEC, labelling indicating the presence of GMOs was not mandatory, so that currently, four authorisations of GMOs for feed use do not require mandatory labelling while four require mandatory labelling.

An appropriate labelling system of genetically modified food and feed is regarded as one of the key issues in ensuring greater acceptance of the application of gene technology in the agro-food sector. The Eurobarometer 2000 and various other surveys throughout Europe show that consumers are demanding clear labelling whether products contain, consist of or have

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10 OJ L 159, 3.6.1998, p. 4.
11 OJ L 6, 11.1.2000, p. 13.
12 OJ L 6, 11.1.2000, p. 15.

been produced from genetically modified organisms in order to be able to make an individual choice.

This proposal extends the current labelling provisions to all genetically modified food irrespective of the detectability of DNA or protein. Food that consists of, contains or is produced from GMOs would have to be labelled as such. Thus, all products which are subject to authorisation under the proposed Regulation, would henceforth also be subject to mandatory labelling. In return, products which are not subject to authorisation would also not be subject to mandatory labelling. As indicated above, cheese 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 would not be subject to the labelling requirements laid down in the proposed Regulation.

This important change to the current Community legislation on the labelling of food produced from genetically modified organisms will result in labelling of a number of foodstuffs, which are currently not required to be labelled, such as highly refined oils of GMO origin.

It may be argued that the impossibility of checking through analytical methods whether refined ingredients, whether sold as such or when incorporated into final food or feed, have or not been derived from a genetically modified material, will make the proposed labelling provisions unenforceable and will result in frauds. However, it must be noted that the absence of analytical methods has never been considered a valid reason for not subjecting the same products to a pre-marketing authorisation in a number of countries around the World; yet the consequences of fraud are much greater in respect of the authorisation process than in respect of mandatory labelling. Furthermore, there are many examples – in the food sector and in other sectors – of mandatory labelling being imposed despite the absence of any existing analytical methods for controlling the truthfulness of the information being provide on labels; origin labelling, which is required in respect of many foods such as fruits and vegetables, is the most obvious example. Finally, where no analytical methods are available, the accuracy and truthfulness of the information being provided on labels can be controlled through an effective traceability system.

The proposal for a Regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms[13] would ensure that information concerning whether a food or a feed is consisting of, containing or produced from a GMO is available at all stages of the placing on the market and should thereby facilitate accurate labelling of the final product and provide the means for inspection and control of labelling claims.

The objective of the harmonised and comprehensive labelling requirements proposed is to respond to an overwhelming need to enable the consumer to make an individual choice and to ensure that consumers are not liable to be misled, and thereby to foster increased public confidence and acceptance of genetically modified foods.

Genetically modified feed should also be labelled based on the same principles as for food to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed which would enable the user to make an individual choice. This would result in labelling of a large number of feeds, which are currently not required to be labelled with regard to the genetic modification, such as all feed produced from GMOs as

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[13] OJ C [x], [x], p. [x]

well as four genetically modified feed authorised under Directive 90/220/EEC without a labelling requirement.

As already laid down in the Novel Food Regulation, the consumer should additionally be informed about any characteristic or property which render a food not equivalent to its conventional counterpart as regards composition, nutritional value or nutritional effects, intended use of the food, health implications for certain sections of the population and in cases where food may give rise to ethical or religious concerns. It is proposed to apply the same additional labelling criteria to feed.

6. IMPLEMENTATION

Despite the fact that some operators make every effort to avoid using genetically modified material, 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 food or feed.

In order to ensure the practicability and feasibility of this Regulation, it is also foreseen to establish a threshold of 1 % for minute traces in food or feed of genetically modified material, with the possibility of lower levels to be established by comitology, including genetically modified material not authorised under Community legislation, where the presence of such material is adventitious or technically unavoidable. In order to ensure consistency, it is proposed that Directive 2001/18/EC be amended accordingly.

In order to ensure enforceability, this proposal stipulates that applicants must provide 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 or in the feed, which can be used for control purposes.

It is proposed to establish a Community Reference Laboratory with the task of testing and validating the proposed methods for sampling and detection, including the reception, preparation, storage and maintenance of control samples submitted by the applicant to provide the means for a harmonious approach for control across the Community. Based on its experience in the field of testing and validation, the Commission’s Joint Research Centre is suggested to be the newly established reference laboratory of the Community, assisted by a consortium of national reference laboratories, which will be referred to as the “European Network of GMO laboratories”

This proposal 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.

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 Commission[14],

Having regard to the opinion of the Economic and Social Committee[15],

Having regard to the opinion of the Committee of the Regions[16],

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

Whereas:

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

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

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

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

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 on

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14 OJ C [x], [x], p. [x]
15 OJ C [x], [x], p. [x]
16 OJ C [x], [x, p. [x]

novel foods and novel food ingredients[17]. This procedure should be streamlined and made more transparent.

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

(7) Feed consisting of or containing genetically modified organisms (GMOs) have so far been authorised in accordance with Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms[18]; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[19]. They should further make use of the new framework for risk assessment in matters of food safety set up by Regulation (EC) No ../… laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety[20]. Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Authority, of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close 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 authorisation under this Regulation, but are subject to the requirements laid down in the authorisation granted in respect of the GMO. Furthermore, foods covered

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17 OJ L 43, 14.2.1997, p. 1.
18 OJ L 117, 8.5.1990, p. 15.
19 OJ L 106, 17.4.2001, p. 1.
20 OJ L [x], [x], p. [x]

by an authorisation granted under this Regulation are exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories laid down in Article 1 (2) (a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

(11) Council Directive 89/107/EEC of 21 December 1988 concerning food additives authorised for use in foodstuffs intended for human consumption[21], as last amended by Directive 94/34/EC of 30 June 1994[22], provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also under the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure laid down in Directive 89/107/EEC.

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

(13) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[23], as last amended by Council Directive 1999/20/EC[24], provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment; these feed materials containing, consisting of or produced from GMOs should fall instead under the scope of this Regulation.

(14) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[25], as last amended by Council Directive 1999/20/EC[26], provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall under the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure laid down in Directive 70/524/EEC.

(15) This Regulation covers food and feed produced “from” a GMO but not food and feed “with” a GMO. The determining criterion is whether or not material derived from the genetically modified starting material is present in the food or in the feed. Processing aids as defined in Council Directive 89/107/EEC, which are only used during the food or feed production process, are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically

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21 OJ L 40, 11.2.1989, p. 27.
22 OJ L 237, 10.9.1994, p. 1.
23 OJ L 213, 21.7.1982, p. 8.
24 OJ L 80, 25.3.1999, p. 20.
25 OJ L 270, 14.12.1970, p. 1.
26 OJ L 80, 25.3.1999, p. 20.

modified processing aid. Thus, food produced with a genetically modified enzyme that does not remain in the final product and products obtained from animals fed with genetically modified feed or treated with genetically modifed medicinal products will be subject neither to the authorisation requirements, nor to the labelling requirements laid down in this Regulation.

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

(17) Article 2 of Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[27] 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 1139/98[28] concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC, as amended by Regulation (EC) No 49/2000[29] and in Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings[30].

(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.

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27 OJ L 109, 6.3.2000, p. 29
28 OJ L 159, 3.6.1998, p. 4.
29 OJ L 6, 11.1.2000, p. 13.
30 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 organisms[31] ensures that the specific information concerning the genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced thereof and should thereby facilitate accurate labelling.

(23) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable contamination during cultivation, harvest, transport and processing; in such cases, this food or feed should not be subject to the labelling requirements of this Regulation; in order to achieve this objective, it is necessary to establish thresholds for the adventitious or technically unavoidable presence of genetically modified material in foods or feed.

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

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

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

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

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

(29) Risks to the environment may be associated with foods and feed which contain or consist of GMOs. Part C of Directive 2001/18/EC provides that no product consisting of or containing a GMO may be placed on the market without *inter alia* a risk assessment having been carried out in accordance with that part of the Directive. However, that requirement is waived in respect of any product covered by sectoral Community legislation that provides for a specific environmental risk assessment at least equivalent to the environmental risk assessment carried out in

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[31] 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 Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.

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

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

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

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

(36) The measures necessary for the implementation of this Regulation are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[32]. The Commission shall be assisted by the Committee referred

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

to in Article 57 (1) of Regulation (EC) No …/2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety.

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

(38) The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I
OBJECTIVE AND DEFINITIONS

Article 1
Objective

The objective of this Regulation is:

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

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

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

Article 2
Definitions

For the purposes of this Regulation:

(1) the definitions of 'food', 'feed', 'placing on the market' and 'traceability', laid down in Regulation (EC) No …./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety[33] shall apply;

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

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

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

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

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[33] OJ L [x], [x], p. [x]

(6) ‘produced from genetically modified organisms’ means derived, in whole or in part, from genetically modified organisms, but not containing or consisting of genetically modified organisms ;

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

CHAPTER II
GENETICALLY MODIFIED FOOD

SECTION 1
AUTHORISATION AND MONITORING

Article 3
Scope

1. This Section shall apply to:

(a) genetically modified organisms for food use,

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

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

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

Article 4
Requirements

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

- present a risk for human health or the environment,

- mislead the consumer,

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

2. No person shall place on the market a genetically modified organism for food use or food falling within the scope of this Section unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are adhered to.

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

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

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

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

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

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

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

Article 5
Adventitious or technically unavoidable presence of genetically modified material

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

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

Article 6
Application for authorisation

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

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

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

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

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

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

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

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

(f) either an analysis, supported by appropriate information and data, demonstrating that the food is not different to a conventional food, having regard to the criteria specified in Article 14(2)(a), or a proposal for labelling the food in accordance with Article 14(2)(a) and (3);

(g) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 14(2)(b);

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

(i) a method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

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

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

(l) a summary of the dossier.

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

5. In the case of genetically modified organisms or foods containing or consisting of genetically modified organisms, the application shall also be accompanied by:

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

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

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

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

7. The Commission, having first consulted the Authority, may establish, in accordance with the procedure laid down in Article 36 (2), implementing rules for the application of this Article.

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

Article 7
Opinion of the Authority

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

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

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

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 6, and examine whether the food complies with the criteria laid down in Article 4 (1);

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

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

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

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

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

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

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

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

(a) the name and address of the applicant;

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

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

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

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

(f) a method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

(g) where appropriate, the monitoring plan referred to in Article 6 (5) (b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the food and stating the reasons for its opinion.

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

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

Article 8
Authorisation by the Community

1. Save in exceptionally complex cases, within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation of the reasons for the differences.

2. In the event of a draft decision which envisages the granting of authorisation, the draft decision shall include the particulars mentioned in Article 7 (5), the name of the authorisation-holder and, where appropriate, the unique code attributed to the genetically modified organism as referred to in the Regulation (EC) No ../……. of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms[34].

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

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

5. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 12. The authorised food shall be entered in the *Register* referred to in Article 30. Each entry in the *Register* shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

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

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

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[34] OJ L [x], [x], p. [x]

Article 9
Status of existing products

1. By derogation to Article 4 (2), a product falling within the scope of this Section which has been placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 or in accordance with the provisions laid down in Regulation (EC) No 258/97 may continue to be placed on the market, used and processed provided that the following conditions are met:

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

(b) within one year of the entry into force of this Regulation, the Authority shall, after verification that all the information required has been submitted, notify the Commission that it has received the information required under this Article. The product concerned shall be entered in the Register. Each entry in the Register shall mention the date at which the concerned product was first placed on the market and shall include the particulars referred to in Article 8 (2) as appropriate.

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

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

4. Where the notification and accompanying particulars referred to in paragraph 1(a) are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 2 within the period specifed, the Commission, acting in accordance with the procedure laid down in Article 36(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

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

Article 10
Supervision

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

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

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

Article 11
Modification, suspension and revocation of authorisations

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

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

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

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

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

Article 12
Renewal of authorisations

1. Without prejudice to the right of a third party to submit an application for authorisation for a food essentially similar to a food for which an authorisation has already been granted, authorisations under this Regulation shall be renewable

for ten-years periods, on application to the Authority by the authorisation-holder at the latest one year before the expiry date of the authorisation.

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

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

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

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

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

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

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

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

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

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

SECTION 2
LABELLING

Article 13
Scope

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

- contain or consist of genetically modified organisms, or

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

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

In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified organisms (or produce thereof).

Article 14
Requirements

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

(a) Where the food consists of more than one ingredient, the words ‘genetically modified’ or ‘produced from genetically modified [name of organism] but not containing a genetically modified organism’ shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned. Alternatively, these words may appear in a footnote to the list of ingredients. It shall be printed in a font of at least the same size as the list of ingredients.

(b) Where the ingredient is designated by the name of a category, the words ‘contains [name of ingredient] produced from genetically modified [name of organism] but not containing a genetically modified organism’ shall appear in the list of ingredients.

(c) Where there is no list of ingredients, the words ‘genetically modified’ or ‘produced from genetically modified [name of organism] but not containing a genetically modified organism’ shall appear clearly on the labelling.

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

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

(a) Where a food is not equivalent to its conventional counterpart as regards:

- composition,

- nutritional value or nutritional effects,

- intended use of the food,

- implications for the health of certain sections of the population.

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

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

Article 15
Implementing measures

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

CHAPTER III
GENETICALLY MODIFIED FEED

SECTION 1
AUTHORISATION AND MONITORING

Article 16
Scope

1. This Section shall apply to:

(a) genetically modified organisms for feed use;

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

(c) feed produced from genetically modified organisms.

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

Article 17
Requirements

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

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

(b) mislead the user;

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

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

2. No person shall place on the market, use or process a product referred to in Article 16 (1) for feed use or feed falling within the scope of this Section unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are adhered to.

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

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

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

- a feed produced from a genetically modified organism as well as feed produced from or containing that feed.

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

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

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

Article 18
Adventitious or technically unavoidable presence of genetically modified material

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

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

Article 19
Application for authorisation

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

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

3. The application shall be accompanied by the following:

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

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

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

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

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

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

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

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

(i) a method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed referred to in Article 16 (1);

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

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

(l) a summary of the dossier.

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

5. For genetically modified organisms and feed referred to respectively in Article 16 (1) (a) and (b), the application shall also be accompanied by:

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

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

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

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

7. The Commission, having first consulted the Authority, may establish, in accordance with the procedure laid down in Article 36(2), implementing rules for the application of this Article.

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

Article 20
Opinion of the Authority

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

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

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

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 19, and examine whether the feed referred to in Article 16 (1) complies with the criteria laid down in Article 17 (1);

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

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

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

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

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

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

4. In the case of genetically modified organisms and feed referred to respectively in Article 16 (1) (a) and (b), the evaluation shall respect the environmental safety requirements laid down in Directive 2001/18/EC to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the Authority with the bodies set up by the Community and/or the Member States in accordance with Directive 2001/18/EC.

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

(a) the name and address of the applicant;

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

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

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

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

(f) a method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed referred to in Article 16 (1);

(g) where appropriate, the monitoring plan as referred to in Article 19 (5) (b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed referred to in Article 16 (1) and stating the reasons for its opinion.

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

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

Article 21
Authorisation by the Community

1. Save in exceptionally complex cases, within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in

accordance with the opinion of the Authority, the Commission shall provide an explanation of the reasons for the differences.

2. In the event of a draft decision which envisages the granting of authorisation, the draft decision shall include the particulars mentioned in Article 20 (5), the name of the authorisation holder, and, where appropriate, the unique code attributed to the genetically modified organism as referred to in the Regulation (EC) No ,,/,,, of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms[35].

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

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

5. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 25. The authorised feed shall be entered in the *Register* referred to in Article 30. Each entry in the *Register* shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used subject to their inclusion in a list of substances authorised to the exclusion of others.

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

Article 22
Status of existing products

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

- under Directives 90/220/EEC or 2001/18/EC, including use as feed,

- under Directive 82/471/EEC, which are produced from GMOs, or

- under Directive 70/524/EEC which contain, consist of or are produced from GMOs,

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

(a) within six months of the entry into force of this Regulation, the person responsible for placing on the market the concerned products shall notify the Authority of the date at which they were first placed on the market in the Community. This notification shall be

[35] OJ L, [x], p. [x]

accompanied by the particulars mentioned in Article 19 (3) and (5), as appropriate, which the Authority shall forward to the Commission and the Member States. The Authority shall forward to the Community reference laboratory referred to in Article 33 the particulars referred to in Article 19 (3) (i) and (j) and shall ask it to test and validate the method of detection and identification proposed by the applicant;

(b) within one year of the entry into force of this Regulation, the Authority shall, after verification that all the information required has been submitted, notify the Commission that it has received the information required under this Article. The products concerned shall be entered in the Register. Each entry in the Register shall mention the date at which the concerned products were first placed on the market and shall include the particulars referred to in Article 21 (2) as appropriate.

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

3. Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 23, 24 and 35, which shall apply in a like manner.

4. Where the notification and accompanying particulars referred to in paragraph 1(a) are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 2 within the period specified, the Commission, acting in accordance with the procedure laid down in Article 36(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

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

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

Article 23
Supervision

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

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

3. The authorisation-holder shall forthwith inform the Authority of any new scientific or technical information which might influence the evaluation of the safety in use of the

feed referred to in Article 16 (1). In particular, the authorisation-holder shall forthwith inform the Authority of any prohibition or restriction imposed by the competent authority of any third country in which the feed referred to in Article 16 (1) is placed on the market.

Article 24
Modification, suspension and revocation of authorisations

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

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

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

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

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

Article 25
Renewal of authorisations

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

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

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

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

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

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

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

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

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

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

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

SECTION 2
LABELLING

Article 26
Scope

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

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

In order to establish that the presence of this feed is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified organisms (or produce thereof).

Article 27
Requirements

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

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

3. No person shall place a feed referred to in Article 16 (1) on the market unless he ensures that the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto:

(a) the name of the feed:

- for genetically modified feed the name shall be: "genetically modified *[name of the feed]";*

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

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

and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms;

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

- composition,

- nutritional properties,

- intended use,

- implications for the health of certain species or categories of animals.

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

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

Article 28
Implementing measures

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

CHAPTER IV
COMMON PROVISIONS

Article 29
Products likely to be used as food and feed

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

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

Article 30
Community Register

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

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

Article 31
Confidentiality

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

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

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

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

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

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

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

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

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

(g) information on waste treatment and emergency response.

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

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

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

Article 32
Data protection

The scientific data and other information in the application dossier required under Article 6 (3) and (5) and Article 19 (3) and (5) may not be used for the benefit of another applicant for a period of ten years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used. On expiry of this ten-years period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if he can demonstrate that the food or feed for which he is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

Article 33
Community reference laboratory

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

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

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

Article 34
Consultation with the European Group on Ethics in Science and New Technologies

1. The Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, with a view to obtaining its opinion on ethical issues.

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

Article 35
Emergency measures

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

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

Article 36
Implementing powers of the Commission

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

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

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

Article 37
Repeals

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

- Regulation (EC) No 1139/98;

- Regulation (EC) No 49/2000;

- Regulation (EC) No 50/2000.

Article 38
Amendments to Regulation (EC) No 258/97

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

(1) The following provisions are deleted:

- Article 1 (2) (a) and (b),

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

- Article 8 (1) (d),

- Article 9,

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

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

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

Article 39
Amendments to Directive 82/471/EEC

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

The following paragraph is added to Article 1:

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

Article 40
Amendments to Directive 70/457/EEC

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

(1) Article 4 (5) is replaced by the following:

"5. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or feed falling within the scope of Article 16 of Regulation ---/---/EC on genetically modified food and feed, the variety shall only be accepted if it has been approved in accordance with that Regulation"

(2) Article 7 (5) is replaced by the following:

"5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No …./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety, is accepted only if it has been authorised pursuant to Regulation (EC) No 258/97 for food or under Directive 90/220/EEC or Directive 2001/18/EC for feed or Regulation ---/---/EC on genetically modified food and feed."

Article 41
Amendments to Directive 70/458/EEC

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

(1) Article 4 (3) is replaced by the following:

"3. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or feed falling within the scope of Article 16 of Regulation ---/---/EC on genetically modified food and feed, the variety shall only be accepted if it has been approved in accordance with that Regulation"

(2) Article 7 (5) is replaced by the following:

"5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No …./2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety, is accepted only if it has been authorised pursuant to Regulation (EC) No 258/97 for food or Directive 90/220/EEC or Directive 2001/18/EC for feed or Regulation ---/---/EC on genetically modified food and feed."

Article 42
Amendments to Directive 2001/18/EC

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

"The following Article 12a is inserted:

Article 12a
Adventitious presence of GMOs in products

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

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

Article 43
Information to be provided in accordance with the Cartagena Protocol on Biosafety

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

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

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

Article 44
Penalties

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

Article 45
Transitional measures

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

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

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

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

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

Article 46
Review

1. No later than two years from the date of entry into force of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation accompanied, where appropriate, by any suitable proposal.

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

Article 47
Entry into force

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

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

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

Done at Brussels,

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

FINANCIAL STATEMENT

1. TITLE OF OPERATION

Regulation of the European Parliament and of the Council (EC) No….. on genetically modified food and feed.

2. BUDGET LINES INVOLVED

A-7031 Standing Committee (and its sections) referred to in Article 57 (1) of Regulation (EC) No …/2001 laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety

A-11 Staff in active employment

B1 333 A Phytosanitary measures

B5 100 Promotion and protection of consumer's interests

B 3-4309 European Food Authority

3. LEGAL BASIS

Articles 37, 95 and 152(4)(b) of the EC Treaty

4. DESCRIPTION OF OPERATION

4.1 General objective

To lay down a centralised authorisation procedure under which the Commission will authorise the placing on the market and use of genetically modified food and feed.

4.2 Period covered and arrangements for renewal

Permanent.

5. CLASSIFICATION OF EXPENDITURE OR REVENUE

5.1 Compulsory/Non-compulsory expenditure

6. TYPE OF EXPENDITURE OR REVENUE

Travelling costs of national experts participating in the meetings of the Standing Committee referred to in point 2.

Drafting, in consultation with outside experts, the measures, conditions or rules described in Articles 3(2), 5, 6(7), 8(3), 9(4) and (5), 11(4), 12(5), 13(2), 15, 16(2), 18, 19(7), 21(3), 22 (4) and (6), 24(4), 25(5), 26(2), 28, 33 and 35(2).

FINANCIAL IMPACT

7.1 Method of calculating total cost of operation (relation between individual and total costs)

Travelling costs are reimbursed for one member per delegation for each meeting of the Standing Committee and its relevant sections. A total of 30 meetings per year ("food" + "feed" sections) are planned with one member per delegation.

The estimated cost of each meeting is EUR 9750 (see details, point 10.3), making a total of EUR 292 500 per year.

In drawing up the rules mentioned in point 6, it is planed to use five scientific experts for 45 working days each. The allowance is that currently paid to members of the Scientific Committee for Animal Nutrition (SCAN), i.e. EUR 300 per working day.

45 days x EUR 300 x 5 experts = EUR 67 500.

The costs of any additional studies are estimated at EUR 30 000 per year.

The travelling costs of EUR 292 500 are to be booked against item A-7031.

The sum of EUR 97 500 for experts' reports and studies is to be booked against item B1-333 A.

The estimated cost for additional meetings (plenary sessions, disputes settlements meetings …) of the Community Reference Laboratory, assisted by the European Network of GMO Laboratories, is EUR 380 000 per year, to be booked against item B5 100. These credits will be covered by credits currently available on this item.

7.2 Itemised breakdown of cost

Commitment appropriations EUR million (at current prices)

Breakdown	Year n	N+ 1	N+ 2	N+3	N+4	N+5 and subs yrs	Total/year
Breakdown							
Travelling costs of participants in meeting of the Standing Committee and its sections	0.2925						0.2925
Allowances for outside experts	0.067500						0.067500
Studies	0.030000						0.030000
Total	0.39						0.39

7.3 Operational expenditure for studies, experts etc. included in Part B of the budget

Commitment appropriations EUR million (at current prices)

B1-333 A	Year n	N+ 1	n+2	n+3	n+4	n+5 and subs. yrs	Total /year
– Studies	0.030000						0.030000
– Allowances	0.067500						0.067500
Total	0.097500						0.097500

7.4 Schedule of commitment and payment appropriations

EUR million

	Year n	N+ 1	n+2	n+3	n+4	n+5 and subs. yrs	Total
Commitment appropriations	0.097500						0.097500
Payment appropriations							
year n n+1 n+2 n+3 n+4 n+5 and subs. Yrs	0.097500						0.097500
Total	0.097500						0.097500

8. FRAUD PREVENTION MEASURES

– Checks on expenditure incurred

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Specific quantified objectives; target population

The rules provide for examination of the dossiers by the Standing Committee to ensure that genetically modified food and feed and food and feed produced from genetically modified organisms are only placed on the market when it has been proven on the basis of scientific studies that, when used correctly, they have no harmful effect on human and animal health and on the environment, they do not prejudice the interests of the consumer.

9.2 Grounds for the operation

Scientific and technical progress over recent years has led to new raw materials obtained using genetic modification technologies. These products can, under certain conditions, be used as food and feed. A centralised procedure at Community level will ensure the safe utilisation of those products, prevent distortions in trade and guarantee comparable trading conditions for the placing on the market.

9.3 Monitoring and evaluation of the operation

Performance indicators selected:

output indicators: number of meetings held and applications for authorisation/renewal/modification examined;

impact indicators: number of authorisations granted/withdrawn/modified.

Details and frequency of planned evaluations: in the interests of consumers and the industry, a system for authorisation is required which allows applications for Community authorisation submitted to the Authority to be examined on an on-going basis by the Standing Committee.

Assessment of the results obtained: the authorisation procedure provided for by the Regulation guarantees a high level of protection for human and animal health and the environment while preventing distortion of trade in the single market.

10. ADMINISTRATIVE EXPENDITURE (SECTION III, PART A OF THE BUDGET)

Human resources and administrative means are to be covered by the credits already allocated to the managing service.

10.1 Effect on the number of posts

Type of post		Staff to be assigned to managing the operation		Source	Duration
		Permanent posts	Temporary posts	Existing and/or additional resources in the DG or depart-ment concerned	
Officials or temporary staff	A	5		5A	Perm.
	B	1		1B	Perm.
	C	2		2C	Perm.
Other resources					
Total		8		8	Perm

The date scheduled for the implementation of the action is approximately April 2002.

10.2 Overall financial impact of human resources

EUR

	Amounts	Method of calculation
Officials 2A 1B 2C	X	8X108.000€ titles A1, A2, A4, A5 and A7
Total	864.000	

The amounts given must express the total cost of posts for the entire duration of the operation, if this duration is predetermined, or for 12 months if it is indefinite.

10.3 Increase in other administrative expenditure as a result of the operation

EUR

Item	Amounts	Method of calculation
A-7031	292 500€	650€X15=9.750€/meeting 9.750€X30=292 500€
Total	292 500€	

Based on the experience with some Directives in the feed and food sector that has a similar procedure of authorisation, an average of 30 meetings (for “food” and “feed” sectors) per year are necessary to discuss applications submitted for authorisation. One representative per Member State is necessary to attend the meeting.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SME's)

TITLE OF PROPOSAL

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

THE PROPOSAL

1. Taking into account the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The objectives of this proposal are:

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' interests in relation to food and feed, consisting of, containing or produced from genetically modified organisms (hereunder called genetically modified food or 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.

In accordance with the commitments in the White Paper on Food Safety and declarations by the Commission in the context of the adoption of Directive 2001/18/EC[36], this proposal introduces a safety assessment, an authorisation procedure and labelling requirements for genetically modified feed and reviews the principles and requirements for authorisation, safety assessment and labelling of genetically modified foods at Community level. 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.

The proposal covers genetically modified food and feed, additives and flavourings. It addresses the gaps in the current legislation in so far as it also covers feed produced from GMOs and provides for a specific evaluation of aspects linked to genetic modification in the area of additives and flavourings.

Genetically modified food and feed already on the market in the EU has been approved so far in accordance with the procedures provided for in Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms or in Regulation (EC) 258/97 on novel foods and novel food ingredients. In total 18 authorisations have been granted for the placing on the market of GMOs under Directive 90/220/EEC, two of which cover use as food (one maize, one soya variety) and eight cover use in feedingstuffs (one for soya, four for

[36] OJ L 106 of 17.4.2001, p. 1.

maize and three for rape). No GM food has so far been authorised under the Novel Foods Regulation, but eleven products, assessed to be substantially equivalent to already existing conventional foods, have been notified.

The Community legislation under the Novel Foods Regulation providing for a safety assessment, an authorisation procedure and labelling requirements for novel foods, remains in place for novel foods, which are not genetically modified.

No specific legislation is in place for feedingstuffs produced from GMOs such as soya meal or soycake from GM soya. Until this Regulation enters into force, the approval and labelling of feed containing non-viable genetically modified material falls under the responsibility of Member States with the one exception for feed materials using proteins as a source that require a safety assessment under Directive 82/471/EEC. However this Directive does not require any specific safety assessment or labelling rules as regards the genetic modification.

As regards genetically modified additives and flavourings, the proposal foresees that the applicants should submit specific information for the safety assessment of the genetic modification while the final authorisation should be granted under the procedure laid down in the specific legislation, which is Council Directive 89/107/EEC concerning food additives, Council Directive 88/388/EEC relating to flavourings for use in foodstuffs and Directive 70/524/EEC concerning additives in feedingstuffs.

In order to make the current authorisation procedure for genetically modified foods more efficient, this proposal requires that the European Food Authority should carry out risk assessments. As envisaged in the proposal for a European Food Authority, the Authority should also carry out risk assessment for genetically modified feed. This will also ensure a harmonised approach to scientific assessment of genetically modified foods and feed and will streamline the procedures.

The proposal builds on the "one door – one key principle" and makes it possible to obtain authorisation for the deliberate release and for the use in food and feed of a GMO provided that the criteria for authorisation are fulfilled.

It is proposed that existing authorisations and notifications for placing on the market genetically modified foods and feed should continue to remain in force, provided that additional information concerning the risk assessment, methods for sampling and detection, including samples of the food and feed, are submitted to the European Food Authority within six months of the entry into force of this proposal.

Rules for data protection and confidentiality are foreseen that will ensure essential business interests.

The labelling of genetically modified foods is currently regulated by several pieces of Community legislation: a) Regulation (EC) No 258/97 on novel foods and novel foods ingredients, b) Regulation (EC) No 1139/98[37] concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC, as amended by Regulation (EC) No 49/2000[38] and c) Regulation (EC) No 50/2000 on the labelling of foodstuffs and food

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37 OJ L 159, 3.6.98, p. 4

38 OJ L 6, 11.1 2000, p.13

ingredients containing additives and flavourings[39]. The labelling is triggered by the presence of DNA or protein resulting from genetic modification.

Genetically modified feed has to be labelled in accordance with Directive 90/220/EEC (now 2001/18/EC). Currently, four authorisations for feed (one soya, one maize and two swede-rape) do not require mandatory labelling, while four require mandatory labelling (three maize and one rape). No labelling requirements are in place for feed produced from GMOs, but no longer containing GMOs. This has the effect that no harmonized labelling requirements exist.

This proposal sets clear and comprehensive rules for all foods and feed, including additives and /or flavourings containing, consisting of or produced from GMOs and will so contribute to the functioning of the internal market.

This proposal extends the current labelling provisions to all genetically modified food and feed irrespective of the detectability of DNA or protein resulting from the genetic modification. The objective is to enable the consumer or user, such as livestock farmers to make his choice in full knowledge of the facts on the composition and properties.

A Community Regulation laying down a harmonised framework for these products would, therefore, provide for legal certainty as well as transparency and such a coherent and consistent approach should give considerable contribution to the effective functioning of the internal market.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

All sizes of businesses related to the production and trade of products and services in the food chain starting from feed production (from farm to table) are affected. The proposal has a similar impact over the entire Community. It is not aimed at any particular region.

3. What will business have to do to comply with the proposal?

As regards feed the main new additional obligations for business will depend on the national legislation already in place.

<u>General obligations for applicants for authorisation</u>:

- To submit an application for authorisation of genetically modified food and feed, including the preparation of a dossier accompanied by the particulars and documents referred to in the proposed Regulation.

<u>General obligations for authorisation–holders:</u>

- The authorisation-holder is responsible for ensuring the conformity of the genetically modified food and feed products with the conditions specified in the authorisation and for placing it on the market.

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

- To carry out the monitoring plan according to Annex VII of Directive 2001/18/EC or the post-marketing monitoring, where required in the authorisation, and to submit reports to the Authority.

- To inform the Authority of any new information which may influence the evaluation of the safety of the product in use or of any prohibition or restriction imposed by a competent authority in a third country.

- To submit an application for renewal of the authorisation one year before the expiry date (renewable for ten-years periods), including presentation of complementary information.

General obligations for persons responsible for placing on the market food or feed authorised before the date of entry into force of this Regulation:

- To submit, within six months of the entry into force of the Regulation, additional information concerning the risk assessment and a method for sampling and detection, including control samples.

- To submit an application for the renewal of the authorisation in accordance with Article 12 within nine years from the date at which the concerned product was first placed on the market.

General obligations for all business operators:

- To comply with the relevant conditions of the authorisation, which are available to the public via the register of genetically modified food and feed.

- To comply with the labelling requirements.

- In case operators want to benefit from thresholds for adventitious or technically unavoidable contamination, to demonstrate that appropriate steps have been taken to avoid the presence of genetically modified food or feed.

4. What economic effects is the proposal likely to have?

The estimated global area of GM crops for 2000 is 44.2 million ha. Soya (almost all herbicide tolerant) and maize (2/3 insect resistant, 1/3 herbicide tolerant) account for 80 % of this area. The European Union does not produce GM crops with the exception of a non-significant quantity of maize.

More than 30 000 products are estimated to contain soya[40] or maize[41] ingredients.

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[40] Today, there are three major soybean commodity products: seeds, oil, and meal. A 27.2 kg bushel of soybeans yields about 21.8 kg of protein-rich meal and 5.0 kg of oil. There is only limited animal feed use, and no food use for unprocessed soybeans, since they contain anti-nutrient factors, such as trypsin inhibitors and lectins. These factors are inactivated by adequate heat processing. Whole soybeans are used to produce soy sprouts, baked soybeans, roasted soybeans, full fat soy flour and the traditional soy foods (miso, soy milk, soy sauce, and tofu). In addition to the use of whole oil for human consumption, refined soybean oil has many other technical and industrial applications. Glycerol, fatty acids, sterols, and lecithin are all derived from soybean

Approximately 32 mio. t of feed are estimated be derived from GMOs. Those products are imported from third countries and used in feed as mainly processed products such as soya meal and corn gluten feed.

The proposal creates a transparent and coherent regulatory system which:

- Improves the procedures for risk assessment and management.
- Increases legal certainty for operators through the authorisation process.
- Creates a harmonised system for authorisation that is centralised, transparent, consistent, efficient and balanced.
- Enables consumer choice: consumers and livestock farmers are informed about the genetic modification and any other characteristic of the food or feed in respect to this fact.
- Safeguards the intellectual property rights of business operators and ensures confidentiality for issues that serve essential business purpose.
- Introduces rules for data protection which are flexible and safeguard during a reasonable period of time business purpose.

Establishing these principles, the proposal will create a safe and reliable framework for the authorisation and control of genetically modified food and feed.

The adoption of this proposal together with the recent adoption of Directive 2001/18/EC and the future proposal on traceability will contribute to overcome the *de facto moratorium* on the commercial release of GMOs and the standstill on the authorisations of GMOs and genetically modified products and will restore market access of this products while at the same time building up public confidence by responding to the questions and concerns raised by the general public and providing a high level of protection for human health and the environment.

This in turn will have an economic impact on the competitiveness of the European Biotechnology industry , the relation with our trading partners and the further development of biotechnology in the long run, which goes beyond the placing on the market of this products. More effective and harmonised provisions will reduce unfair competition between businesses within the internal market and also in the context of the globalisation of world trade as for importers the same obligations apply. At present, businesses that provide for lower standards with respect to the protection of the environment and human health and safety may have an unfair advantage compared to businesses that provide for a higher standard of protection.

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oil. (from OECD Task Force for the Safety of Novel Foods and Feeds: DRAFT CONSENSUS DOCUMENT ON COMPOSITIONAL CONSIDERATIONS FOR NEW VARIETIES OF SOYBEAN: KEY FOOD AND FEED NURTIENTS AND ANTINUTRIENTS, ENV/JM/FOOD(99)5/REV1, 27. September 2000)

[41] The main use of maize in food (ca. 10% of total consumption) is in form of flour for baking, snack foods and porridge/polenta, as grit for brewing, snacks , breakfast cereals as well as starch and starch hydrolysed derivatives such as glucose syrups and other sweeteners, to a lesser extend in maize oil (from: Genetically Modified Crops. Economic and Strategic Issues through the Food Chain. Maize, PG Economics Ltd. October 1999)

The new approach on labelling would result in labelling of a number of products, which are currently not required to be labelled, such as highly refined oils of GMO origin, because the presence of modified DNA or protein cannot be detected by current methodology. This will mainly affect highly processed food ingredients.

Due to the fact that the food segment of the economy is characterised by extreme diversification and a variety of agricultural systems that are applied, the total cost of labelling is a very complex topic. The economic impacts on trade in agricultural commodities and food products and the distribution of these costs along the production (and finally consumers) chain depends largely on the nature of the product itself, to whom and to which part of the production chain it will bring benefits and more generally depend on supply and demand in different markets.

For industry, it would imply that in the documentation accompanying the product reference would have to be made to whether the product is produced from a GMO. The proposal for a Regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products derived from genetically modified organisms[42] would ensure that the necessary information concerning the genetic modification is available at all stages of the placing on the market and should thereby facilitate accurate labelling of the final product and reduce reliance on detection methodology and costs involved.

The proposed requirements for traceability largely build on the general requirements in the Commission's proposal for a Regulation laying down the general principles and requirements of food law, which establishes the principle of traceability at all stages of the production and distribution chain in the food and feed sectors as well as on existing systems for transactions and accordingly should not lead to significant extra costs for operators.

On the other hand, costs for operators who do not want to label products as genetically modified, would accrue through the establishment of segregation / identity preservation systems necessary to supply non-GMO products in response to market driven demand[43].

An OECD report from December 2000 states that the labelling strategy should be determined as a function of both the costs of labelling and consumer reluctance towards genetically modified foods. Where the ratio of consumers highly reluctant to consume genetically

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42 OJ L [x], [x], p. [x]

43 Various sources have provided data for some examples for IP costs (soya, maize, oilseed rape) at elevator level of 0,6 % - 5 % of farmgate prices and additional costs for the processing industry of 0,6 % – 3 % of prize/t. Some examples for total costs of IP for GM/non-GM crops are given which range from 6 % -17 % (Report published by DG AGRI, 2000).
Costs for an IP testing system have been estimated to range from 1 €/t for a simple checking to as much as 20 €/t for the most disciplined systems of overlapping documentation, field inspections, product sampling and laboratory testing by third parties. A 1996 Canadian IP example for herbicide resistant GM oilseed rape indicates a total cost for testing, administration and monitoring the IP system of 2.9 €/t (DG AGRI report). These figures suggest that the costs for IP are manageable and could even enhance trade.

A study on IP systems (Warenflusstrennung von GVO in Lebensmitteln, Basel 2001) carried out in Switzerland demonstrates that the premium costs for the non –GMO supply of maize and soya commodities, including sampling, testing and certification, were identified as 3-7 % for raw material. The main costs for industry arise from changing recipes (in order to avoid the use of GMO or of possible GMO-contaminated raw materials) and the introduction or maintenance of quality systems.

modified foods is greater than those that are indifferent to such foods, positive labels are found to maximise economic welfare[44].

In order to ensure the practicability and feasibility of this Regulation and also reduce costs for operators, it is foreseen to establish thresholds for minute traces of genetically modified material not authorised under Community legislation, provided certain preconditions are met. Products containing genetically modified material below these thresholds shall not be subject to the requirements of the proposed Regulation.

Furthermore transitional measures for currently pending approvals as well as labelling requirements are foreseen.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

The scope of the proposal is entirely horizontal and its provisions are generic. Therefore, it does not contain measures specifically aimed at or adapted for small and medium-sized firms.

CONSULTATION

6. Organisations that have been consulted about the proposal and who have outlined their main points.

The labelling requirements of this proposal have been discussed in the context of the discussion of the Working Document of the Commission Services on traceability and labelling of GMOs and GMO-derived products of November 2000 which was widely disseminated, including to the Council and the European Parliament, and was placed on the Internet. The document was discussed with experts from Member States, in the fields of environment and the food, feed and seed sectors, on 29 November 2000 and also in the Environment Council on 18 December 2000.

Furthermore, the Working Document was presented to the Standing Group "Cereals" of the Advisory Committee "Arable Crops" on 8 December 2000.

Comments on labelling were received from Dutch Consumentenbond, EuroCoop, the Association of European Consumers, Consumers' Association, BEUC, Friends of the Earth,

Several meetings with representatives of the various stakeholders (industry: Mc Donalds, Du Pont, Unilever, Aventis, Novartis, Eurocommerce, Fediol, CIAA, UK Food and Drink Association, European Lecithin Manufacturer Association, EuropaBio, American Soybean Association, North American Export Grain Association, NGOs: BEUC, Friends of the Earth, Consumers' Association, Greenpeace, and several third country representatives) have taken place.

As regards feed, various aspects of the proposed legislation has been discussed in different meetings with representatives of various stake holders (Pioneer, Syngenta, Cargill, Degussa-Hüls, AWT, Finnfeeds, Toepfer International, Aventis, Novartis, Europa Bio, American Soybean Association, Comité du Commerce des Céréales,

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[44] OECD, Directorate for Food, Agriculture and Fisheries "Modern Biotechnology and Agricultural Markets: a Discussion of Selected Issues", December 2000.

Aliments de Bétail, Oléagineux, Huile D'Olive, Huiles et Graisses et Agrofournitures de l'UE-COCERAL-, European Feed Manufacturers Federation –FEFAC-, European Federation of Animal feed additive Federation –FEFANA- the Grain and Feed Trade Association-GAFCA- and Greenpeace. The most important associations that represent industry and trade in the feed sector (COCERAL, FEFAC, and GAFTA) have submitted their views on different aspects related to GM feed legislation. Other associations such as Greenpeace or Friends of the Earth have also addressed their comments.

The former proposal on novel feed materials was discussed in a meeting organised with five Member States by the Commission on 16 November 2000. Representatives of some Member States were present and a discussion took place on issues related to the scope, labelling, traceability, thresholds and procedure for authorisation.

An exchange of views on the main issues concerning GM feed legislation and the proposal on novel feed materials took place at the Standing Groups "Oil and legume crops" and "Cereals" of the Advisory Committee "Arable Crops" on 20 October 2000 and 8 December 2000.

Various aspects of the proposed legislation were discussed at the Third Annual Assembly of Consumer Organisations in November 2000, at the meetings of the Transatlantic Consumer Dialogue in February 2000 and in May 2001.