COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, xxx
COM(2001) yyy final

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(presented by the Commission)
(Text with EEA relevance)

EXPLANATORY MEMORANDUM

Introduction

During the conciliation procedure concerning the revision of Directive 90/220/EEC and in a subsequent declaration, the Commission affirmed its intention to present appropriate Proposals concerning traceability and labelling of GMOs at all the stages of the placing on the market. As part of this declaration, the Commission also committed to provide for appropriate traceability of products produced from GMOs.

General traceability provisions have already been laid down in Community legislation concerning food, feed and seed and more specifically, a traceability scheme for beef products has been laid down under Regulation (EC) 1760/2000[1] following the recent BSE crisis. The concept of traceability specifically for GMOs was introduced into Community legislation for the first time in Directive 2001/18/EC[2] in so far as Article 4(6) requires that Member States shall ensure traceability at all stages of the placing on the market for GMOs.

However, whilst the Directive includes provisions on which a traceability system for GMOs could be founded, it neither provides for a definition of traceability for GMOs, the objectives of traceability or a complete approach for its implementation. The Directive provides for labelling of GMOs under the consent, which is addressed to the notifier, but this does not extend to operators who subsequently place the GMO on the market. The traceability and labelling of products produced from GMOs are not covered under the Directive given that its scope does not extend to such products.

Differences and overlap between national laws, regulations and administrative provisions concerning traceability of GMOs and food and feed products produced from GMOs may hinder the free movement of products, creating conditions of unequal and unfair competition.

A Community Regulation, taking as a base the requirements of Directive 2001/18/EC, laying down a harmonised framework for traceability of such products would, therefore, provide for legal certainty as well as a coherent and consistent approach that should contribute to the effective functioning of the internal market.

Objectives for traceability of GMOs and food and feed produced from GMOs

Traceability in the context of this proposal can be defined as the ability to trace GMOs and products produced from GMOs at all stages of the placing on the market throughout the production and distribution chains facilitating quality control and also the possibility to withdraw products. Importantly, effective traceability provides a ‘safety net’ should any unforeseen adverse effects be established.

The retro-active tracking of the movement of GMOs and products produced from GMOs through the production and distribution chains will be facilitated by traceability requirements based on transmission and retention of relevant information for such products, at all stages of their placing on the market. Such a traceability "system" limits discontinuity of product specific information through the chains and thereby facilitates

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1 OJ C […], […], p. […][1] Regulation (EC) 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, OJ L204, 11.8.2000, p.1.

2 OJ L 106, 17.4.2001, p.1.

- withdrawal of products should an unforeseen risk to human health or the environment be established;

- targeted monitoring of potential effects on human health or the environment, where appropriate;

- control and verification of labelling claims.

The framework for traceability of GMOs and food and feed products produced from GMOs

This Proposal concerns the traceability of GMOs, as defined under Directive 2001/18/EC, as or in products including seeds, as well as food and feed products produced from GMOs. The term "produced from GMOs", for the purpose of this proposal, is as defined under Article 1.2 (b) of Regulation (EC) No 258/97 concerning novel foods and novel foods ingredients. This refers to products that are produced from but do not contain genetically modified organisms. The Proposal does not prejudice more specific requirements concerning traceability and labelling under other Community legislation such as batch numbering for pre-packaged products.

The Proposal lays down the following requirements to ensure a harmonised framework for traceability of such products at all stages of their placing on the market:

- Operators shall have in place systems and procedures to identify to whom and from whom products are made available.

- Operators shall transmit specified information (see below) concerning the identity of a product in terms of the individual GMOs it contains or whether it is produced from GMOs.

- Operators shall retain specified information for a period of 5 years and make it available to competent authorities on demand.

The Proposal does not specify the means to transmit and retain this information given that existing systems to do so are already in place in many organisations.

The objectives for traceability of GMOs and products produced from GMOs are not identical and therefore the specified information to be transmitted and retained differs for each. This Proposal provides for the traceability of individual GMOs within a product on the basis of authorised transformation events. Traceability for products produced from GMOs, on the other hand, does not require identification of the GMOs from which they are produced.

Traceability and labelling for GMOs

Specific traceability requirements

Article 4(6) of Directive 2001/18/EC requires that Member States shall take measures to ensure traceability, in line with the requirements laid down in Annex IV, at all stages of the placing on the market of GMOs under Part C. The Directive does not differentiate between uses of GMOs in terms of the requirements under Annex IV, which include the information and methodology to be provided in the notification to identify and detect a specific GMO.

Directive 2001/18/EC also includes a requirement to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market.

Possible unforeseen or long-term effects on the environment arising from a GMOs will be dependent on the inherent nature of a GMO and its specific genetic modification. For example, potential effects arising from transfer of genetically modified pollen to conventional crops or related wild types will, in the first instance, be largely dependent on whether the genetically modified crop is out-crossing or self-pollinating. However, the potential development of, for example, insect resistance to the Bt-toxin will only be linked to GMOs modified to express this specific toxin. This would not be the case for GMOs modified specifically for tolerance to herbicides, however, as these GMOs do not contain a Bt-toxin gene.

Traceability to facilitate targeted withdrawals and environmental monitoring of GMOs will, therefore, require that the specific identity of a GMO and its associated traits and characteristics can be established. This can be facilitated via a traceability system that utilises a means of unique identification for GMOs.

Establishing the specific identities of GMOs may also be of importance where authorisation of a GMO under the current legal system allows for restricted use, for example, use in feed but not food. This would apply to mixtures of GMOs, including bulk shipments, as well as products containing a single GMO.

In order to facilitate traceability for GMOs, the Proposal requires that operators shall transmit to the operator receiving products the following specified information:

- That the product contains or consists of GMOs
- The unique code(s) relating to the GMO(s) contained in the product

Specification of identity – Unique codes

Authorisation of a GMO under Community legislation relates to the specific transformation event(s). The Proposal takes, as its point of departure, the authorised transformation events from which GMOs are developed. A transformation event is where a conventional organism is ‘transformed’, through the introduction of modified DNA sequences, resulting in formation of a GMO. It is the introduction of these sequences that ultimately determine the modified characteristics of the GMO, including the likes of insect resistance and herbicide tolerance.

In order to specify the identities of GMOs, Directive 2001/18/EC requires that the written consent shall, in all cases, explicitly specify the identity of the GMO(s) to be placed on the market as or in products, and their unique identifier. This unique identification must, therefore, reflect the authorised transformation event, which is subject of the consent. The Directive refers to a system to be designed, using the appropriate committee procedure, for the assignment of a unique identifier (code) to GMOs, taking into account relevant developments in international fora. This would include requirements to specify the identity of GMOs as is foreseen under the Cartegena Protocol on Biosafety and also in ongoing work under the OECD.

This Proposal, therefore, provides that the Commission shall establish a system to develop and assign simple numeric or alphanumeric unique codes to GMOs. On the basis of information in the notification relating to the transformation event, it is envisaged that this system will automatically prescribe the unique codes to be assigned to GMOs. It is foreseen that the Commission will take account of international developments in this respect. Unique codes have relevance for all sectors, including food, feed and seed, it is proposed, therefore, to establish a Committee under this Proposal to develop a system for the development and assignment of unique code(s) to GMOs.

Unique codes in the context of the Biosafety Protocol/OECD

The Cartagena Protocol on Biosafety does not include reference to traceability but does refer to requirements for specifying the identity of GMOs. Unlike Directive 2001/18/EC, the Protocol differs between GMOs in terms of their use. Article 18(2)(c) requires that the identity of living modified organisms intended for intentional introduction into the environment is specified together with the relevant traits and/or characteristics of that GMO.

A decision as to the detailed requirements for products intended for use as food or feed or for processing as required under Article 18(2)(a) including specification of their identity remains to be taken but no later than two years after the Protocol enters into force. This includes specification of the identity of the GMOs concerned and any unique identification (as referred to in Annex II of the Protocol). Use of unique identifiers to facilitate search and retrieval of information relating to GMOs through the Biosafety Clearing House, particularly if the recommended centralised approach to storage and management of information relating to procedures for GMOs used as food or feed or for processing is implemented, has already been discussed.

Unique identification systems are additionally being discussed within the OECD, with particular reference to GM crop varieties. The Report of the OECD Workshop on Unique Identification Systems for Transgenic Plants[3] in October 2000 provides that consensus agreement suggested that unique codes (identifiers) be assigned at the level of the transformation event, as is the case under this Proposal. This OECD Working Group, by majority consensus, also concluded that unique codes should be assigned in accordance with regulatory approval for commercial purposes. These codes should also be suitable for products that already have approval.

Other key issues to be developed within the OECD Working group include the alphanumeric make-up of the code and also links to their central databases of products that have been authorised for commercial purposes, namely environmental release, food and feed. This includes digits and/or letters to represent, for example, the likes of year of authorisation, notifying company, modified species, type of modification and intended use for that GMO. This work in the OECD continues to progress.

Operation

The requirement for operators to transmit and retain the above information from the stage when GMOs are first placed on the market through to their final ultimate use as a food or feed or for processing, will enable competent authorities to trace GMOs back through the

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[3] OECD Environmental Health and Safety Publications. Series on Harmonisation of Regulatory Oversight in Biotechnology (ENV/JM/MONO(2001)5

production and distribution chains. This information will facilitate post-market withdrawals should an unforeseen effect come to light, as well as labelling.

Further information, in particular precise information as to the genetic modifications of GMOs, may be necessary for post-market control and monitoring, including verification of the identity of GMOs contained within a product. Article 31(2) of Directive 2001/18/EC provides that the Commission will establish one or several registers for the purpose of recording such information, including methodology for identification and detection. Paragraph 3 of this Article additionally requires that Member States shall establish registers for recording the location of GMOs grown under Part C of the Directive for the purpose of environmental monitoring. It is foreseen that such registers will also serve to assist requirement under sector based legislation and that unique codes will act as 'keys' to such registers as a means to gain access to the information held for authorised transformation events.

The effectiveness of traceability requires that the identity of GMOs contained within a product can be established at its first stage of the placing on the market within the production or distribution chain. This should not present undue problems for products that originate from within the Community.

However, consideration has to be given to products imported from third countries, in particular bulk shipments of commodity crops that may contain an unknown mixture of GMOs. Operators importing such shipments into the Community will have to specify the identity of these products, namely in terms of the GMOs that they contain. If this information is not available from the exporter, then importers would have to determine the identity of the GMOs in the product, which is likely to require sampling and analytical testing. The Proposal, therefore, provides for the possibility of establishing guidance with respect to sampling and testing of bulk commodities as a means to facilitate a common approach within the Community.

Determination of the identity of GMOs in products, at this initial stage is crucial given that this information will be transmitted and retained through the subsequent stages of the placing on the market of this product. The Proposal foresees that this information will continue to accompany the product, whether it is subsequently placed on the market as a whole or divided into separate assignments. Where an initial assignment or bulk shipment is sub-divided, subsequent operators placing this product on the market would not be liable for guaranteeing the continued presence of all GMOs that have been established to be present in the initial assignment. Operators would, however, be obliged to transmit to the next operator in the chain the information, including unique codes, specified for that initial assignment.

The Proposal does not, therefore, foresee a mandatory requirement for operators to test at each stage of the placing on the market, which would not be cost-beneficial although testing may be conducted on a voluntary basis or by inspection authorities as required.

In order to facilitate a co-ordinated approach for inspection and control by Member States, the Commission shall develop technical guidance on sampling and testing methodology prior to the application of this Regulation. The Commission will continue to work at the international level and with trading partners with the aim of achieving a common approach to such methodology, particularly with regard to bulk commodities. Moreover, notifications for the placing on the market of GMOs and products produced from GMOs under Directive 2001/18/EC and under the Regulation (EC) No …/2002 on genetically modified food and feed must include methods for their detection and identification.

To further ensure the practicability and feasibility of traceability and labelling, thresholds may also have to be established for products where adventitious or technically unavoidable traces of GMOs cannot be excluded, below which these products would not have to be traced or labelled.

Labelling

Article 21 of Directive 2001/18/EC requires that Member States shall take all necessary measures, in accordance with the relevant requirements specified in the written consent, to ensure the labelling of GMOs at all stages of their placing on the market. The current Proposal, with regard to traceability, places a legal obligation on operators to transmit and retain specified information for GMOs, including their unique codes, at all stages of the placing on the market. This obligation has been extended to include labelling of such products, when pre-packaged, in accordance with the appropriate wording as required under Directive 2001/18/EC.

The Proposal requires that operators placing pre-packaged products consisting of, or containing GMOs on the market, at any stage of the production and distribution chain, have to ensure that such products are labelled with the words "This product ***contains*** genetically modified organisms". Where products, including bulk quantities, are not packaged and use of a label is not possible, operators have to ensure that this information is transmitted with the product. This may be in the form of accompanying documentation.

Traceability for products produced from GMOs

General traceability provisions have already been established in Community legislation concerning food and feed and more specifically, a traceability scheme for beef products, following the recent BSE crisis, has been laid down under Regulation (EC) 1760/2000[4].

Council Directive 89/396/EEC[5] concerning indications or marks identifying the lot to which a foodstuff belongs, specifies that a foodstuff may not be marketed unless it is accompanied by an indication of the lot to which it belongs. This Directive implements a Codex standard with the objective of providing for better information with respect to the identity of products and a useful source of information where foodstuffs are the subject of a dispute or constitute a health hazard to consumers. The Directive, therefore, provides for a degree of traceability in the production and distribution chains, but does not cover all food ingredients. Notably bulk products are not included in the scope.

Feed legislation, such as Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector, also provides for certain traceability requirements.

The Commission Proposal for a Council and Parliament Regulation[6] laying down the general principles and requirements of food law (General Food Law), establishes the principle of traceability at all stages of the production and distribution chain in the food and feed sectors. The objective of traceability in the Proposal is to facilitate targeted individual withdrawals

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4 Regulation (EC) 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, OJ L 204, 11.8.2000, p.1.

5 OJ L 186, 30.6 1989, p.21

6 COM(2000)716 final, 8 November 2000

and/or to provide appropriate information to consumers or control officials. The Proposal requires that food and feed business operators are able to identify from whom a product has been received and to retain and transmit information concerning products to the next operator in the chain. The information must also be made available to competent authorities upon request.

However, traceability provisions in current Community law governing food and feed and in the Proposal for a General Food Law do not specifically address traceability of products produced from GMOs.

This proposal builds on the traceability systems in current food and feed legislation and the proposal for general principles and requirements of food law with the objective of extending these requirements to include information on whether a food or feed is produced from GMOs.

This is achieved via an obligation on operators to transmit specified information that a product is produced from GMOs to the next operators in the production and distribution chain. This Proposal does not, however, require the unique code(s) assigned to GMOs to be transmitted with a produced product based on the following;

- Unforeseen environmental effects, in particular, are unlikely to arise from the placing on the market of products produced from GMOs, such as the flour produced from genetically modified maize grains, where processing results in 'non-viable' genetic material.

- The labelling requirements for GM foods do not include information concerning the transformation event of GMOs from which the product is produced.

Transmission and retention of information that a food or feed is produced from GMOs throughout the production and distribution chain would facilitate labelling of the final product for operators under the current EU food labelling scheme. It would also provide the means for inspection and control of compliance with current labelling provisions for GM foods and reduce reliance on detection methodology.

It is not necessary to establish the detailed history and origin of individual GMOs, through a traceability system, to provide for comprehensive labelling. For the purpose of providing appropriate information to the purchaser or consumer it is sufficient that the label documents that the product is produced from GMOs. The introduction of the traceability requirements under this Proposal will provide the basis for extending the current labelling requirements for foods produced from GMOs to cover all foods and food ingredients produced from GMOs.

Operators importing products into the Community would have to follow the requirements in this Proposal and transmit the information that the product is produced from GMO(s).

Costs

It is difficult to estimate the exact costs of introducing traceability specifically for GMOs and products produced from GMOs. However, 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.

Transmission and retention of the information specified in the Proposal could largely be incorporated into existing systems for transactions and as such, should not imply significant extra costs for operators. Information with respect to the supplier, customer, price and transaction date as well as the nature, source, contents and amount of the product already accompanies the majority of transactions. This information has also to be retained by operators under national administrative systems as a means to complete the likes of VAT returns. A non-harmonised approach resulting in the establishment of different traceability requirements in Member States may hinder the free movement of products, creating conditions of unequal and unfair competition. The costs of such an approach are also difficult to estimate but would most likely result in much higher costs for all operators.

The Proposal foresees that transmission and retention of information as a means to facilitate traceability will limit the need for sampling and testing of products to confirm their identity at every stage of the placing on the market. This Proposal would also reduce the need for testing for presence of GM material in the final product, thereby result in a reduction of the costs for companies to meet the current labelling criteria in Community legislation.

Sampling and testing would, however, still be required for verification whenever reliable documentation is not available from exporting countries and for control and inspection purposes. A degree of cost must, therefore, be considered in this respect. The Proposal foresees that the Commission may develop guidance on sampling. This will minimise legal uncertainty and alleviate the burden in terms of testing and sampling for operators.

The establishment of effective traceability requirements could also prevent excessive economic losses or brand damage in case an unforeseen risk to human health or the environment appears. The recent case in the US, where a genetically modified maize variety approved only for use in animal feed entered the food chain, demonstrates that the lack of mandatory traceability requirements imposed on all operators in the production and distribution chain can result in huge costs. This applies not only to the companies involved but also to the public authorities. A system only capable of initiating partial or voluntary withdrawals could also result in a further decrease in consumer confidence.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

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

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

Whereas:

(1) Directive 2001/18/EC of the European Parliament and the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC of the Council[4] requires Member States to take measures to ensure traceability and labelling of authorised GMOs at all stages of their placing on the market.

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

(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects to human health, animal health or the environment are established, and the targeting of monitoring to examine potential effects on, in particular, the environment.

(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No …/2002 on genetically modified food and feed,

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1 OJ C […], […], p. […]

2 OJ C […], […], p. […]

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4 OJ L106, 17.4.2001, p.1.

so as to enable operators and consumers to exercise their freedom of choice in an effective manner as well as control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use;

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

(6) Transmission and retention of information that food and feed have been produced from GMOs also provides the basis for appropriate traceability of products produced from GMOs.

(7) Guidance on sampling and detection should be developed in order to facilitate a co-ordinated approach for control and inspection, and provide legal certainty for operators.

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

(9) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements.

(10) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[5], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

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

(12) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union as general principles of Community law;

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5 OJ L184, 17.7.1999, p.23.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation provides a framework for the traceability of genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objective of facilitating accurate labelling, environmental monitoring and withdrawals of products.

Article 2

Scope

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

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

   (b) foods and food ingredients, including food additives and flavourings, produced from GMOs placed on the market in accordance with Community legislation;

   (c) feed materials, compound feedingstuffs and feed additives, produced from GMOs placed on the market in accordance with Community legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under the provisions of Council Regulation (EEC) No 2309/93[6].

Article 3

Definitions

For the purpose of this Regulation:

(1) 'genetically modified organism' is as defined under Article 2(2) of Directive 2001/18/EC;

(2) 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

(3) ‘traceability’ means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

(4) 'unique code' means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was

6 OJ L 214, 24.8.1993, p.1..

developed and providing the means to retrieve specific information pertinent to that GMO;

(5) 'operator' means a person who places a product on the market and also a person who receives a product that has been placed on the market in the Community, at any stage of the production and distribution chain, but does not include the ultimate consumer;

(6) 'food' means food within the meaning of [Article 2 of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];

(7) 'food additive' is as defined in Article 1.2 of Directive 89/107/EEC[7] on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption;

(8) 'flavouring' is as defined in Article 1.2 of Directive 88/388/EEC[8] on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production;

(9) 'feed' or 'feedingstuff' is as defined in [Article 3 (4) of the Proposal for a Regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];

(10) 'Compound feedingstuffs' means products as defined in Article 2(b) of Council Directive 79/373/EEC[9] on the circulation of compound feedingstuffs;

(11) 'Feed materials' means products as defined in Article 2(a) of Council Directive 96/25/EC[10] on the circulation of feed materials;

(12) 'Feed additives' means products as defined in Article 2(a) of Directive 70/524/EEC[11] concerning additives in feedingstuffs;

(13) 'placing on the market' means making available to third parties, whether in return for payment or free of charge;

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

(15) 'pre-packaged' means any single item for sale to the ultimate user, consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, but in such a way that the contents cannot be altered without opening or changing the packaging.

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7 OJ No L 40, 11.2.1989, p.27
8 OJL 184, 15.7.1988, p.61.
9 OJ N°L 86, 6.4.1979, p.30.
10 OJ N° L 125, 23.5.1996, p.35.
11 OJ L 270, 14.12.1970, p.1.

Article 4

Traceability and labelling requirements for GMOs

1. When placing pre-packaged products consisting of, or containing GMOs on the market, operators shall ensure that the words "This product contains genetically modified organisms" appear on a label.

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

   (a) that it contains or consists of GMOs;

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

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

4. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of [five] years from each transaction, as to the person from whom and to whom the products mentioned in paragraph 2 have been made available.

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

Article 5

Traceability requirements for products produced from GMOs

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

   (a) an indication of each of the food ingredients, including additives and flavouring(s), which is produced from GMOs;

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

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

2. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of [five] years from each transaction, as to the person from whom and to whom the products referred to in paragraph 1 have been made available.

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

Article 6

Exemptions

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

2. By way of derogation from Articles 4(3), 4 (4) and 5(2), operators delivering food to the ultimate consumer shall not be obliged to retain documentation detailing to whom products were sold.

3. Products intended for direct use as food, feed or processing which consist of or contain GMOs in respect of which the conditions set out in Article 12a of Directive 2001/18/EC as amended by Regulation (EC) No …/2002 on genetically modified food and feed are met shall be exempt from the requirements of Article 4.

4. Food and feed produced from GMOs in respect of which the conditions set out in Articles 5 and 18 of Regulation (EC) No …/2002 on genetically modified food and feed are met shall be exempt from the requirements of Article 5.

Article 7

Amendment of Directive 2001/18/EC

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

1. Article 4(6) is deleted.

Article 8

Unique codes

In accordance with the procedure referred to in Article 30(2) of Directive 2001/18/EC, the Commission shall;

1. Prior to the application of Articles 1 to 7 and taking into account international developments, establish the system for development and assignment of unique codes to GMOs;

2. Adapt the system referred to in paragraph (1), as appropriate, taking into account further developments in international fora.

Article 9

Inspection and control measures

1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.

2. Prior to the application of Articles 1 to 7, the Commission shall develop technical guidance on sampling and testing to facilitate a co-ordinated approach for the implementation of paragraph 1.

Article 10

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Chapter 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 [180 days following the date of publication of this Regulation in the *Official Journal of the European Communities]* at the latest and shall notify it without any delay of any subsequent amendment affecting them.

Article 11

Entry into force

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

2. Articles 1 to 7 and 9 (1) shall apply with effect from [90 days] following the date of publication in the *Official Journal of the European Communities* of the measure referred to in Article 8(1).

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*

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Environment

Activity(ies): NA

TITLE OF ACTION: Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms

1. BUDGET LINE(S) + HEADING(S)

A0701, A07030, A07031

2. OVERALL FIGURES

2.1. Total allocation for action (Part B):0 € million for commitment

2.2. Period of application:

The first activity in paragraph 5.1.1 will be carried out during a period beginning 1 June 2001 until the entry into force of this Regulation.

There may be a need to subsequently adapt the system and also specific information requirements under the Regulation, depending on developments in international fora.

2.3. Overall multiannual estimate on expenditure:

a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million (*to 3rd decimal place)*

	2001	2002	2003				Total
Commitments							
Payments							

b) Technical and administrative assistance and support expenditure*(see point 6.1.2)*

Commitments							
Payments							

Subtotal a+b							
Commitments							
Payments							

c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

Commitments/ payments	0.124	0.124	0.124				0.372

TOTAL a+b+c							
Commitments	0.124	0.124	0.124				0.372
Payments	0.124	0.124	0.124				0.372

2.4. Compatibility with the financial programming and the financial perspective

☒ Proposal compatible with the existing financial programming

☐ This proposal will entail reprogramming of the relevant heading in the financial perspective

☐ This may entail application of the provisions of the Interinstitutional Agreement.

2.5. Financial impact on revenue[1]:

☒No financial implications (involves technical aspects regarding implementation of a measure)

OR

☐ Financial impact – the effect on revenue is as follows:

Note: All details and observations pertaining to the method of calculating the effect on revenue should be included in a separate annex.

€ million *(to 1 decimal place)*

		Prior to action (Year n-1)	Situation following action					
Budget line	Revenue		Year n	n+1	n+2	n+3	n+4	n+5
	a) Revenue in absolute terms							
	b) Change in Revenue	*Δ*						

(Please state each budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line)

[1] For further information see a separate guidance paper

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA participation	Participation applicant countries	Heading Financial Perspective
Non-comp	**Non Dissociated credit**	**YES**	**NO**	**NO**	**5**

4. LEGAL BASIS

Articles 95 of the Treaty establishing the European Community.

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention [2]

5.1.1. Objectives pursued

The Proposal will establish requirements and obligations to ensure traceability and labelling of GMOs and GMO-derived products, at all stages of the placing on the market. These are based upon the transmission and retention of specified information pertaining to such products, at each stage of the placing on the market, including use of unique codes attributed to GMOs.

This Proposal for a Regulation provides for the establishment of a system to develop and assign unique codes to GMOs, in accordance with the committee procedure foreseen under the Regulation. On this basis, funding for the system will be provided for under the financial arrangements for this Regulation.

The objective is to permit the funding of the activities to implement certain provisions of this Regulation with respect to the unique code and information requirements, once adopted.

Establishment of a system to develop and assign unique codes to GMOs authorised under Community legislation;

5.1.2. Measures taken in connection with ex ante *evaluation*

Not applicable

5.1.3. Measures taken following ex post *evaluation*

Not applicable

5.2. Actions envisaged and arrangements for budget intervention

- General objectives: links with the overall aim

[2] For further information see a separate guidance paper

The overall aim of the Regulation, in the context of the placing on the market of GMOs and products derived from GMOs, is to contribute to the protection of human health and the environment and to provide purchasers and consumers with relevant information as to the nature of such products.

- Specific and quantifiable objectives

Introduce a harmonised framework to ensure the traceability and labelling of GMOs and traceability of products derived from GMOs through the transmission and retention of specified information including for GMOs, a unique code to specify their identity as a means to facilitate;

- withdrawal of products should an unforeseen risk to human health or the environment be established;
- targeted monitoring of potential effects on human health or the environment, where appropriate;
- control and verification of labelling claims.

Introduce, as a means to specify the identity of GMOs, a system to develop and assign unique codes to GMOs authorised for the placing on the market under Community legislation.

- Target population

Members of the general public, importantly consumers, are the ultimate beneficiaries of the proposed measures. Consideration must also be given to the protection of the environment and animal health in this respect.

5.3. Methods of implementation

Expenditure for the legislative process will be largely based upon the cost of meetings with relevant experts from Member States. This will include determination of the alphanumeric format of the unique coding system and also the means of assignation.

It is foreseen that Working Group Meetings, comprising relevant experts from Member States, will be convened for this purpose. Experts will be required in the fields of environment and the food, feed and seed sectors. Attendance at relevant international meetings, for example OECD, and meetings with relevant stakeholders, including industry, consumer organisations and research organisations, will further this objective.

Final agreement to and adoption of the system will be via the comitology procedure under this Regulation. It is foreseen that two meetings of the appropriate Regulatory Committee comprising individuals from Member States will be convened for this purpose.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. Financial intervention

Commitments in € million (to the 3rd decimal place)

Breakdown	Year N	N + 1	N + 2	N + 3	N + 4	N + 5 and subs. years	Total
Action 1							
Action 2							
Etc.							
TOTAL							

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (Commitment appropriations)

	2001	2002	2003				Total
1) Technical and administrative assistance							
a) Technical assistance offices							
b) Other technical and administrative assistance: - intra muros : - extra muros : *of which for construction and maintenance of computerised management systems*							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[3]

(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.).

Commitments in € million (to the 3rd decimal place)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1…n)	Average unit cost	Total cost (total for years 1…n)
	1	2	3	4=(2X3)
Action 1 - *Measure 1* - *Measure 2* Action 2 - *Measure 1* - *Measure 2* - *Measure 3* *Etc.*	NA			
TOTAL COST				

If necessary explain the method of calculation

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Permanent officials or Temporary staff	A	0.5			*Duration 3 years*
	B	0.2			
	C	0.2			
Other human resources					
Total		0.9			

[3] For further information see a separate guidance paper

7.2. Overall financial impact of human resources

Type of human resources	Amount €	Method of calculation *
Officials Temporary staff	54 000 21 600 21 600	0.5 A x 108 000 0.2 B x 108 000 0.2 C x 108 000
Other human resources (give budget line)		
Total	97 200	0.5 A+ 02 B + 0.2 C years (2001-2003)

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount €	Method of calculation
Overall allocation (Title A7)		
A0701 – Missions	1rst year: 1500 2nd&3rd year: 1300	5 one-day missions to Luxembourg or Strasbourg: EUR 220 each 3 three-days missions to OECD meetings: EUR 1000 each
07030 – Meetings	2nd year: 52 800	2 meetings of 1 day with 6 private experts: EUR 400 each expert 2 working group meetings of 2 days with 30 experts each: EUR 800 each expert
A07031 – Compulsory committees (1): Regulatory Committee	3rd year: 24 000	2 Regulatory Committee meetings of 1 day with 30 experts each: EUR 400 each experts
Information systems (A-5001/A-4300)		
Other expenditure - Part A (state which)		
Total	1rst year: 1 500 2nd year: 54 100 3rd year: 25 300	

The amounts are total expenditure for twelve months.

(1) Specify the type of committee and the group to which it belongs.

I. Annual total (7.2 + 7.3)	1rst year:	98 700 €
	2nd year:	151 300 €
	3rd year	122 500 €
II.Duration of action	3 years	
III. Total cost of action (I x II)		372 500 €

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

Member States must ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation. Member States are also required to take appropriate legal or administrative measures in case of non-compliance with the provisions of this Regulation and communicate these measures to the Commission.

8.2. Arrangements and schedule for the planned evaluation

The Commission has to consider the effectiveness of the system on the basis of possible complaints and reports from Member states.

9. ANTI-FRAUD MEASURES

Not applicable for financial risks encountered.