

**GUIDANCE NOTES FROM FOOD STANDARDS AGENCY AND  
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS**

**Regulation (EC) No 1829/2003, genetically modified food and feed**

**Regulation (EC) No 1830/2003, traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18**

***Important note***

***These notes have been produced with the aim of providing informal, non-statutory guidance to operators and should be read in conjunction with the appropriate legislation. They should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, ultimately it is the responsibility of individual businesses, in consultation with their Local Authority Environmental Health or Trading Standards departments, as necessary, to decide the most appropriate way forward.***

<b><u>Contents</u></b>	<b><u>Page</u></b>
Introduction	3
SECTION I - Purpose of the EC Regulations on GM Food and Feed and Traceability and Labelling of Genetically Modified Organisms	
1.1 GM Food and Feed Regulation	4
1.2 Traceability and Labelling Regulation	4
SECTION II - Scope of the EC Regulations	
2.1 GM Food and Feed Regulation	6
2.1.1 Authorisation	6
2.1.2 Thresholds for the adventitious presence of GM materials in non-GM supplies	7
2.1.3 Labelling requirements	8
2.2 Traceability and Labelling Regulation	11
SECTION III - National Regulations	13
3.1 The Genetically Modified Food (England) Regulations 2004 No. [2335]	14
3.2 The Genetically Modified Feed (England) Regulations 2004 No. [2334]	15
3.3 The Genetically Modified Organisms (Traceability and Labelling) regulations No. [2412]	17
SECTION IV - How will the EC Regulations work in practice?	18

4.1	Procedures for applying for authorisation of a GMO for food, feed and environmental release	18
4.2	Procedures for assessing an application submitted under the GM food and feed regulation	18
4.3	Procedures in the UK for considering an application submitted under the GM food and feed regulation	18
4.4	Procedures for public comment	19
4.5	Procedures for sampling and testing	19
4.6	What is the lead in time for compliance of the regulations?	19
4.7	What businesses are affected?	20
SECTION V – How will the regulations be enforced?		21
5.1	Traceability	21
5.2	Thresholds	21
5.3	Labelling	22
5.4	Authorisation	22
SECTION VI - Frequently asked questions		23
6.1	General topics	23
6.2	Authorisation	23
6.3	Traceability and labelling	24
SECTION VII - Further information		27
SECTION VIII – Appendices		29
Appendix 1 – Glossary		
Appendix 2 – EC Regulation No. 1829/2003 on genetically modified food and feed		
Appendix 3 – EC Regulation No. 1830/2003 on the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18		
Appendix 4 – Diagram – interaction between EFSA, FSA and Defra		
Appendix 5 – Diagram – over-view of traceability requirements		
Appendix 6 – Regulation on implementing rules for authorisation		
Appendix 7 – Table – labelling requirements under EC Regulation No.1829/2003		
Appendix 8 – EC Regulation No. 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms		
Appendix 9 – EC guidance on sampling and testing		

## **Introduction**

A Glossary of terms is provided at Appendix 1.

This booklet provides guidance on the following EC and National Regulations on genetically modified organisms (GMOs):

**(1) Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed (OJ L268, 18.10.03, P1) (The GM food and feed regulation) (Appendix 2)**

Statutory Instruments providing for the enforcement of EC Regulation on GM food and feed (EC 1829/2003) in England:

**(2) The Genetically Modified Food (England) Regulations 2004**

**(3) The Genetically Modified Animal Feed (England) Regulations 2004**

and

**(4) Regulation (EC) No 1830/2003 of the European Parliament and the Council of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18 (OJ L268, 18.10.03 p24) (The traceability and labelling of GMOs regulation) (Appendix 3)**

A Statutory Instrument providing for the enforcement of the EC Regulation on the traceability and labelling of GMOs (EC 1830/2003) in England:

**(5) The Genetically Modified Organisms (Traceability and Labelling) (England) Regulation 2004**

The EC Regulations apply to the whole of the UK. The Statutory Instruments (SIs) apply only in England. Similar legislation has been made in Scotland, Wales and Northern Ireland.

Operators should be aware that as well as meeting the labelling requirements of the GM food and feed regulation and the traceability and labelling of genetically modified organisms, products are still subject to horizontal food labelling legislation. They should therefore also consult the Food Labelling Regulations 1996 (as amended) and their accompanying Guidance Notes. In addition, general food law (e.g. the Food Safety Act 1990, Trade Description Act 1968 and Environmental Protection Act 1990) is also applicable.

## SECTION I

### **Purpose of the EC Regulation on GM Food and Feed (EC 1829/2003) and EC Regulation on Traceability and Labelling of GMOs (EC 1830/2003)**

The EC Regulations came into force in all member states on the 7 November 2003 and became legally binding on 18 April 2004.

#### **1.1 GM Food and Feed Regulation (EC 1829/2003)**

The GM food and feed regulation provides a harmonised procedure for the scientific assessment and authorisation of GMOs and GM food and feed. The assessment procedure is centralised, with the European Food Safety Authority (EFSA) taking responsibility for undertaking this process. It provides for a uniform and transparent Community procedure for all marketing applications, whether they concern the GMO itself or the food and feed derivatives. The regulation has replaced the existing approval procedures for GM foods under the Novel Foods Regulations (EC) No 258/97. The role of the EFSA in relation to the roles of the UK Food Standards Agency (FSA) and Department for Environment, Food and Rural Affairs (Defra) is presented in Appendix 4.

Authorisations apply to GMOs for food or feed use, food or feed containing or consisting of GMOs; and food or feed produced from or containing ingredients produced from GMOs. A 'one door one key' approach operates whereby authorisation for deliberate release of GMOs into the environment can also be sought as part of the application for authorisation for GM food and feed. However, EFSA has an obligation to seek the views of the relevant competent authority in each Member State on the risk assessment of any proposed product approval for seeds or plant propagating material.

The Regulation requires labelling of all GM food and feed, which contain or consist of GMOs or are produced from or contain ingredients produced from GMOs regardless of the presence or absence of GM material in the final food or feed product. This is an extension to the previous labelling rules which were only triggered by the demonstrable presence of GM material in the final product.

The Regulation provides for two thresholds for the adventitious presence of GM material in non-GM food or feed. These thresholds are set at 0.9% for GMOs that have an EU authorisation, and 0.5% for material not yet authorised but that has received a favourable risk assessment from an EC scientific committee. The latter threshold is for a transitional period of three years from the date of application of the regulations (18 April 2004).

#### **1.2 Traceability and Labelling Regulation (EC 1830/2003)**

The traceability and labelling regulation provides a harmonised EU system for identifying GM products throughout the supply chain with the objective of

facilitating accurate labelling in accordance with Regulation (EC) No. 1829/2003. The regulation covers the following products placed on the market:

- Any products (including food or feed) consisting of or containing GMOs
- Food produced from GMOs
- Feed produced from GMOs

A system of unique identifier codes has been developed to allow access to specific information on GMOs from a register and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC. However, these codes are only required in documentation relating to the traceability and labelling of products consisting of or containing GMOs (e.g. soya beans). They are not required in relation to the traceability and labelling of food and feed products produced from GMOs (rapeseed oil, maize gluten feed).

## **SECTION II**

### **Scope of the EC Regulations on GM Food and Feed and Traceability and Labelling of GMOs**

#### **2.1 GM Food and Feed Regulation (EC 1829/2003)**

##### **2.1.1 Authorisation**

The GM food and feed regulation replaces the previous approval procedures concerning foods and food ingredients which contain or consist of a GMO or food and food ingredients derived from a GMO in Regulation (EC) No 258/97 and feed and feed ingredients consisting of or containing GMOs, which were previously subject to authorisation procedure provided by Council Directive 2001/18/EC.

Articles 3 to 8 and 15 to 20 describe the criteria and procedure for authorisation for applications submitted under this Regulation. These articles provide that authorisation must be sought:

- (i) for the use of a GMO as a source material for production of food or feed (for example, imported GM soya beans for processing into meal for use in animal feed); or
- (ii) for the use of ingredients in food and/or feed which contain, consist of or are produced from a GMO ( for example, lecithin from GM soya for use as an emulsifier in chocolate bars); or
- (iii) for the use of food or feed produced from a GMO (for example, cooking oil produced from GM maize, or tomato paste from GM tomatoes)

The scope of authorisation can include the cultivation of GM crops for feed or food uses. Decisions on authorisation must be taken in consultation with the relevant competent authorities under Directive 2001/18/EC on the deliberate release of GMOs into the environment. However, the cultivation of GM crops for non-food or non-feed uses (for example, growing GM potatoes for processing into industrial starch) is still governed solely by Directive 2001/18/EC.

For all new authorisations there is a requirement for applicants to provide detection methods and reference material as part of a dossier. Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material provides details on applying for the authorisation of a GMO (Appendix 6).

In addition, the safety assessment of the genetic modification under the scope of this regulation also applies to:

- (i) food additives containing, consisting of or produced from GMOs. Final authorisation should be granted under the procedure referred to in Directive 89/107/EEC for additives authorisation for use in foodstuffs intended for human consumption.
- (ii) flavourings falling within the scope of Council Directive 88/388/EEC for use in foodstuffs and source materials for their production which contain, consist of or produced from GMOs.
- (iii) feed materials containing, consisting of or produced from GMOs which fall within the scope of Council Directive 82/471/EEC.
- (iv) feed additives containing, consisting of or produced from GMOs which are authorised under Council Directive 70/524/EEC (or as from 18 October 2004, EC Regulation No. 1831/2003).

Operators responsible for placing existing products on the market authorised under 90/220/EEC, 2001/18/EC or EC 258/97 are required to notify the Commission of the date when they were first placed on the market and are required to provide detection methods and reference material. Re-authorisation will be required within 9 years but not earlier than 3 years from that date. Authorisations under the GM Food and Feed Regulation are renewable for ten-year periods. EC Regulation 641/2004 provides details regarding existing products (Appendix 6).

Consistent with the 'one door, one key' principle:

- a GMO for food or feed use that has been approved for deliberate release into the environment under the GM Food and Feed Regulation does not require separate authorisation under Council Directive 2001/18/EC.
- a single authorisation under the new GM Food and Feed Regulation for the use of a GMO in the production of food and/or feed can cover different uses of it in food and/or feed containing, consisting of or produced from that GMO without the need for separate authorisations, providing the conditions and requirements of the original authorisation are adhered to.

### **2.1.2 Thresholds for the adventitious presence of GM material in non-GM supplies**

Article 12(2) and (3), 24(2) and (3) and article 47 describe when a threshold for the presence of GM material may be relevant in order to determine whether particular requirements of the Regulations do, or do not, apply.

The EC regulation provides for two different threshold levels:

- 0.9%, applying to GM material which has already been approved under Council Directive 90/220/EEC or 2001/18/EC or Regulation (EC) No 258/97, and Regulation (EC) No 1829/2003

- 0.5%, applying to GM material which has received a favourable risk evaluation from an EU scientific committee or EFSA before the date of application of the Regulation (18 April 2004).

Products containing GM material which fall within the scope of these threshold levels do not have to be traced, labelled, (or – only in the case of the 0.5% threshold, – authorised) providing the GM presence can be demonstrated to be adventitious or technically unavoidable. Operators will need to demonstrate to enforcement bodies that they have taken appropriate steps to avoid any GM presence. There is no tolerance level for GM presence that is avoidable, or is unavoidable but above the relevant threshold. What would be considered as appropriate steps for avoiding GM presence is a matter for Local Authority Trading Standards Officers who have responsibility for enforcing this Regulation. The intentional use of GMOs at any level must be labelled.

The threshold for unauthorised GMOs is transitional and applies only for three years from 18 April 2004, after which it will be reviewed. EC Regulation 641/2004 provides details regarding thresholds (Appendix 6). The European Commission has published a list of authorised GMOs and those, which have received a favourable safety assessment to which the 0.9 and 0.5% thresholds respectively may apply. This can be accessed at [http://europa.eu.int/comm/food/food/biotechnology/authorisation/index\\_en.htm](http://europa.eu.int/comm/food/food/biotechnology/authorisation/index_en.htm)

### **2.1.3 Labelling Requirements**

Articles 12 and 24 describe the scope of the labelling requirements for GM food and feed. The labelling must indicate where foods or feeds contain or consist of GMOs or are produced 'from' or contain ingredients produced 'from' GMOs. Labelling applies regardless of the presence or absence of novel DNA or protein in the food or feed ingredient. There is no requirement to state that a product does not contain GM ingredients. Equally there is no provision for 'non-GM' and 'GM free' labelling though this can lawfully be used on a voluntary basis if appropriate to the product.

Any food on sale labelled "GM-free" is subject to the general requirements of food law, in particular the Food Safety Act 1990. This Act makes it an offence to describe, by way of labelling or advertising, a food falsely, or in a way likely to mislead a purchaser as to its nature, substance or quality. Also, the Trade Descriptions Act 1968 makes it an offence for a trader to supply food to which a false trade description has been applied, or to which a trade description has been applied which is misleading to a material degree.

The FSA view is that "GM free" should mean completely free from the use of GM technology and without a threshold for the accidental presence of GM material in a non-GM source. The use of this term would clearly be limited to a small range of products. The use of the term may vary from one food/feed



manufacturer to another and consumers should check with individual manufacturers regarding their use of the term.

This regulation does not cover food and feed produced 'with' a GMO. The determining criteria are whether or not material derived from the genetically modified source material is present in the food or the feed. Processing aids, which are only used during 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, and therefore products produced with processing aids do not need to be labelled. Food or feeds that are manufactured with the help of a GM processing aid are also exempt from this regulation. As a result, products obtained from animals fed GM feed are not subject to authorisation or labelling requirements.

Labelling applies to foods, which contain or consist of GMOs or are produced from or contain ingredients produced from GMOs and are delivered to the final consumer or mass caterers in the EU. Labelling is not required where the presence of an authorised GMO is less than 0.9% of the food or feed ingredients considered individually or of food consisting of a single ingredient, provided that the presence is adventitious or technically unavoidable. For an unauthorised GMO which has received a favourable safety assessment from an EC scientific committee the threshold is 0.5%. This latter threshold is for a transitional period of 3 years from the date of application of the Regulation (18 April 2004).

#### Labelling requirements for GM Food

Article 13 of the (EC) Regulation No 1829/2003 on genetically modified food and feed describes the specific food labelling requirements. The labelling must indicate where foods contain or consist of GMOs, or are produced or contain ingredients produced from GMOs.

Specific requirements are:

- Where a food contains more than one ingredient, the following indication must be given; 'genetically modified' or 'produced from genetically modified [name of ingredient]';
- Where a food is designated by the name of a category e.g. 'Emulsifiers', the following must appear in the list of ingredients; 'contains genetically modified (name of organism)', or contains (name of ingredient) produced from (name of organism)';
- If there is normally no list of ingredients given on a specific product the following must appear clearly on the labelling, 'produced from genetically modified (name of organism)';
- Where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10cm<sup>2</sup>, the information required must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

In the first two situations the information may be given in the list of ingredients or as a footnote to list of ingredients, providing the font is the same size as that of the ingredient list.

Further to the above requirements, additional labelling is required if:

- the food is different from its conventional counterpart in terms of its composition, nutritional value or effects,
- there are particular indications in relation to the intended use of the food,
- the food has implications for the health of certain sectors of the population
- the food gives rise to ethical or religious concerns.

#### Labelling requirements for GM Feed

Article 25 describes the specific feed labelling requirements. Labelling will apply to GMOs for feed use, feed containing or consisting of GMOs and feed produced from GMOs. Labelling will not apply to feed containing GM material in a proportion no higher than 0.9% of the feed provided that the presence is adventitious or technically unavoidable. The rules for the labelling of feed extend to feed for all animals – that is, all living organisms excluding humans, plants and micro-organisms. This includes fish, fowls and reptiles as well as mammals, including pets and wild birds, and applies irrespective of whether the animals are producing food for human consumption.

Specific requirements are:

- For GMOs for feed use or feed containing or consisting of GMOs the words ‘genetically modified (name of the organism)’ shall follow in parentheses the name of the feed or alternatively can appear in a footnote.
- For feed produced from GMOs the words ‘produced from genetically modified (name of organism)’ will need to appear in parentheses following the specific feed name or appear in a footnote to the list of feed.
- Any characteristic which renders the feed different from its conventional counterpart will need to be specified. For example:
  - (i) Composition
  - (ii) Nutritional properties
  - (iii) Intended use
  - (iv) Implications for health of certain species or categories of animals

In addition any characteristic or property of the feed which may give rise to ethical or religious concerns must be indicated.

In considering the scope of the labelling requirements stakeholders have asked for clarification regarding when the labelling rules will apply. A table summarising this information is included in Appendix 7. This table has been compiled in consultation with the European Commission.

## 2.2 Traceability and Labelling of GMOs Regulation (EC 1830/2003)

The Traceability and Labelling of GMOs Regulation is an elaboration of, and replaces, provisions in Directive 2001/18/EC that require Member States to take measures to ensure traceability and labelling of authorised GMOs at all stages of their placing on the market. The regulation recognises that there are differences between national laws, regulations and provisions concerning the traceability and labelling of GMOs and therefore establishes a harmonised EU system on the documentation required to account for and identify GM products throughout the supply chain, with the objective of facilitating accurate labelling. Article 4 & 5 of the regulation provides details of the traceability and labelling requirements and is outlined below:

Products consisting of or containing GMOs (Article 4) (e.g. soya, flowers for import)

At the first stage of placing on the market, written documentation will be required to be transmitted throughout all stages of the supply chain stating that the product a) contains or consists of GMOs, and b) giving the unique identifiers for the GMOs (Required only for a product that “contains or consists” of a living GMO e.g. soya bean – not for derived products e.g. flour or oil). All operators will be required to retain documentation for a period of 5 years detailing the operator providing the product and who the product was sold on to.

For products consisting of or containing mixtures of GMOs to be used only and directly for food, feed or processing, an alternative traceability procedure may be used. This involves; a) a declaration of use by the operator and b) a list of the unique identifiers “for all those GMOs that have been used to constitute the mixture”.

For pre-packaged products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)] must appear on the label.

For non-pre-packaged products offered to the final consumer the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)] will need to appear on, or in connection with, the display of the product.

Products for Food and Feed produced from GMOs (Article 5) (e.g. rapeseed oil, maize gluten feed, soya lecithin)

For these products there is a requirement for written documentation to be transmitted to the operator receiving the product. For each transaction, information regarding a) an indication of each of the food ingredients, feed materials, or feed additives which are produced from GMOs, or b) in the case

of products for which no ingredient list exists, an indication that the product is produced from GMOs will be required. All operators will be required to retain documentation for a period of 5 years, and adopting a 'one step up one step down' approach, detailing the operator providing the product and who the product was sold on to.

Where specific identification systems such as lot numbering is used for pre-packaged products then specific information on unique identifiers or which ingredients are produced from GMOs do not need to be held by operators providing the information and the lot number is clearly marked on the package and the information on lot numbers is held for a period of five years.

An over-view of the traceability requirements can be found at Appendix 5.

The thresholds in Articles 12, 24 or 47 of EC Regulation No 1829/2003 will apply to the labelling requirements detailed above for the adventitious or technically unavoidable presence of GMOs. Labelling will not be required in such cases.

In relation to the above regulation, EC Regulation 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (Appendix 8) provides a system for the development and assignment of unique identifiers for GMOs. Unique identifiers are not required in the relation to documentation for the traceability of food and feed produced from GMOs. Traceability and labelling requirements do not apply to non-food or non-feed products produced from GM material (for example, there is no requirement to label clothing produced from GM cotton). The Commission has also produced guidance on sampling and testing (Appendix 9) – Commission Recommendation (2004/787/EC) on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003.

## **SECTION III**

### **National Regulations**

The following Statutory Instruments provide enforcement powers and penalties for non-compliance of EC Regulations 1829/2003 and 1830/2003.

**The Genetically Modified Food (England) Regulations 2004 No. [2335]**

**The Genetically Modified Feed (England) Regulations 2004 No. [2334]**

**The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations No. [2412]**

### 3.1 The Genetically Modified Food (England) Regulations 2004 No. [2335]

This covers the following offences and penalties:

(a) It is an offence to place on the market a food referred to in Article 3.1 of EC 1829/2003 unless it is covered by an authorisation and satisfies relevant conditions of the authorisation. (Article 4.2 of EC 1829/2003)

On conviction for an offence as in (a) above, penalties apply as follows:

- On summary conviction, imprisonment for a term not exceeding 6 months or a fine not exceeding level 5 on the standard scale; or

On conviction on indictment, imprisonment for a term not exceeding two years or a fine, or both.

(b) There are requirements which must be met for the marketing of products as described below:

- GM products lawfully on the market prior to the date of application of the regulation and which continue to be on the market will have a maximum time of 6 months to notify the Commission of the date on which they were first placed on the market. (Article 8.1 of EC 1829/2003). Within 9 years from that date but not earlier than 3 years the applicant will submit a renewal for authorisation. (Article 8.4 of EC 1829/2003). The provision for enforcement measures is provided in Article 8.6 of EC 1829/2003.
- An applicant will comply with any conditions or restrictions, which have been imposed in the authorisation. (Article 9 of EC 1829/2003)
- Applicants will be required to inform the Commission of any new scientific or technical information relating to the food product which may influence the evaluation of the safety in use of the food or of any prohibition or restriction on the food in a third country. (Article 9.3 of EC 1829/2003)

(c) Food falling within the scope of EC 1829/2003 will be subject to specific labelling provisions. (Article 13 of EC 1829/2003).

On conviction of an offence as in (b) and (c) above, penalties apply as follows:

- On summary conviction, imprisonment for a term not exceeding 6 months or a fine not exceeding level 5 on the standards scale, or to both.

### 3.2 The Genetically Modified Feed (England) Regulations 2004 No. [2334]

This covers the following offences and penalties:

(a) It is an offence to place on the market use or process a GMO for feed use unless it is covered by an authorisation and satisfies relevant conditions of the authorisation (Article 16.2 of EC 1829/2003).

On conviction for an offence as in (a) above, penalties apply as follows:

- On summary conviction, imprisonment for a term not exceeding 3 months or a fine not exceeding level 5 on the standards scale or to both; or

On conviction on indictment to a term of imprisonment not exceeding two years or to a fine, or both.

(b) There are provisions for the manner of marketing products as described below:

- If an applicant does not notify the Commission within 6 months of the date on which their product was first placed on the market and within 9 years from that date applicant does not submit a renewal for authorisation the Commission shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. (Article 20.6 of EC 1829/2003)
- An authorisation holder will comply with any conditions or restrictions which have been imposed in the authorisation for that product and with post-market monitoring requirements. (Article 21.1 of EC 1829/2003)
- Authorisation holders will be required to inform the Commission of any new scientific or technical information relating to the food product which may influence the evaluation of the safety of the feed. (Article 21.3 of EC 1829/2003)

(c) Feed falling within the scope of the regulation will be subject to specific labelling provisions. (Article 25 of EC 1829/2003)

On conviction for an offence as in (b) and (c) above, penalties apply as follows:

- On summary conviction, imprisonment for a term not exceeding 3 months or a fine not exceeding level 5 on the standards scale, or to both.



### **3.3 The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations No. [2412]**

This covers the following offences and penalties:

- (a) It is an offence if an operator does not ensure that the following information is transmitted in writing at the first stage of placing on the market of a product consisting of or containing GMOs:
  - That it contains or consists of GMOs
  - The unique identifier assigned to the GMOs (Article 4.1 of EC 1830/2003)
- (b) It is an offence if an operator does not ensure subsequent transmission of the information specified in Article 4.1 of 1830/2003 (Article 4.2 of 1830/2003)
- (c) It is an offence if operators fail to ensure that products consisting of or containing GMOs to be used as food or feed or for processing are accompanied by a declaration of use, along with a list of the unique identifiers for all those GMOs used to constitute the mixture (Article 4.3 of 1830/2003)
- (d) It is an offence if operators do not keep specified information listed above for a period of 5 years (Article 4.4 of 1830/2003).
- (e) It is an offence if an operator does not ensure that:
  - Pre-packed products consisting or containing GMOs have the words, 'this product contains genetically modified organisms' or, 'this product contains genetically modified (name of organisms), on the label.
  - Non-pre-packed products consisting or containing GMOs have the words, 'this product contains genetically modified organisms' or, 'this product contains genetically modified (name of organisms), on or in connection with the display of the product.
- (f) It is an offence when placing products from GMOs on the market for specified information not to be transmitted in writing to the operator receiving the product (Article 5.1 of 1830/2003)
- (g) It is an offence not to keep records of the information referred to in Article 5.1 for the specified period (Article 5.2 of 1830/2003)

On summary conviction an offence under this regulation shall be punishable by imprisonment for a term not exceeding 3 months or a fine not exceeding level 5 on the standards scale, or to both.

## **SECTION IV**

### **How will the Regulations work in practice?**

#### **4.1 Procedures for applying for authorisation of a GMO for food, feed and environmental release**

Regulation (No 641/2004) (attached at Appendix 6) provides details regarding the presentation and preparation of applications and the scope of the application as outlined in articles 5, 8, 17 and 20 of Regulations 1829/2003. EFSA has produced further guidelines on the format of applications, this can be accessed at: [www.efsa.eu.int/science/gmo/gmo\\_guidance/660\\_en.html](http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html)

Guidelines on the information to be provided for detection methods have also been provided. The European Network of GMO Laboratories (ENGL) has compiled the method acceptance criteria and method performance requirements required for each application. This was published in the OJ in November 2004 and can be accessed at: <http://europa.eu.int/eur-lex/lex/JOhtml.do?uri=OJ:L:2004:348:SOM:EN:HTML>

#### **4.2 Procedures for assessing an application submitted under the EC Regulation on GM food and feed**

Applications for authorisation should be sent to the national competent authority of a member state, which will acknowledge receipt and forward the information to EFSA. EFSA will then inform the other member states and the Commission of the application and make the information from the applicant available to them as soon as it has checked the dossier for completeness and if necessary requested additional information from the company. A summary of the dossier will be made publicly available by EFSA. In the UK, applications should be sent to the Food Standards Agency which is the National Competent Authority for EC Regulation 1829/2003.

EFSA and its scientific panels may carry out the entire assessment procedure or may ask for assistance from the appropriate food or feed assessment body of a member state or the designated competent authority under Directive 2001/18/EC (Deliberate Release Directive). EFSA will endeavour to reach an opinion on an application within 6 months unless supplementary information needs to be requested from the applicant.

Where an authorisation is requested that includes the environmental release of a GMO, EFSA will consult the national competent authorities designated under Directive 2001/18/EC. The competent authorities will have three months to inform EFSA of their opinions. If the application includes GMOs that will be used as seeds or other plant propagating material, EFSA does not have the option of carrying out an environmental risk assessment itself and must instruct the relevant competent authority of a Member State to do it.

When it is finalised, EFSA will forward its initial opinion to the Commission, member states and the applicant. This will include a report describing its assessment, the reasons for its opinion and the information on which the opinion is based, and the opinions of the competent authorities under Directive 2001/18/EC. The opinion minus any confidential information will be made publicly available by EFSA.

#### **4.3 Procedures in the UK for considering an application submitted under the GM food and feed regulation**

The Food Standards Agency (FSA) is the UK competent authority under the GM Food and Feed Regulation. Any applications submitted through the UK will be received by the FSA, who will forward the request and the associated dossier of information to EFSA.

The FSA may be asked by EFSA to review the food and feed aspects of the dossier on its behalf, in which case it will take advice from its scientific advisory committees, the Advisory Committee on Novel Foods and Processes (ACNFP) and the Advisory Committee on Animal Feedingstuffs (ACAF). Applications that involve the environmental release of the GMO will be forwarded by EFSA to the competent authorities under Directive 2001/18/EC for review. In the UK, this will be the Department for Environment, Food and Rural Affairs (Defra) for advice, which will seek advice from its scientific advisory committee, the Advisory Committee on Releases into the Environment (ACRE).

Once EFSA's opinion on an application is published, a final decision on authorisation will be taken by the 25 EU member states. The UK position will be an agreed UK Government position and not the position of the Competent Authority under this regulation or an individual department.

#### **4.4 Procedures for public comment**

EFSA will publish the summary of the application and its opinion minus any information identified as confidential. The public may forward comments to the Commission within 30 days of the final opinion being published.

#### **4.5 Procedures for Sampling and testing**

Guidance on sampling and testing has been published by the European Commission (Appendix 9). The aim of this guidance is to facilitate a consistent approach by member states.

#### **4.6 What is the lead in time for compliance of the Regulations?**

The Regulations do not apply retrospectively. Products for which the manufacturing process began before the date of implementation will not need to be labelled in accordance with the labelling criteria laid down in the GM food and feed Regulation. The use of the term 'manufacturing process' in the context of this regulation refers to the start of the process for manufacturing a

particular product after 18 April 2004. Clearly the length of time for the manufacturing process will be different for each product and could range from several weeks to several years. Similarly for products containing GM ingredients which are on sale on the date of implementation a paper audit trail demonstrating the traceability of the GM ingredients will not be required. Traceability systems will need to begin from the day the Regulations are implemented. Operators should contact their Local Authority Trading Standards Officers for further practical guidance in this area. Ultimately it is for the courts to decide exactly how the Regulation should be interpreted.

#### **4.7 What businesses are affected?**

The Regulations apply to a wide range of businesses in the European Community. The requirements for authorisation will apply to the biotechnology industry. The labelling requirements will apply to food/feed sold to the final consumer/final user in the EC. The provision of information on traceability and labelling will apply throughout the food and feed chain and will have impacts on the food and drink industry, the hospitality industry, the animal feed industry and the farming industry.

## SECTION V

### How will the regulations be enforced?

Responsibility for inspection and other control measures to ensure compliance with these two regulations will fall to local authorities.

#### 5.1 Traceability

Documentation will be required throughout the food chain in the EU to demonstrate the identity of the product in question. A company will need to be satisfied their suppliers have carried out the necessary checks to ensure that the documentation provides accurately describes the source of the product in question and this is correctly labelled. A 'one up one down' approach should be adopted whereby an operator retains documentation from a supplier and a record of who the product was sold on to. The European Commission has published technical guidance on sampling and testing to facilitate a co-ordinated approach across member states (Appendix 9). When importing GM crops the onus is on the importer to ensure that this complies with these rules before it is sold to the final user. Enforcement of the Regulations in England is the responsibility of Local Authority Trading Standards Departments and Port Health Authorities. Businesses are expected to take all reasonable precautions and exercise due diligence to ensure that the labelling of products which they sell meets the requirements of the EC Regulations. Businesses may seek advice from their local enforcement bodies on whether the information they receive from their suppliers in terms of the documentation provided and any testing carried out is appropriate to ensure that the products comply with these regulations.

#### 5.2 Thresholds

As previously discussed, the GM Food and Feed Regulation sets thresholds for the adventitious presence of GM material in non-GM food or feed. These thresholds are set at 0.9% and 0.5%. The 0.9% threshold applies to GMOs that have an EU authorisation and 0.5% applies to material not yet authorised but that has a favourable assessment from an EC scientific committee. The latter of which is a temporary threshold for 3 years from the date of application of the regulation (18 April 2004).

This threshold will only apply to ingredients obtained from non-GM sources. There will be no threshold for supplies obtained from sources of unknown origin. The threshold is applied at the level of each individual ingredient and **not** the final food. For the threshold levels to apply a company must be able to demonstrate that the ingredient concerned was obtained from a non-GM source, e.g. through the use of a suitable Identity Preservation (IP) system.

The threshold levels are in place solely for the adventitious presence of GM from non-GM sources and are **not** a provision for lack of due diligence or intentional mixing of GM and non-GM. Any operator in breach of this Regulation will be subject to the penalties outlined in section III. It will be for

the operator to produce evidence to show that presence of GM is adventitious or technically unavoidable.

Businesses may wish to consult their Local Authority Trading Standards department (who are responsible for the enforcement of the Regulation) for further practical guidance in this area. Ultimately it is for the courts to decide exactly how the Regulation should be interpreted.

### **5.3 Labelling**

Businesses will need to take all reasonable precautions and exercise all due diligence (a defence provided by the Food Safety Act 1990 and the Statutory Instrument on Traceability and Labelling) to see that the labelling of products which they sell meets the requirements of the EC regulation. What is considered reasonable depends on all of the circumstances, including the size and resource of the business concerned. Companies might want to seek advice, on whether the due diligence systems they have in place would be enough to establish a defence, from their relevant enforcement officer or lawyer.

### **5.4 Authorisation**

The Commission has undertaken to develop a central register for competent authorities which will contain all the available sequencing information and reference material for authorised GMOs. The register will also contain relevant information concerning GMOs not authorised in the EU.

## SECTION VI

### Frequently Asked Questions

#### 6.1 General topics

1. What is a GMO?

*A "genetically modified organism" GMO means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.*

2. Who will be responsible for the enforcement of the new regulations?

*Local Authorities, Port Health Authorities and Trading Standards Officers will have responsibility for enforcement of the two regulations in England as detailed in the Statutory Instruments for the Regulations.*

3. How will these Regulations work in Scotland, Wales and Northern Ireland?

*Scotland, Wales and Northern Ireland will have their own legislation providing for enforcement of these Regulations in their own administrations.*

#### 6.2 Authorisation

4. How can the public comment on the EFSA opinion and dossier?

*There is an opportunity for comments from the public to be forwarded to the Commission after the EFSA opinion is published. The public will have 30 days to comment.*

5. Will consumer and ethical views be taken into account?

*ACNFP has two consumer representatives and an ethicist who will consider such issues where the Committee is consulted on the dossier. Organisations, with particular interests in these issues should forward views separately to the Commission. The public have 30 days to comment on applications after the EFSA opinion is published.*

6. How will the final decision on approval be made?

*The final decision for approval will be by qualified majority vote at the Standing Committee for Animal Health and the Food Chain. This process is the same as that used for authorising GMOs under the Novel Foods Regulation and the Deliberate Release Directive.*

7. What is the position concerning applications which are already being considered under EC Regulation No 258/97 and EC Directive 2001/18?

*GM applications submitted under EC Regulation No 258/97 which were referred to EFSA for consideration will be considered under EC Regulation No 1829/2003. Where sufficient progress has been made on applications under EC Regulation No 258/97 and the Commission is in a position to take these forward for vote at Standing Committee shortly these applications will be concluded under that regulation. However the applications will need to meet all the criteria under Regulation No 1829/2003 e.g. provision of detection methods and reference materials.*

*Applications submitted under EC Directive 2001/18 will continue to be assessed under that directive. However, there is a provision in Regulation No 1829/2003 for future applications for import and cultivation of GMOs to be considered under this Regulation which offers a 'one door one key' approach for food, feed and environmental assessment.*

8. How do I know what GMOs are approved in the EU and third countries?

*The OECD database provides details of approved GMOs in EU and third countries; <http://www2.oecd.org/biotech/frameset.asp>*

*The Commissions will publish up to date lists of approved GMOs in the EU: [http://europa.eu.int/comm/food/food/biotechnology/authorisation/index\\_en.htm](http://europa.eu.int/comm/food/food/biotechnology/authorisation/index_en.htm) Risk assessment and approval data forms part of the role of the Biosafety Clearing House being developed under the Cartagena Protocol on Biosafety, an international agreement focusing on global movements of GM products from one country to another.*

### **6.3 Traceability and labelling**

9. How can labelling be enforced when products can't be analysed?

*Traceability through the use of a paper audit trail will provide the necessary information regarding product origin and ensure that products derived from GMOs are labelled as such. Operators that don't label when they know a GMO has been used will be subject to penalties as provided in the Statutory Instruments for GM food (SI No [2335]) and GM animal feed (SI No [2334]).*

10. When will traceability systems be in place?

*Traceability systems for GMOs were applicable from 18<sup>th</sup> April 2004. Such systems were not required to be in place retrospectively for GMOs.*

11. Will a paper audit need to be in place for a GM product on a supermarket shelf on 18 April 2004?

*No. As traceability systems were required to be in place from 18<sup>th</sup> April, any GM product produced after the 18<sup>th</sup> April will have to be labelled as will any foods which contain a GM ingredient. Labelling will not be required until a particular product reaches the supermarket shelf or is sold to the final consumer. However, the product will still have to satisfy existing labelling law as it was before the new Regulation came into force.*



12. Will a paper audit need to be in place for a non-GM product?

*There is no requirement in these regulations for paper audit trails to be in place for non-GM supplies. We are nevertheless aware that some food and feed manufacturers have adopted identity preserved supply chains for non-GM supplies.*

13. What rules will apply for identity preserved non-GM supplies?

*There are no EC or national rules for identity preserved non-GM supplies. (see above)*

14. Is there an option for "may contain" labelling?

*There is no option for "may contain" declarations in traceability documentation or on labels. If there is a mixture of GMOs in a product then under the Traceability and Labelling regulation products must state which GMOs have been used in its composition. However, if an operator declares that certain products containing a mixture of GMOs intended for use in food, or feed, or for processing contains particular GMOs that, in the event, are not there, he or she incurs no liability to prosecution.*

15. How will the GM labelling requirement work?

*The regulation requires that all foods produced from GMOs irrespective of whether there is GM material in the final product must be labelled. The label has to state that "this product contains genetically modified organisms" or "... produced from genetically modified (name of organism)"*

- *For packaged food the words 'genetically modified' must be used together with the name of the food, or in association with the particular ingredient within the ingredient list. An asterisk and footnote to the ingredient list may be used to indicate the ingredient is from a GM source.*
- *For unpackaged foods for retail sale the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.*

16. What is the requirement for food that does not contain GM ingredients?

*The regulation does not cover labelling of food that is not genetically modified. There is no provision for labelling such as "GM free" or "non GM" and these terms have no legal definition. Any food on sale labelled 'GM free' would be subject to the general requirements of food law, in particular the Food Safety Act 1990 as it is an offence to describe, by way of labelling or advertising, a food falsely, or in a way likely to mislead a purchaser as to its nature, substance or quality. Also, the Trade Descriptions Act 1968 makes it an offence for a trader to supply food to which a false trade description has been applied, or to which a trade description has been applied which is misleading to a material degree.*

17. What about labelling of foods/ingredients sold to caterers?

*Our legal interpretation of the regulation is that food sold to caterers will need to be labelled.*

18. Will catering establishments continue to provide labelling information to consumers for foods sold in restaurants, cafes etc?

*Article 12 of EC Regulation No 1829/2003 reads 'this section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community'. As mass caterers are delivering to the final consumer then ingredients should be labelled. We are aware there is disagreement between the Council and European Commission as to whether catering establishments are required to provide labelling information to the final consumer. The European Commission is seeking advice from its lawyers and this issue will be discussed further at a future Standing Committee meeting. The FSA's legal view is that labelling is required across EU Member States under EC Regulation 1829/2003.*

19. What is the definition of manufacturing process as referred to in article 46(2) of food and feed regulation?

*The use of the term 'manufacturing process' in the context of this regulation refers to the start of the process for manufacturing a particular product after 18 April 2004. Clearly the length of time for the manufacturing process will be different for each product and could range from several weeks to several years.*

20. Is it feasible for wholesalers to keep documents for 5 years?

*This is a requirement of the regulation and will therefore have to be complied with.*

21. How should operators handle complaints or challenges as to the accuracy of a product label?

*Operators will need to be in a position to demonstrate the origin of the GM products and defend their position with respect to labelling.*

## **SECTION VII**

### **Further information**

For further information on GM Food and Feed Regulation (Regulation (EC) No 1829/2003) contact:

Novel Foods, Additives and Supplements Division  
Food Standards Agency  
Aviation House  
125 Kingsway  
London WC2B 6NH

Switchboard: Tel 020 7276 8000

Web address: [www.food.gov.uk](http://www.food.gov.uk)

Email: [gmconsult@foodstandards.gsi.gov.uk](mailto:gmconsult@foodstandards.gsi.gov.uk)

For further information on Traceability and Labelling Regulation (EC Regulation No 1830/2003) contact:

GM Policy, Science and Regulation Team  
Department for Environment, Food and Rural Affairs  
3<sup>rd</sup> Floor, Ashdown House  
123 Victoria Street  
London SW1E 6DE

Switchboard: Tel 08459 335577

Web address: [www.defra.gov.uk](http://www.defra.gov.uk)

Email: [gm@defra.gsi.gov.uk](mailto:gm@defra.gsi.gov.uk)

For general enquiries on the Food Labelling Regulations 1996, as amended, contact:

Consumer Choice, Food Standards and Special Projects  
Division – Food Labelling and Marketing Terms Branch

Advisory Committee on Novel Foods and Processes contact:

ACNFP Secretariat  
Novel Foods, Additives and Supplements Division  
Food Standards Agency (as above)

Tel: 020 7276 8595

Email: [acnfp@foodstandards.gsi.gov.uk](mailto:acnfp@foodstandards.gsi.gov.uk)

Advisory Committee Releases to Environment contact:

ACRE Secretariat  
GM Policy, Science and Regulation Team  
Department for Environment, Food and Rural Affairs  
(address as above)

Local Authorities contact:

LACORS  
10 Albert Embankment  
London SE1 7SP

Tel: 020 7840 7200

Web address: [www.lacors.gov.uk](http://www.lacors.gov.uk)

Port Health Authorities contact:

Association of Port Health Authorities  
Dutton House  
46 Church Street  
Runcorn  
Cheshire WA7 1LL

Tel: 08707 444505

Web address: [www.apha.org.uk](http://www.apha.org.uk)

Email: [apha@cieh.org.uk](mailto:apha@cieh.org.uk)

## **SECTION VIII**

### **Appendices**

Appendix 1 – Glossary

Appendix 2 – EC Regulation No.1829/2003 on genetically modified food and feed

Appendix 3 – EC Regulation No. 1830/2003 on the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18

Appendix 4 – Diagram – interaction between EFSA, FSA and Defra

Appendix 5 – Diagram – over-view of traceability requirements

Appendix 6 – EC Regulation on implementing rules for authorisation (draft)

Appendix 7 – Table - labelling requirements under EC Regulation No. 1829/2003

Appendix 8 – EC Regulation No. 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

Appendix 9 – EC Guidance on sampling and testing (draft)

## **Appendix 1 – Glossary**

Adventitious presence – in the case of these regulations, the accidental or unavoidable presence of GM material in a non-GM source.

Control sample – The genetically modified organism or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample).

Conventional counterpart – A similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use.

Contamination – Contamination of non-GM material by GM material.

Deliberate release – Any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment.

Due diligence – Statutory requirement for food businesses to comply with as provided by the Food Safety Act 1990 and the Environmental Protection Act, England.

Environmental risk assessment – The evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose (further clarification see Annex II of Directive 2001/18/EC).

Final consumer – The last person to receive the product who will not use the product as part of any business operation or activity.

Food' (or 'foodstuff') – Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

Food law – The laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals.

Food business – Any undertaking whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

Food business operator – The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

Feed (or 'feedingstuff') – Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

Feed business – Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding.

Feed business operator – The natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control.

Genetically modified organism (GMO) – An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Genetically modified food – Food containing, consisting of or produced from GMOs.

Genetically modified feed – Feed containing, consisting of or produced from GMOs.

Genetically modified organism for food use – A GMO that may be used as food or as a source material for the production of food.

Genetically modified organism for feed use – A GMO that may be used as feed or as a source material for the production of feed.

Identity Preserved – A system to ensure that a product is traceable and demonstrates that steps have been taken to ensure that the composition of the product has not altered through the food chain.

Ingredient – Any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

Mass caterers – Organisations which supply food products to a number of individuals e.g. restaurants, hospitals, canteens etc.

Notification – The submission of the information required under Regulation to the competent authority of a Member State.

Non-GM or GM-free – Not containing, consisting of or produced from GMOs. There is no legal basis for the use of this term.

Operator – The natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control.

Placing on the market – The holding of food or feed for the purpose of sale including offering for sale, or any form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

Pre-packaged product – Any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

Primary production – The production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

Processing aid – any substances not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

Produced from GMOs – Derived, in whole or in part, from GMOs, but not containing or consisting of GMOs.

Retail – The handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

Risk – A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

Risk assessment – A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Stages of production, processing and distribution – Any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed.

Traceability – The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution. This requires a one-step up, one-step down approach for information to be passed through the supply chain.



Unique identifier – A simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO. Required only for a product that “contains or consists” of a living GMO – not for derived products

**Appendix 2** – EC Regulation No.1829/2003 on genetically modified food and feed

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00010023.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf)

## I

(Acts whose publication is obligatory)

**REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 22 September 2003  
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 Article 152(4)(b) thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee <sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(3)</sup>,

Acting in accordance with the procedure referred to in Article 251 of the Treaty <sup>(4)</sup>,

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 ensured in the pursuit of Community policies.
- (3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

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

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(5)</sup>. This procedure should be streamlined and made more transparent.

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

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990 <sup>(6)</sup> and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms <sup>(7)</sup>; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

<sup>(1)</sup> OJ C 304 E, 30.10.2001, p. 221.

<sup>(2)</sup> OJ C 221, 17.9.2002, p. 114.

<sup>(3)</sup> OJ C 278, 14.11.2002, p. 31.

<sup>(4)</sup> Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.

<sup>(5)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(6)</sup> OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.

<sup>(7)</sup> OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

- (9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety<sup>(1)</sup>. Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.
- (10) 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.
- (11) Under this Regulation, authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.
- (12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption<sup>(2)</sup> provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC.
- (13) Flavourings falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production<sup>(3)</sup> which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.
- (14) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition<sup>(4)</sup> provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment. These feed materials containing, consisting of or produced from GMOs should fall instead within the scope of this Regulation.
- (15) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>(5)</sup>, provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall within the scope of this Regulation.
- (16) This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore,

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(2)</sup> OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

<sup>(3)</sup> OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

<sup>(4)</sup> OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

<sup>(5)</sup> OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

- (17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.
- (18) Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>(1)</sup> provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.
- (19) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97, in Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC<sup>(2)</sup> and in Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms<sup>(3)</sup>.
- (20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.
- (21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

- (22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.
- (23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC<sup>(4)</sup> ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.
- (24) 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 presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.
- (25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.
- (26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for

<sup>(1)</sup> OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

<sup>(2)</sup> OJ L 159, 3.6.1998, p. 4. Regulation as amended by Commission Regulation (EC) No 49/2000 (OJ L 6, 11.1.2000, p. 13).

<sup>(3)</sup> OJ L 6, 11.1.2000, p. 15.

<sup>(4)</sup> See page 24 of this Official Journal.

- GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.
- (27) 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.
- (28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.
- (29) The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.
- (30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed.
- (31) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the Authority. However, as specific acts or omissions on the part of the Authority under this Regulation could produce direct legal effects on applicants, it is appropriate to provide for the possibility of an administrative review of such acts or omissions.
- (32) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.
- (33) Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.
- (34) In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of Directives 68/193/EEC<sup>(1)</sup>, 2002/53/EC<sup>(2)</sup> and 2002/55/EC<sup>(3)</sup>, which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues; nor should they affect the provisions of Directives 66/401/EEC<sup>(4)</sup>, 66/402/EEC<sup>(5)</sup>, 68/193/EEC, 92/33/EEC<sup>(6)</sup>, 92/34/EEC<sup>(7)</sup>, 2002/54/EC<sup>(8)</sup>, 2002/55/EC, 2002/56/EC<sup>(9)</sup> or 2002/57/EC<sup>(10)</sup> which regulate in particular the certification and the marketing of seeds and other plant-propagating materials.

<sup>(1)</sup> OJ L 93, 17.4.1968, p. 15. Directive as last amended by Directive 2002/11/EC (OJ L 53, 23.2.2002, p. 20).

<sup>(2)</sup> OJ L 193, 20.7.2002, p. 1.

<sup>(3)</sup> OJ L 193, 20.7.2002, p. 33.

<sup>(4)</sup> OJ L 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2001/64/EC (OJ L 234, 1.9.2001, p. 60).

<sup>(5)</sup> OJ L 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2001/64/EC.

<sup>(6)</sup> OJ L 157, 10.6.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

<sup>(7)</sup> OJ L 157, 10.6.1992, p. 10. Directive as last amended by Regulation (EC) No 806/2003.

<sup>(8)</sup> OJ L 193, 20.7.2002, p. 12.

<sup>(9)</sup> OJ L 193, 20.7.2002, p. 60. Directive amended by Commission Decision 2003/66/EC (OJ L 25, 30.1.2003, p. 42).

<sup>(10)</sup> OJ L 193, 20.7.2002, p. 74. Directive amended by Commission Directive 2003/45/EC (OJ L 138, 5.6.2003, p. 40).



- (35) It is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory under Directive 2001/18/EC.
- (36) To facilitate controls on genetically modified food and feed, applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.
- (37) Technological progress and scientific developments should be taken into account when implementing this Regulation.
- (38) Food and feed falling within the scope of this Regulation which have been lawfully placed on the Community market before the date of application of this Regulation should continue to be allowed on the market, subject to the transmission to the Commission by the operators of information concerning the risk assessment, methods for sampling, identification and detection as appropriate, including the transmission of samples of the food and feed and their control samples within six months after the date of application of this Regulation.
- (39) A register of genetically modified food and feed authorised under this Regulation should be established, including product specific information, studies which demonstrate the safety of the product, including, where available, references to independent and peer-reviewed studies, and to methods for sampling, identification and detection. Non-confidential data should be made available to the public.
- (40) In order to stimulate research and development into GMOs for food and/or feed use, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials which would be against the public interest.
- (41) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(1)</sup>.
- (42) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, or any other appropriate body established by the Commission, with a view to obtaining advice on ethical issues regarding the placing on the market of genetically modified food or feed. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.
- (43) In order to provide a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles referred to in Regulation (EC) No 178/2002. The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.
- (44) Certain instruments of Community law should be repealed and others amended as a result of this Regulation.
- (45) The implementation of this Regulation should be reviewed in the light of experience gained in the short term, and the impact of the application of this Regulation on human and animal health, consumer protection, consumer information and the functioning of the internal market should be monitored by the Commission,

HAVE ADOPTED THIS REGULATION:

#### CHAPTER I

#### OBJECTIVE AND DEFINITIONS

##### Article 1

##### Objective

The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to:

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

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

- (b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;
- (c) lay down provisions for the labelling of genetically modified food and feed.

## Article 2

### Definitions

For the purposes of this Regulation:

1. the definitions of 'food', 'feed', 'final consumer', 'food business' and 'feed business' given in Regulation (EC) No 178/2002 shall apply;
2. the definition of 'traceability', laid down in Regulation (EC) No 1830/2003;
3. 'operator' means the natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control;
4. the definitions of 'organism', 'deliberate release' and 'environmental risk assessment' referred to in Directive 2001/18/EC shall apply;
5. 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;
6. 'genetically modified food' means food containing, consisting of or produced from GMOs;
7. 'genetically modified feed' means feed containing, consisting of or produced from GMOs;
8. 'genetically modified organism for food use' means a GMO that may be used as food or as a source material for the production of food;
9. 'genetically modified organism for feed use' means a GMO that may be used as feed or as a source material for the production of feed;
10. 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;
11. 'control sample' means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample);
12. 'conventional counterpart' means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use;
13. 'ingredient' means 'ingredient' as referred to in Article 6(4) of Directive 2000/13/EC;
14. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.
15. 'pre-packaged food' means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.
16. 'mass caterer' means 'mass caterer' as referred to in Article 1 of Directive 2000/13/EC.

## CHAPTER II

### GENETICALLY MODIFIED FOOD

#### Section 1

### Authorisation and supervision

#### Article 3

#### Scope

1. This Section shall apply to:
  - (a) GMOs for food use;
  - (b) food containing or consisting of GMOs;
  - (c) food produced from or containing ingredients produced from GMOs.
2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of food falls within the scope of this Section.



*Article 4***Requirements**

1. Food referred to in Article 3(1) must not:
  - (a) have adverse effects on human health, animal health or the environment;
  - (b) mislead the consumer;
  - (c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.
2. No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.
3. No GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.
4. The authorisation referred to in paragraph 2 may cover:
  - (a) a GMO and foods containing or consisting of that GMO as well as foods produced from or containing ingredients produced from that GMO; or
  - (b) food produced from a GMO as well as foods produced from or containing that food;
  - (c) an ingredient produced from a GMO as well as food containing that ingredient.
5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.
6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.
7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

*Article 5***Application for authorisation**

1. To obtain the authorisation referred to in Article 4(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

- (a) The national competent authority:
  - (i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
  - (ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the Authority); and
  - (iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.
- (b) The Authority
  - (i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;
  - (ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.
3. The application shall be accompanied by the following:
  - (a) the name and the address of the applicant;
  - (b) the designation of the food, and its specification, including the transformation event(s) used;
  - (c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);
  - (d) where applicable, a detailed description of the method of production and manufacturing;
  - (e) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1);
  - (f) either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3);
  - (g) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b);
  - (h) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

## Article 6

**Opinion of the Authority**

- (i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;
- (j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;
- (k) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;
- (l) a summary of the dossier in a standardised form.

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

5. In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by:

- (a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;
- (b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

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

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

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

1. In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion the Authority:

- (a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 5 and examine whether the food complies with the criteria referred to in Article 4(1);
- (b) may ask the appropriate food assessment body of a Member State to carry out a safety assessment of the food in accordance with Article 36 of Regulation (EC) No 178/2002;
- (c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;
- (d) shall forward to the Community reference laboratory referred to in Article 32 the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;
- (e) shall, in verifying the application of Article 13(2)(a), examine the information and data submitted by the applicant to show that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

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

- (a) the name and address of the applicant;
- (b) the designation of the food, and its specification;
- (c) where applicable, the information required under Annex II to the Cartagena Protocol;
- (d) the proposal for the labelling of the food and/or foods produced from it;
- (e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;
- (f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it; an indication of where appropriate reference material can be accessed;
- (g) where appropriate, the monitoring plan referred to in Article 5(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the food and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

#### Article 7

##### Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 6(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in the Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 11. The authorised food shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

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

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

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

#### Article 8

##### Status of existing products

1. By way of derogation from Article 4(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

- (a) in the case of products placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 or in accordance with the provisions referred to in Regulation (EC) No 258/97, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;
- (b) in the case of products which have been lawfully placed on the market in the Community but are not covered by point (a), operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 5(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 7(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and food containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 9, 10 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure referred to in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

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

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

#### Article 9

### Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and parties concerned shall comply with any conditions or restrictions which have

been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 5(3)(k) and/or monitoring as referred to in Article 5(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 5(2). Articles 5, 6 and 7 shall apply *mutatis mutandis*.

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

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

#### Article 10

### Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 7.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

#### Article 11

### Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.



2. The application shall be accompanied by the following:
- (a) a copy of the authorisation for placing the food on the market;
  - (b) a report on the results of the monitoring, if so specified in the authorisation;
  - (c) any other new information which has become available with regard to the evaluation of 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. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.
4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.
5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.
6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

## Section 2

### Labelling

#### Article 12

##### Scope

1. This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:
- (a) contain or consist of GMOs; or
  - (b) are produced from or contain ingredients produced from GMOs.
2. This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.
3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2) in particular in respect of foods containing or consisting of GMOs or in order to take into account advances in science and technology.

#### Article 13

### Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods falling within the scope of this Section shall be subject to the following specific labelling requirements:
- (a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;
  - (b) where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients;
  - (c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labelling;
  - (d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;
  - (e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm<sup>2</sup>, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.
2. In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:
- (a) where a food is different from its conventional counterpart as regards the following characteristics or properties:
    - (i) composition;
    - (ii) nutritional value or nutritional effects;

- (iii) intended use of the food;
- (iv) implications for the health of certain sections of the population;

*Article 16*

### Requirements

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

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

*Article 14*

### Implementing measures

1. Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

2. Specific rules concerning the information to be given by mass caterers providing food to the final consumer may be adopted in accordance with the procedure referred to in Article 35(2).

In order to take into account the specific situation of mass caterers, such rules may provide for adaptation of the requirements of Article 13(1)(e).

## CHAPTER III

### GENETICALLY MODIFIED FEED

#### Section 1

### Authorisation and supervision

*Article 15*

#### Scope

1. This Section shall apply to:
  - (a) GMOs for feed use;
  - (b) feed containing or consisting of GMOs;
  - (c) feed produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of feed falls within the scope of this Section.

1. Feed referred to in Article 15(1) must not:

- (a) have adverse effects on human health, animal health or the environment;
- (b) mislead the user;
- (c) harm or mislead the consumer by impairing the distinctive features of the animal products;
- (d) differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

2. No person shall place on the market, use or process a product referred to in Article 15(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No product referred to in Article 15(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

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

- (a) a GMO and feed containing or consisting of that GMO as well as feed produced from that GMO; or
- (b) feed produced from a GMO as well as feeds produced from or containing that feed.

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

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

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

*Article 17*

### Application for authorisation

1. To obtain the authorisation referred to in Article 16(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.
- (a) The national competent authority:
- (i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
  - (ii) shall inform the Authority without delay; and
  - (iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.
- (b) The Authority:
- (i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;
  - (ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.
3. The application shall be accompanied by the following:
- (a) the name and the address of the applicant;
  - (b) the designation of the feed and its specification, including the transformation event(s) used;
  - (c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;
  - (d) where applicable, a detailed description of the method of production and manufacturing and intended uses of the feed;
  - (e) a copy of the studies including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the feed complies with the criteria referred to in Article 16(1), and, in particular for feed falling within the scope of Directive 82/471/EEC, the information required under Council Directive 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition <sup>(1)</sup>;
  - (f) either an analysis, supported by appropriate information and data, showing that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 25(2)(c), or a proposal for labelling the feed in accordance with Article 25(2)(c) and (3);
  - (g) either a reasoned statement that the feed does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 25(2)(d);
  - (h) where appropriate, the conditions for placing the feed on the market, including specific conditions for use and handling;
- (i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in the feed produced from it;
  - (j) samples of the feed and their control samples and information as to the place where the reference material can be accessed;
  - (k) where appropriate, a proposal for post-market monitoring for the use of the feed for animal consumption;
  - (l) a summary of the dossier in a standardised form.
4. In the case of an application relating to a GMO for feed use, references to 'feed' in paragraph 3 shall be interpreted as referring to feed containing, consisting of or produced from the GMO in respect of which an application is made.
5. In the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by:
- (a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMOs has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;
  - (b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.
- In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.
6. Where the application concerns a substance, the use and placing on the market of which is subject under other provisions of Community law to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.
7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.
8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

<sup>(1)</sup> OJ L 126, 13.5.1983, p. 23.

## Article 18

**Opinion of the Authority**

1. In giving its opinion, the Authority shall endeavour to comply with a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

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

- (a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 17, and examine whether the feed complies with the criteria laid down in Article 16(1);
- (b) may ask the appropriate feed assessment body of a Member State to carry out a safety assessment of the feed in accordance with Article 36 of Regulation (EC) No 178/2002;
- (c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;
- (d) shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;
- (e) shall, in verifying the application of Article 25(2)(c), examine the information and data submitted by the applicant to show that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or feed containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC, designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

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

- (a) the name and address of the applicant;
- (b) the designation of the feed, and its specification;
- (c) where applicable, the information required under Annex II to the Cartagena Protocol;
- (d) the proposal for the labelling of the feed;
- (e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;
- (f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in feed produced from it; an indication of where appropriate reference material can be accessed;
- (g) where appropriate, the monitoring plan as referred to in Article 17(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

## Article 19

**Authorisation**

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.



2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 18(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 23. The authorised feed shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

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

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

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

#### Article 20

##### Status of existing products

1. By way of derogation from Article 16(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC, which are produced from GMOs, or under Directive 70/524/EEC, which contain, consist of or are produced from GMOs, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but which are not referred to in point (a), operators responsible for placing on the market

in the Community the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 17(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 19(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure laid down in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

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

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

## Article 21

**Supervision**

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and the parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 17(3)(k) and/or monitoring as referred to in Article 17(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 17(2). Articles 17, 18 and 19 shall apply *mutatis mutandis*.

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

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

## Article 22

**Modification, suspension and revocation of authorisations**

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 19.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

## Article 23

**Renewal of authorisations**

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following 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. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

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

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

## Section 2

**Labelling**

## Article 24

**Scope**

1. This Section shall apply to feed referred to in Article 15(1).

2. This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2), in particular in respect of feed containing or consisting of GMOs, or in order to take into account advances in science and technology.

#### Article 25

### Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) shall be subject to the specific labelling requirements laid down below.

2. No person shall place a feed referred to in Article 15(1) on the market unless the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto.

Each feed of which a particular feed is composed shall be subject to the following rules:

(a) for the feeds referred to in Article 15(1) (a) and (b), the words 'genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

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

(b) for the feed referred to in Article 15(1)(c), the words 'produced from genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

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

(c) as specified in the authorisation, any characteristic of the feed referred to in Article 15(1) such as those indicated hereunder, which is different from its conventional counterpart:

- (i) composition;
- (ii) nutritional properties;
- (iii) intended use;
- (iv) implications for the health of certain species or categories of animals;

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

3. In addition to the requirements referred to in paragraph 2(a) and (b) and as specified in the authorisation, the labelling or accompanying documents of feed falling within the scope of this Section which does not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the feed concerned.

#### Article 26

### Implementing measures

Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

#### CHAPTER IV

### COMMON PROVISIONS

#### Article 27

### Products likely to be used as both food and feed

1. Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision.

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

#### Article 28

### Community register

1. The Commission shall establish and maintain a Community register of genetically modified food and feed, hereinafter referred to as 'the Register'.

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

#### Article 29

### Public access

1. The application for authorisation, supplementary information from the applicant, opinions from the competent authorities designated in accordance with Article 4 of Directive 2001/18/EC, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public.

2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents<sup>(1)</sup> when handling applications for access to documents held by the Authority.

3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

### Article 30

#### Confidentiality

1. The applicant may indicate which information submitted under this Regulation it wishes to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

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

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

- (a) name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;
- (b) general description of the GMO and the name and address of the authorisation-holder;
- (c) physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);
- (d) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on human and animal health and on the environment;
- (e) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;
- (f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3(1) and 15(1);
- (g) information on waste treatment and emergency response.

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

5. The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.

6. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

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

### Article 31

#### Data protection

The scientific data and other information in the application dossier required under Article 5(3) and (5) and Article 17(3) and (5) may not be used for the benefit of another applicant for a period of 10 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 the expiry of this 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

### Article 32

#### Community reference laboratory

The Community reference laboratory and its duties and tasks shall be those referred to in the Annex.

National reference laboratories may be established in accordance with the procedure referred to in Article 35(2).

Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the Community reference laboratory and the European Network of GMO laboratories mentioned in the Annex.

<sup>(1)</sup> OJ L 145, 31.5.2001, p. 43.



The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

Detailed rules for implementing this Article, the Annex and any changes to it may be adopted in accordance with the procedure referred to in Article 35(2).

#### Article 33

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

1. The Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics in Science and New Technologies or any other appropriate body it might establish, with a view to obtaining its opinion on ethical issues.

2. The Commission shall make these opinions available to the public.

#### Article 34

### Emergency measures

Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.

#### Article 35

### Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002, hereinafter referred to as the 'Committee'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

#### Article 36

### Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.

#### Article 37

### Repeals

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

- Regulation (EC) No 1139/98,
- Regulation (EC) No 49/2000,
- Regulation (EC) No 50/2000.

#### Article 38

### Amendments to Regulation (EC) No 258/97

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

1. The following provisions shall be deleted:

- Article 1(2)(a) and (b),
- Article 3(2), second subparagraph, and (3),
- Article 8(1)(d),
- Article 9.

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

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

#### Article 39

### Amendment to Directive 82/471/EEC

The following paragraph shall be added to Article 1 of Directive 82/471/EEC with effect from the date of application of this Regulation:

'3. This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (\*).

(\* ) OJ L 268, 18.10.2003, p. 1.'

*Article 40***Amendments to Directive 2002/53/EC**

Directive 2002/53/EC is hereby amended with effect from the date of application of this Regulation as follows:

## 1. Article 4(5) shall be replaced by the following:

'5. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (\*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(\*) OJ L 268, 18.10.2003, p. 1.'

## 2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (\*) is accepted only if it has been authorised under the relevant legislation.

(\*) OJ L 31, 1.2.2002, p. 1.'

*Article 41***Amendments to Directive 2002/55/EC**

Directive 2002/55/EC is hereby amended with effect from the date of application of this Regulation as follows:

## 1. Article 4(3) shall be replaced by the following:

'3. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (\*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(\*) OJ L 268, 18.10.2003, p. 1.'

## 2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing

the European Food Safety Authority, and laying down procedures in matters of food safety (\*) is accepted only if it has been authorised under the relevant legislation.

(\*) OJ L 31, 1.2.2002, p. 1.'

*Article 42***Amendment to Directive 68/193/EEC**

Article 5ba(3) of Directive 68/193/EEC shall be replaced by the following wording with effect from the date of application of this Regulation:

'3. (a) Where products derived from vine-propagating material are intended to be used as or in food falling within the scope of Article 3 or as or in a feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (\*), the vine variety concerned shall be accepted only if it has been authorised pursuant to the said Regulation.

(b) Member States shall ensure that a vine variety, from the propagating material of which products were derived intended for use in food and feed pursuant to Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (\*\*) shall be accepted only if it has been authorised pursuant to the relevant legislation.

(\*) OJ L 268, 18.10.2003, p. 1.

(\*\*) OJ L 31, 1.2.2002, p. 1.'

*Article 43***Amendments to Directive 2001/18/EC**

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

## 1. The following Article shall be inserted:

'Article 12a

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

1. Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to

21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (\*).

2. This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.

(\* OJ L 268, 18.10.2003, p. 1.'

2. The following Article shall be inserted:

*Article 26a*

#### **Measures to avoid the unintended presence of GMOs**

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.'

*Article 44*

#### **Information to be provided in accordance with the Cartagena Protocol**

1. Any authorisation, renewal, modification, suspension or revocation of authorisation of a GMO, food or feed referred to in Articles 3(1)(a) or (b) or 15(1)(a) or (b) shall be notified by the Commission to the Parties to the Cartagena Protocol through the biosafety clearing house in accordance with Article 11(1) or Article 12(1) of the Cartagena Protocol, as the case may be.

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

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

*Article 45*

#### **Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are imple-

mented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission six months after the date of entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

*Article 46*

#### **Transitional measures for requests, labelling and notifications**

1. Requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be transformed into applications under Chapter II, Section 1 of this Regulation where the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of this Regulation.

2. The labelling requirements referred to in this Regulation shall not apply to products, the manufacturing process of which has commenced before the date of application of this Regulation, provided that these products are labelled in accordance with the legislation applicable to them before the date of application of this Regulation.

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

4. Requests submitted for products referred to in Article 15(1)(c) of this Regulation under Article 7 of Directive 82/471/EEC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation.

5. Requests submitted for products referred to in Article 15(1) of this Regulation under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be supplemented by applications under Chapter III, Section 1 of this Regulation.

*Article 47***Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation**

1. The presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0,5 % shall not be considered to be in breach of Article 4(2) or Article 16(2), provided that:

- (a) this presence is adventitious or technically unavoidable;
- (b) the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;
- (c) the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and
- (d) detection methods are publicly available.

2. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

3. The thresholds referred to in paragraph 1 may be lowered in accordance with the procedure referred to in Article 35(2), in particular for GMOs sold directly to the final consumer.

4. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

5. This Article shall remain applicable for a period of three years after the date of application of this Regulation.

*Article 48***Review**

1. No later than 7 November 2005 and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 47, accompanied, where appropriate, by any suitable proposal. The report and any proposal shall be made accessible to the public.

2. Without prejudice to the powers of national authorities, the Commission shall monitor the application of this Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

*Article 49***Entry into force**

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

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

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

Done at Brussels, 22 September 2003.

*For the European Parliament*  
*The President*  
P. COX

*For the Council*  
*The President*  
R. BUTTIGLIONE



## ANNEX

**DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY**

1. The Community reference laboratory referred to in Article 32 is the Commission's Joint Research Centre.
  2. For the tasks outlined in this Annex, the Commission's Joint Research Centre shall be assisted by a consortium of national reference laboratories, which will be referred to as the 'European Network of GMO laboratories'.
  3. The Community reference laboratory shall be responsible, in particular, for:
    - reception, preparation, storage, maintenance and distribution to national reference laboratories 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, for the detection and identification of the transformation event in the food or feed,
    - evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection,
    - submitting full evaluation reports to the Authority.
  4. The Community reference laboratory shall play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.
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**Appendix 3** – EC Regulation No. 1830/2003 on the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00240028.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf)

**REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 22 September 2003**

**concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC**

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 <sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee <sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(3)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(4)</sup>,

Whereas:

- (1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms <sup>(5)</sup> requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.
- (2) Differences between national laws, regulations and administrative provisions concerning traceability and labelling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market. Directive 2001/18/EC should therefore be amended accordingly.
- (3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.
- (4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(6)</sup>, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.
- (5) The transmission and holding of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provide the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.
- (6) The transmission and holding of information that food and feed have been produced from GMOs also provide the basis for the appropriate traceability of products produced from GMOs.
- (7) The Community legislation concerning GMOs as or in feed should also apply to feed intended for animals which are not destined for food production.
- (8) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection and provide legal certainty for operators. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No 1829/2003.
- (9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.

<sup>(1)</sup> OJ C 304 E, 30.10.2001, p. 327 and OJ C 331 E, 31.12.2002, p. 308.

<sup>(2)</sup> OJ C 125, 27.5.2002, p. 69.

<sup>(3)</sup> OJ C 278, 14.11.2002, p. 31.

<sup>(4)</sup> Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 21), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.

<sup>(5)</sup> OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

<sup>(6)</sup> See page 1 of this Official Journal.

- (10) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material consisting, containing or produced from GMOs both when the marketing of such GMOs is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article 47 of Regulation (EC) No 1829/2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the above material in a food or feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.
- (11) It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product.
- (12) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(1)</sup>.
- (13) Systems for the development and assignment of unique identifiers for GMOs should be established before the measures relating to traceability and labelling can be applied.
- (14) The Commission should submit a report to the European Parliament and the Council on the implementation of this Regulation and, more specifically, on the effectiveness of the rules on traceability and labelling.
- (15) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

#### Article 1

#### Objectives

This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs,

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

#### Article 2

#### Scope

1. This Regulation shall apply, at all stages of the placing on the market, to:
  - (a) products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;
  - (b) food produced from GMOs, placed on the market in accordance with Community legislation;
  - (c) feed produced from GMOs, placed on the market in accordance with Community legislation.
2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93 <sup>(2)</sup>.

#### Article 3

#### Definitions

For the purpose of this Regulation:

1. 'Genetically modified organism' or 'GMO' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;
2. 'Produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;
3. 'Traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;
4. 'Unique identifier' means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO;
5. 'Operator' means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the Community, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer;

<sup>(2)</sup> Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (OJ L 214, 24.8.1993, p. 1). Regulation as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

6. 'Final consumer' means the ultimate consumer who will not use the product as part of any business operation or activity;
7. 'Food' means food as defined in Article 2 of Regulation (EC) No 178/2002<sup>(1)</sup>;
8. 'Ingredient' means ingredient as referred to in Article 6(4) of Directive 2000/13/EC<sup>(2)</sup>;
9. 'Feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;
10. 'Placing on the market' means placing on the market as defined in the specific Community legislation under which the relevant product has been authorised; in other cases, it is defined as in Article 2(4) of Directive 2001/18/EC;
11. 'The first stage of the placing on the market of a product' means the initial transaction in the production and distribution chains, where a product is made available to a third party;
12. 'Pre-packaged product' means any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

#### Article 4

### Traceability and labelling requirements for products consisting of or containing GMOs

#### A. TRACEABILITY

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

- (a) that it contains or consists of GMOs;
- (b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

<sup>(1)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(2)</sup> Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

3. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

4. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.

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

#### B. LABELLING

6. For products consisting of or containing GMOs, operators shall ensure that:

- (a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label;
- (b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice to other specific requirements in Community legislation.

#### C. EXEMPTIONS

7. Paragraphs 1 to 6 shall not apply to traces of GMOs in products in a proportion no higher than the thresholds established in accordance with Article 21(2) or (3) of Directive 2001/18/EC and in other specific Community legislation, provided that these traces of GMOs are adventitious or technically unavoidable.

8. Paragraphs 1 to 6 shall not apply to traces of GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

*Article 5***Traceability requirements for products for food and feed produced from GMOs**

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

- (a) an indication of each of the food ingredients which is produced from GMOs;
- (b) an indication of each of the feed materials or additives which is produced from GMOs;
- (c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of the information specified in paragraph 1 and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products referred to in paragraph 1 have been made available.

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

4. Paragraphs 1, 2 and 3 shall not apply to traces of GMOs in products for food and feed produced from GMOs in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

*Article 6***Exemptions**

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

2. Paragraph 1 shall not apply to the first stage of placing on the market of a product or to primary manufacture or re-packaging of a product.

*Article 7***Amendment of Directive 2001/18/EC**

Directive 2001/18/EC is amended as follows:

1. Article 4(6) is deleted;

2. the following paragraph is added to Article 21:

'3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9 % or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable.'

*Article 8***Unique identifiers**

In accordance with the procedure referred to in Article 10(2), the Commission shall:

- (a) prior to the application of Articles 1 to 7 establish a system for development and assignment of unique identifiers to GMOs;
- (b) adapt the system provided for in point (a), as appropriate.

In so doing, account shall be taken of developments in international fora.

*Article 9***Inspection and control measures**

1. Member States shall ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with this Regulation. Inspection and control measures may also include inspection and control regarding the holding of a product.

2. Prior to the application of Articles 1 to 7, the Commission, in accordance with the procedure referred to in Article 10(3), shall develop and publish technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1 of this Article. In developing the above technical guidance, the Commission shall take account of the work of national competent authorities, the committee referred to in Article 58(1) of Regulation (EC) No 178/2002 and the Community Reference Laboratory established under Regulation (EC) No 1829/2003.

3. In order to help the Member States meet the requirements set out in paragraphs 1 and 2, the Commission shall ensure that a central register is put in place at Community level, which shall contain all available sequencing information and reference material for GMOs authorised to be put into circulation in the Community. The competent authorities in the Member States shall have access to the register. The register shall also contain, where available, relevant information concerning GMOs which are not authorised in the European Union.



*Article 10***Committee**

1. The Commission shall be assisted by the committee set up by Article 30 of Directive 2001/18/EC.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.  
The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
4. The Committee shall adopt its rules of procedure.

*Article 11***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

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

Done at Brussels, 22 September 2003.

*For the European Parliament*

*The President*

P. COX

*For the Council*

*The President*

R. BUTTIGLIONE

Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them.

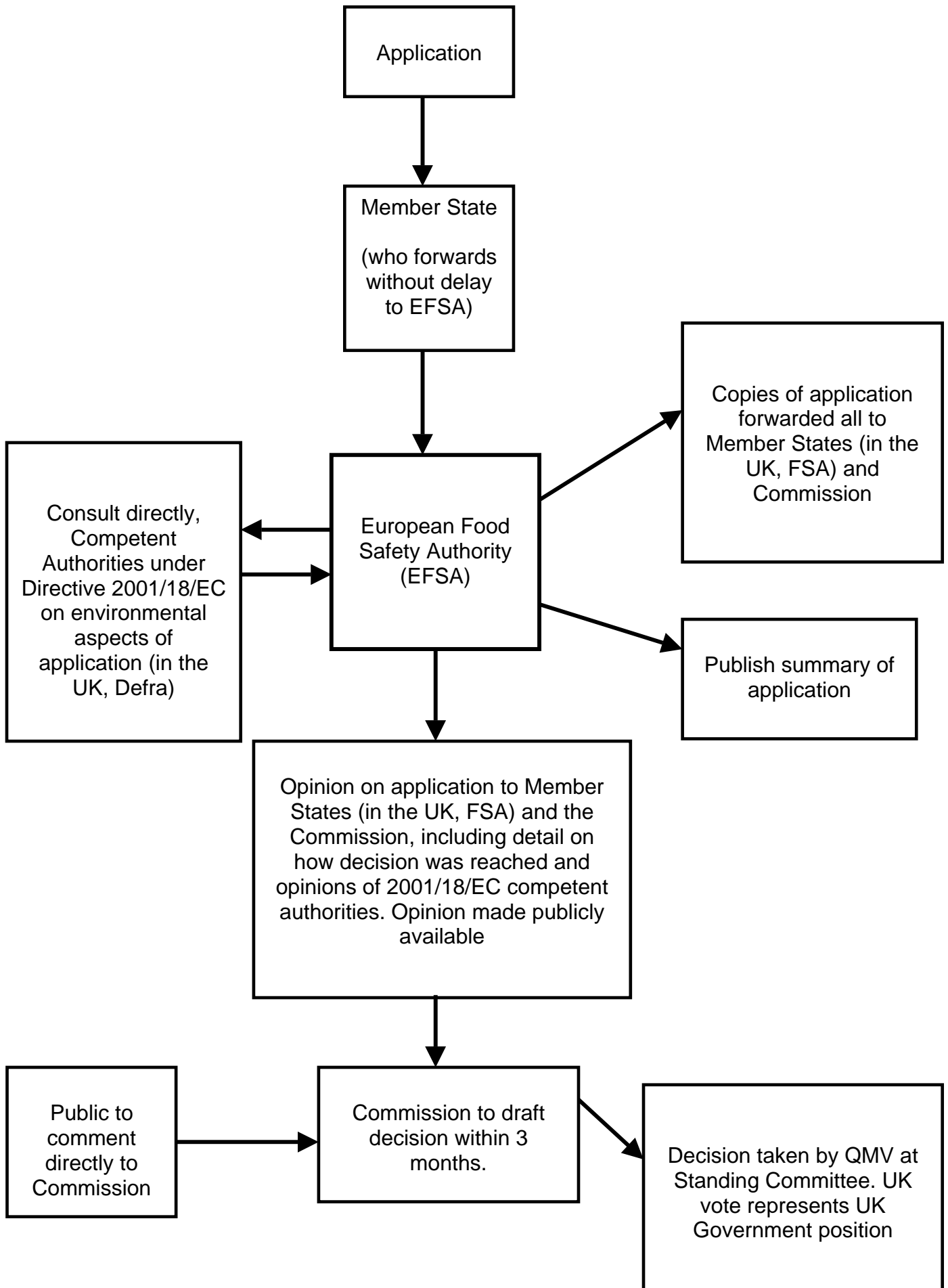
*Article 12***Review clause**

No later than 18 October 2005, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation, in particular with regard to Article 4(3) and, where appropriate, bring forward a proposal.

*Article 13***Entry into force**

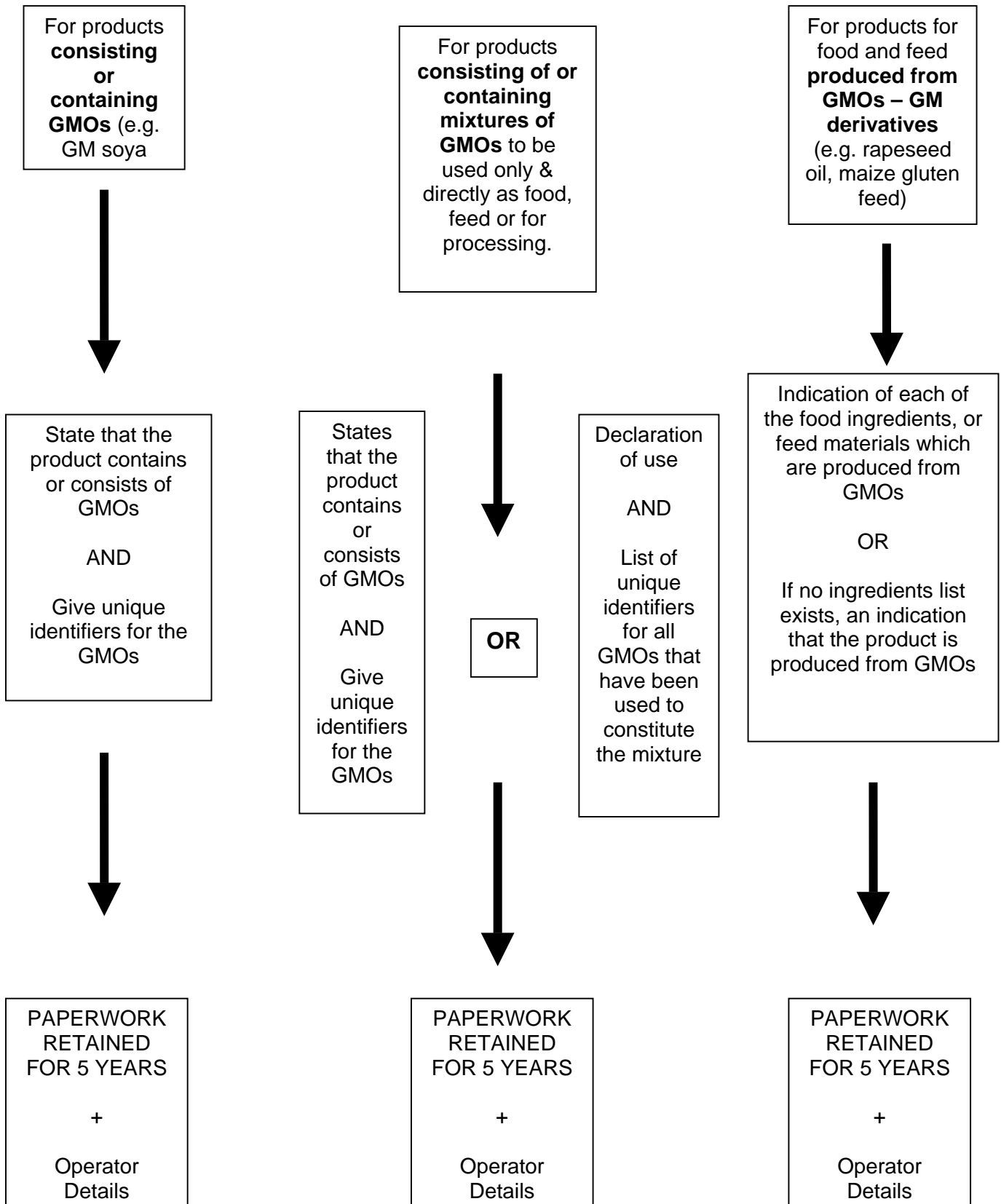
1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.
2. Articles 1 to 7 and Article 9(1) shall apply with effect from the 90th day following the date of publication in the *Official Journal of the European Union* of the measure referred to in Article 8(a).

**Appendix 4 – Interaction between EFSA, FSA and Defra**





## Appendix 5 – Traceability requirements



**Appendix 6** – EC Regulation No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material provides details on applying for the authorisation of a GMO

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l\\_102/l\\_10220040407en00140025.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00140025.pdf)

**COMMISSION REGULATION (EC) No 641/2004****of 6 April 2004****on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 5(7), 8(8), 17(7), 20(8) and 47(4) thereof,

After consulting the European Food Safety Authority in accordance with Articles 5(7) and 17(7) of Regulation (EC) No 1829/2003,

Whereas:

- (1) Regulation (EC) No 1829/2003 lays down Community procedures for the authorisation and supervision of genetically modified food and feed and for the labelling of such food and feed.
- (2) It is necessary to provide detailed rules concerning applications for authorisations submitted in accordance with Regulation (EC) No 1829/2003.
- (3) In addition, Regulation (EC) No 1829/2003 provides that the European Food Safety Authority (the Authority) is to publish detailed guidance to assist the applicant in the preparation and the presentation of the application, concerning notably the information and data to be provided in order to demonstrate that the product complies with the criteria referred to in Articles 4(1) and 16(1) of that Regulation.
- (4) In order to ensure a smooth transition to the regime provided by Regulation (EC) No 1829/2003 transitional measures laid down in that Regulation as regards requests and notifications of products falling within the scope of other Community legislation, should be subject to implementing rules.

- (5) It is also necessary to provide detailed rules on the preparation and presentation of notifications of existing products submitted to the Commission under Regulation (EC) No 1829/2003 as regards products placed on the market in the Community before 18 April 2004.

- (6) Such rules should facilitate the task of operators, in preparing applications for authorisations and in the preparation of notifications of existing products, and the Authority in evaluating such applications and verifying such notifications.

- (7) The scope of Regulation (EC) No 1829/2003 includes food which consists of, contains or is produced from genetically modified organisms (GMOs) such as genetically modified plants and micro-organisms. Therefore, in the interests of consistency of Community legislation, the scope of the present Regulation should also cover existing food consisting of, containing or produced from genetically modified plants and micro-organisms.

- (8) The scope of Regulation (EC) No 1829/2003 covers feed, including feed additives as defined in Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs <sup>(2)</sup> consisting of, containing or produced from GMOs such as genetically modified plants and micro-organisms. Therefore, the scope of the present Regulation should also cover existing feed, including feed additives consisting of, containing or produced from genetically modified plants and micro-organisms.

- (9) The scope of Regulation (EC) No 1829/2003 does not cover processing aids, including enzymes used as processing aids. Therefore, the scope of the present Regulation similarly should not cover existing processing aids.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

- (10) Regulation (EC) No 1829/2003 provides that detailed rules are to be adopted for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. In the interests of consistency of Community legislation those rules should in particular clarify which genetically modified material is covered by such transitional measures and how the 0,5 % threshold is to be applied.
- (11) It is necessary for this Regulation to apply as a matter of urgency as Regulation (EC) No 1829/2003 applies from 18 April 2004.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### CHAPTER I

### Applications for authorisation

#### Article 1

This chapter provides detailed rules concerning applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation.

#### SECTION 1

Requirements for applications for authorisation of genetically modified food and feed

#### Article 2

1. Without prejudice to Article 5(3) and (5) and Article 17(3) and (5) of Regulation (EC) No 1829/2003, and taking into account the guidance of the European Food Safety Authority (the Authority) provided for in Articles 5(8) and 17(8) of that Regulation, applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (the applications) shall comply with the requirements of paragraphs 1 to 4 of this Article and with Articles 3 and 4 of this Regulation.

2. In supplying the information required under Article 5(3)(b) and Article 17(3)(b) of Regulation (EC) No 1829/2003, the application shall clearly identify the products covered by it in accordance with Articles 3(1) and 15(1) of that Regulation. Where the application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation should not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003.

3. The application shall clearly state which parts of the application are considered to be confidential, together with a verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts shall be submitted in separate documents.

4. The application shall specify, in supplying the information required under Article 5(3)(c) and Article 17(3)(c) of Regulation (EC) No 1829/2003, whether the information included in the application may be notified as such to the biosafety clearing house under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol) approved by Council Decision 2002/628/EC <sup>(1)</sup>.

If the application may not be notified as such, it shall include the information which complies with Annex II to the Cartagena Protocol and which may be notified to the biosafety clearing house by the Commission as provided in Article 44 of Regulation (EC) No 1829/2003 in a separate and clearly identified document.

5. Paragraph 4 shall not apply to applications concerning only food and feed produced from genetically modified organisms (GMOs) or containing ingredients produced from GMOs.

#### Article 3

1. The application shall include the following:
- (a) the monitoring plan referred to in Article 5(5)(b) and Article 17(5)(b) of Regulation (EC) No 1829/2003, taking into account Council Decision 2002/811/EC <sup>(2)</sup>;
- (b) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for labelling complying with the requirements of Annex IV to Directive 2001/18/EC of the European Parliament and of the Council <sup>(3)</sup>;

<sup>(1)</sup> OJ L 201, 31.7.2002, p. 48.

<sup>(2)</sup> OJ L 280, 18.10.2002, p. 27.

<sup>(3)</sup> OJ L 106, 17.4.2001, p. 1.

(c) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for a unique identifier for the GMO in question, developed in accordance with Commission Regulation (EC) No 65/2004 <sup>(1)</sup>;

(d) a proposal for labelling in all official Community languages, where a proposal for specific labelling is needed in accordance with Article 5(3)(f) and Article (g) and 17(3)(f) and (g) of Regulation (EC) No 1829/2003;

(e) a description of a method(s) of detection, sampling and event specific identification of the transformation event, as provided for in Article 5(3)(i) and Article 17(3)(i) of Regulation (EC) No 1829/2003, in accordance with Annex I to this Regulation;

(f) a proposal for post-market monitoring regarding the use of the food for human consumption or the feed for animal consumption, as provided for in Article 5(3)(k) and Article 17(3)(k) of Regulation (EC) No 1829/2003, and according to the characteristics of the products concerned, or a verifiable justification to the effect that a post-market monitoring is not necessary.

2. Points (a), (b) and (c) of paragraph 1 shall not apply to applications concerning only food and feed produced from GMOs or containing ingredients produced from GMOs.

#### Article 4

1. Samples of the food and feed and their control samples which are to be submitted in accordance with Article 5(3)(j) and Article 17(3)(j) of Regulation (EC) No 1829/2003 shall be in accordance with the requirements set out in Annexes I and II to this Regulation.

The application shall be accompanied by information concerning the place where the reference material developed in accordance with Annex II may be found.

2. The summary to be provided in accordance with Article 5(3)(l) and Article 17(3)(l) of Regulation (EC) No 1829/2003 shall:

(a) be presented in an easily comprehensible and legible form;

(b) not contain parts which are considered to be confidential.

#### SECTION 2

Transformation of requests and notifications into applications in accordance with Regulation (EC) No 1829/2003

#### Article 5

1. Where a request submitted under Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(2)</sup> is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(1) of that Regulation, the national competent authority of the Member State in which the request was submitted shall, without delay, ask the applicant to submit a complete dossier in accordance with Article 5 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

(a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt. The acknowledgement shall state the date of receipt: of the information;

(b) inform the Authority without delay;

(c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the initial assessment report provided for in Article 6(3) of Regulation (EC) No 258/97, as well as any comments or objections which may have been made by Member States or the Commission under Article 6(4) of that Regulation.

3. The Authority shall:

(a) inform the other Member States and the Commission without delay that the request under Article 4 of Regulation (EC) No 258/97 has been transformed into an application under Regulation (EC) No 1829/2003 and make the application and any supplementary information supplied by the applicant available to them;

(b) make the summary of the dossier referred to in Article 5(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 6(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 5 of Regulation (EC) No 1829/2003.

<sup>(1)</sup> OJ L 10, 16.1.2004, p. 5.

<sup>(2)</sup> OJ L 43, 14.2.1997, p. 1.

## Article 6

1. Where a notification concerning a product including its use as feed submitted under Article 13 of Directive 2001/18/EC is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(3) of that Regulation, the national competent authority, within the meaning of Directive 2001/18/EC, of the Member State in which the notification was submitted shall ask without delay the notifier to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

- (a) acknowledge receipt of the information supplied by the notifier in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;
- (b) inform the Authority without delay;
- (c) make the notification and the information supplied by the notifier in accordance with paragraph 1 available to the Authority;
- (d) where applicable, make available to the Authority the assessment report provided for in Article 14(2) of Directive 2001/18/EC.

3. The Authority shall:

- (a) inform the other Member States and the Commission without delay that the notification under Article 13 of Directive 2001/18/EC has been transformed into an application under Regulation (EC) No 1829/2003 and shall make the application and any supplementary information supplied by the notifier available to them;
- (b) make the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

## Article 7

1. Where a request submitted under Article 7 of Council Directive 82/471/EEC<sup>(1)</sup>, concerning products produced from GMOs, is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(4) of that

<sup>(1)</sup> OJ L 213, 21.7.1982, p. 8.

Regulation, the Commission shall ask the applicant without delay to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

The applicant shall send the complete dossier to the Member States and to the Commission.

2. The Commission shall:

- (a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;
- (b) inform the Authority without delay;
- (c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;
- (d) where applicable, make available to the Authority the dossier provided for in Article 7(1) of Directive 82/471/EEC.

3. The Authority shall make:

- (a) any supplementary information supplied by the applicant available to the Member States and the Commission;
- (b) the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

## SECTION 3

Supplementation of requests under Directive 70/524/EEC by an application under Regulation (EC) No 1829/2003

## Article 8

1. Where a request submitted under Article 4 of Directive 70/524/EEC, concerning products referred to in Article 15(1) of Regulation (EC) No 1829/2003, is supplemented by an application under Regulation (EC) No 1829/2003, in accordance with Article 46(5) of that Regulation, the Member State acting as rapporteur shall ask the applicant without delay to submit a separate application for authorisation in accordance with Article 17 of Regulation (EC) No 1829/2003.



2. The application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

(ii) information as to the place where the reference material, which shall be developed in accordance with Annex II to this Regulation, may be found.

## CHAPTER II

### Notification of existing products

#### Article 9

This chapter provides the requirements concerning the preparation and presentation of notifications of existing products submitted to the Commission in accordance with Articles 8 and 20 of Regulation (EC) No 1829/2003 and applies to existing products covered by the scope of that Regulation and placed on the market in the Community prior to 18 April 2004.

#### SECTION 1

General requirements for notifications of certain products placed on the market before 18 April 2004

#### Article 10

1. Notifications submitted in accordance with Articles 8(1) and 20(1) of Regulation (EC) No 1829/2003 shall:
  - (a) clearly identify the products covered by the notification, taking account of Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003;
  - (b) include relevant information and studies, including, where available, independent and peer-reviewed studies, which demonstrate that the product complies with the requirements provided for in Articles 4(1) or 16(1) of Regulation (EC) No 1829/2003;
  - (c) clearly indicate which parts of the notification are considered to be confidential, together with a verifiable justification, and those parts shall be submitted in separate documents;
  - (d) include a method(s) of detection, sampling and identification of the transformation event in accordance with Annex I to this Regulation;
  - (e) in accordance with Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 provide:
    - (i) samples of the food and feed and their control samples in accordance with Annex I to this Regulation;

2. The notifications referred to in paragraph 1 shall be submitted to the Commission before 18 October 2004.

#### SECTION 2

Additional requirements for notifications of certain products placed on the market before 18 April 2004

#### Article 11

1. In addition to the requirements of Article 10, notifications of GMOs which have been placed on the market in accordance with part C of Council Directive 90/220/EEC <sup>(1)</sup> or part C of Directive 2001/18/EC shall include a copy of the relevant consent granted under those directives.

2. The date of publication in the *Official Journal of the European Union* of the Decision to grant consent under Directive 90/220/EEC or Directive 2001/18/EC shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date

#### Article 12

1. In addition to the requirements of Article 10, notifications of food produced from GMOs which have been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97 shall include a copy of the original notification letter to the Commission.

2. The date of the letter from the Commission forwarding the original notification to the Member States shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date.

#### Article 13

1. In addition to the requirements of Article 10, notifications of genetically modified food which have been placed on the market in accordance with Articles 6 and 7 of Regulation (EC) No 258/97 shall include a copy of the authorisation of that food.

<sup>(1)</sup> OJ L 117, 8.5.1990, p. 15.

2. The date the authorisation of the product took effect under Regulation No (EC) 258/97 shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

#### Article 14

1. In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been placed on the market in accordance with Articles 3 and 4 of Directive 82/471/EEC shall include a copy of the authorisation at Community level or, where applicable, the authorisation granted by a Member State.

2. The date the authorisation of the product took effect in accordance with Directive 82/471/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

#### Article 15

1. In addition to the requirements of Article 10, notifications of feed containing, consisting of or produced from GMOs which have been authorised in accordance with Directive 70/524/EEC shall include:

- (a) the identification of the feed additive(s) to be covered by the number or the EC number, where applicable, as laid down in Article 9(l) of Directive 70/524/EEC;
- (b) a copy of the authorisation.

2. The date the authorisation of the product took effect under Directive 70/524/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

#### Article 16

In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been lawfully placed on the market in the Community, which are not covered by Articles 11, 14 and 15, and for which the GMO(s) has been notified for authorisation for use as animal feed under part C of Directive 2001/18/EC shall:

- (a) contain a reference to the notification under evaluation submitted according to Article 13 of Directive 2001/18/EC;

- (b) include a declaration that the product was placed on the market before 18 April 2004.

#### Article 17

In addition to the requirements of Article 10, notifications of food and feed produced from GMOs which have been lawfully placed on the market in the Community and which are not covered by Articles 11 to 16 shall include a declaration that the product was placed on the market before 18 April 2004.

### CHAPTER III

#### **Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation**

#### Article 18

1. For the purpose of implementing Article 47 of Regulation (EC) No 1829/2003, the Commission shall, on 18 April 2004, publish a list of the genetically modified material that has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before that date and for which an application for authorisation has not been rejected in accordance with the relevant Community legislation.

2. This list shall distinguish between:

- (a) material in respect of which the Commission has been informed, by any interested party, that a detection method is publicly available; an indication of where the detection method has been made available shall be included;
- (b) material in respect of which the Commission has not yet been informed that a detection method is publicly available.

Any interested party may, at any time, inform the Commission that a detection method for material referred to in point (b) of the first subparagraph is publicly available, with an indication of where the detection method is available.

3. The list referred to in paragraph 1 shall be maintained by the Commission. Amendments to the list may result, in particular, from:

- (a) the granting of an authorisation or the rejection of an application for authorisation for material included in the list, in accordance with the relevant Community legislation;



- (b) notifications to the Commission, in accordance with Articles 8 or 20 of Regulation (EC) No 1829/2003, that material included in the list has been lawfully placed on the market in the Community before 18 April 2004, or adoption by the Commission of a measure in accordance with Article 8(6) or 20(6) of Regulation (EC) No 1829/2003;
- (c) information received by the Commission that a detection method in respect of material included in the list is publicly available.

Information about amendments brought to the list shall be compiled in an Annex to the list.

#### *Article 19*

1. The 0,5 % threshold provided for in Article 47(1) of Regulation (EC) No 1829/2003 shall apply to genetically modified material included in part (a) of the list referred to in Article

18(2) of the present Regulation. Where a lower threshold has been established in accordance with Article 47(3) of Regulation (EC) No 1829/2003, it shall be specified in that list.

2. The thresholds provided for in Article 47 of Regulation (EC) No 1829/2003 shall apply to food ingredients considered individually or food consisting of a single ingredient and to feed and each feed of which it is composed.

#### CHAPTER IV

#### **Final provision**

#### *Article 20*

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

It shall apply from 18 April 2004.

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

Done at Brussels, 6 April 2004.

*For the Commission*

David BYRNE

*Member of the Commission*

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## ANNEX I

## METHOD VALIDATION

## 1. INTRODUCTION

- A. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, this Annex provides technical provisions on the type of information on detection methods that shall be provided by the applicant and that is needed to verify the preconditions for the fitness of the method. This includes information about the method as such and about the method testing carried out by the applicant. All guidance documents referred to in this Annex or produced by the Community Reference Laboratory (CRL) shall be made available by the CRL.
- B. The method acceptance criteria and method performance requirements have been compiled by the European Network of GMO Laboratories (ENGL) in a document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing', which shall be made available by the CRL. 'Method acceptance criteria' are criteria, which should be fulfilled prior to the initiation of any method validation by the CRL. The 'method performance requirements' define the minimum performance criteria that the method should demonstrate upon completion of a validation study carried out by the CRL according to internationally accepted technical provisions and this in order to certify that the method validated is fit for the purpose of enforcement of Regulation (EC) No 1829/2003.
- C. The CRL, established under Regulation (EC) No 1829/2003 and assisted by ENGL, will evaluate the provided information for its completeness and fitness for the purpose. Here, the method acceptance criteria recommended by ENGL, which are described under 1(B), will be taken into account.
- D. If the information provided about the method is considered adequate and fulfils the method acceptance criteria, the CRL will initiate the validation process for the method.
- E. The validation process will be carried out by the CRL according to internationally accepted technical provisions.
- F. The CRL, together with ENGL, shall provide further information about the operational procedures of the validation process and shall make the documents available.
- G. The CRL, assisted by ENGL, shall evaluate the results obtained in the validation study for the fitness for the purpose. Here, the method performance requirements as described under 1(B) shall be taken into account.

## 2. INFORMATION ABOUT THE METHOD

- A. The method shall refer to all the methodological steps needed to analyse the relevant material in accordance with Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003.

For a particular material this must include the methods for DNA extraction and the subsequent quantification in a polymerase chain reaction (PCR) system. In such a case, the whole process from extraction up to the PCR-technique (or equivalent) constitutes a method. The applicant shall provide information about the whole method.

- B. As described in the document referred to under 1(B), ENGL recognises the modularity of a method. According to this principle, the applicant is allowed to refer to existing methods for a certain module(s), if available and appropriate. This could be, for instance, a DNA extraction method from a certain matrix. In such a case, the applicant shall provide experimental data from an in-house validation in which the method module has been successfully applied in the context of the application for authorisation.
- C. The applicant shall demonstrate that the method fulfils the following requirements.
  1. The method shall be event-specific and thus must only be functional with the GMO or GM based product considered and shall not be functional if applied to other events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised events and conventional counterparts, in the case of GM plants. This testing shall include closely related events, where relevant, and cases where the limits of the detection are truly tested. The same specificity principle must be applied for products that consist of or contain GMOs other than plants.
  2. The method shall be applicable to samples of the food or feed, to the control samples and to the reference material, which is referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003.

3. The method shall be developed taking the following documents in consideration as appropriate:
    - General requirements and definitions: draft European standard prEN ISO 24276:2002,
    - Nucleic acid extraction prEN ISO 21571:2002,
    - Quantitative nucleic acid based methods: draft European standard prEN ISO 21570:2002,
    - Protein based methods: adopted European standard EN ISO 21572:2002,
    - Qualitative nucleic acid based methods: draft European standard prEN ISO 21569:2002.
  - D. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, the applicant shall provide:
    - (a) in the case of an application for authorisation covering a GMO, products consisting of or containing a GMO or products produced from a GMO, the event-specific quantitative detection method of the GM material;
    - (b) in addition, in the case of an application for authorisation covering products produced from a GMO where the genetically modified material is detectable, the event-specific quantitative detection method in the foods or feeds produced from the GMO.
  - E. The applicant shall provide a complete and detailed description of the method. The following points shall be clearly addressed.
    1. Scientific basis: An overview of the principles of how the method works, such as DNA molecular biology based (e.g. for real-time PCR) information must be provided. It is recommended to provide references to relevant scientific publications.
    2. Scope of the method: Indication of the matrix (e.g. processed food, raw materials), the type of samples and the percentage range to which the method can be applied.
    3. Operational characteristics of the method: The required equipment for the application of the method shall be clearly mentioned, with regard to the analysis *per se* and the sample preparation. Further information of any specific aspects crucial for the application of the method shall also be mentioned here.
    4. Protocol: The applicant shall provide a complete optimised protocol of the method. The protocol shall present all the details as required to transfer and apply the method independently in other laboratories. It is recommended to use a protocol template, which can be obtained from the CRL. The protocol shall include details of:
      - analyte to be tested,
      - working conditions, instructions and rules,
      - all the materials needed, including an estimation of their amounts and storage and handling instructions,
      - all the equipment needed, including not only the main equipment such as a PCR system or centrifuge but also small items such as micropipettes and reaction tubes with an indication of their appropriate sizes, etc.,
      - all the steps of the operative protocol, clearly described,
      - instructions for the data recording (e.g. the programme settings or parameters to be included).
    5. The prediction model (or alike) needed to interpret results and to make inferences must be described in full details. Instructions for the correct application of the model should be provided.
3. INFORMATION ABOUT THE METHOD TESTING CARRIED OUT BY THE APPLICANT
- A. The applicant shall provide all the available and relevant data of the method optimisation and testing carried out. These data and results shall be presented, where possible and appropriate, by using the performance parameters recommended by the ENGL as referred to under 1(B). A summary of the testing carried out and the main results as well as all the data including the outliers shall be provided. The CRL, together with ENGL, shall continue to provide further technical provisions about the appropriate formats for these data.
  - B. The information provided shall demonstrate the robustness of the method for inter-laboratory transferability. This means that the method should have been tested by at least one laboratory that is independent from the laboratory which has developed the method. This is an important pre-condition for the success of the validation of the method.
  - C. Information required about the method development and the method optimisation:
    1. primer pairs tested (in the case of a PCR-based test): justification shall be given of how and why the proposed primer pair has been selected;
    2. stability testing: experimental results from testing the method with different varieties shall be provided;
    3. specificity: the applicant shall submit the full sequence of the insert(s), together with the base pairs of the host flanking sequences needed to establish an event-specific detection method. The CRL shall enter these data in a molecular database. By running homology searches, the CRL will thus be in a position to assess the specificity of the proposed method.

- D. Testing report. Besides the values obtained for the performance indices, the following information regarding the testing shall be provided, as appropriate:
- participating laboratories, time of the analysis and outline of the experimental design, including the details about the number of runs, samples, replicates etc.,
  - description of the laboratory samples (e.g. size, quality, date of sampling), positive and negative controls as well as reference material, plasmids and alike used,
  - description of the approaches that have been used to analyse the test results and outliers,
  - any particular points observed during the testing,
  - references to relevant literature or technical provisions used in the testing.

#### 4. SAMPLES OF THE FOOD AND FEED AND THEIR CONTROL SAMPLES

In view of implementing Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003, the applicant shall, together with the information specified under sections 1, 2 and 3 of this Annex, also provide samples of the food and feed and their control samples of a type and amount to be specified by the CRL for the specific application for authorisation.

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## ANNEX II

## REFERENCE MATERIAL

The reference material as referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 shall be produced in accordance with internationally accepted technical provisions such as ISO Guides 30 to 34 (and more particularly ISO Guide 34, specifying the general requirements for the competence of reference material producers). The reference material shall be preferably certified and, if such is the case, certification shall be done in accordance with ISO Guide 35.

For verification and value assignment, a method that has been properly validated (see ISO/IEC 17025:5.4.5) shall be used. Uncertainties have to be estimated according to GUM (ISO Guide to the Expression of Uncertainty in Measurement: GUM). Major characteristics of these internationally accepted technical provisions are given below.

## A. Terminology:

reference material (RM): material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials;

Certified reference material (CRM): reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

## B. GM RM containers:

- GM RM container (bottles, vials, ampoules, etc.) must be tight and contain not less than the stated amount of material,
- samples must have appropriate homogeneity and stability,
- the commutability of the GM RM has to be assured,
- packaging must be appropriate to the purpose,
- labelling must be of good aspect and quality.

## C. Homogeneity testing:

between-bottle homogeneity must be examined;

any possible between-bottle heterogeneity must be accounted for in the overall estimated RM uncertainty. This requirement applies even when no statistically significant between-bottle variation is present. In this case, the method variation or the actual calculated between-bottle variation (whichever is larger) must be included in the overall uncertainty;

## D. Stability testing:

stability must be positively demonstrated by appropriate statistical extrapolation for the GM RM shelf-life to be within the stated uncertainty; the uncertainty related to this demonstration is normally part of the estimated RM uncertainty;

assigned values are valid only for a limited time and must be subject to a stability monitoring.

## E. Batch characterisation:

the methods used for verification and for certification must:

- be applied under metrologically valid conditions,
- have been properly technically validated before use,
- have precision and accuracy compatible with the target uncertainty;

each set of measurements must:

- be traceable to the stated references, and
- be accompanied by an uncertainty statement whenever possible;

participating laboratories must:

- have the required competence for the execution of the task,
- be able to achieve traceability to the required stated references,
- be able to estimate its measurement uncertainty,
- have in place a sufficient and appropriate quality assurance system.

## F. Final storage:

- to avoid a posterior degradation, all samples are best stored under conditions designated for the final storage of the GM RM before measurements are started,
- otherwise, they must be transported from door to door keeping them at all times under such storage conditions for which it has been demonstrated that there is no influence on the assigned values.

## G. Establishment of a certificate for CRMs:

- a certificate complemented by a certification report has to be established, containing all information relevant to and needed by the user. The certificate and report must be made available when the GM CRM is distributed,
  - certified values must be traceable to stated references and be accompanied by an expanded uncertainty statement valid for the entire shelf-life of the GM CRM.
-

**Appendix 7 – Theoretical Examples of labelling requirements under EC Regulation No. 1829/2003 for authorised GMOs**

<b>GMO-type</b>	<b>Example</b>	<b>Labelling required from 18 April 2004</b>
GM plant	Chicory	Yes
GM seed	Maize seeds	Yes
GM food	Maize, soybean, tomato	Yes
Food produced from GMOs	Maize flour, highly refined soya oil, glucose syrup from maize starch	Yes
Food from animals fed GM animal feed	Meat, milk, eggs	No
Food produced with help from a GM enzyme	Cheese, bakery products produced with the help of amylase	No
Food additive/flavouring produced from GMOs*	Highly filtered lecithin extracted from GM soybeans used in chocolate	Yes
Feed additive produced from a GMO*	Vitamin B2 (Riboflavin)	No
GMM used as a food ingredient	Yeast extract	Yes
Alcoholic beverages which contain a GM ingredient		Yes
Products containing GM enzymes where the enzyme is acting as an additive or performing a technical function		Yes
GM feed	Maize	Yes
Feed produced from a GMO	Corn gluten feed, soybean meal	Yes
Food containing GM ingredients which are sold in catering establishments		Yes. (The FSA's legal view is that labelling is required across EU Member States under EC Regulation 1829/2003. However, there is disagreements between the Commission and the Council as whether labelling is required).

GM – genetically modified

GMM – genetically modified micro-organism

\*Food and feed produced by a fermentation process using a GMM which is kept under contained conditions and is not present in the final product are not included in the scope of this regulation. These food and feed are considered as having been produced with the GMM, rather than from the GMM.

This agreement was reached at the Standing Committee on the Food Chain and Animal Health – Section on Genetically Modified Food and Feed and Environmental Risk meeting of 24 September 2004. Minutes of the meeting are available at [http://europa.eu.int/comm/food/committees/regulatory/modif\\_genet/index\\_en.htm](http://europa.eu.int/comm/food/committees/regulatory/modif_genet/index_en.htm)

The scope of this regulation in relation to products from a fermentation process will be considered as part of the Commission's review of the regulations in November 2005.

**Appendix 8** – EC Regulation No. 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l\\_010/l\\_01020040116en00050010.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_010/l_01020040116en00050010.pdf)



**COMMISSION REGULATION (EC) No 65/2004****of 14 January 2004****establishing a system for the development and assignment of unique identifiers for genetically modified organisms**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1830/2003, of the European Parliament and of the Council, of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC <sup>(1)</sup>, and in particular Article 8 thereof,

Whereas:

- (1) Regulation (EC) No 1830/2003 lays down a harmonised framework for the traceability of genetically modified organisms, hereinafter 'GMOs', and of food and feed products produced from GMOs through the transmission and holding of relevant information by operators for such products at each stage of their placing on the market.
- (2) Under that Regulation, an operator placing on the market products containing or consisting of GMOs is required to include, as part of that relevant information, the unique identifier assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorisation for placing that GMO on the market.
- (3) Unique identifiers should be developed in accordance with a particular format in order to ensure consistency both at Community and international level.
- (4) The consent or authorisation granted for the placing on the market of a given GMO under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC <sup>(2)</sup> or other Community legislation should specify the unique identifier for that GMO. Moreover, the person applying for such consent should ensure that the application specifies the appropriate unique identifier.
- (5) Where, prior to the entry into force of this Regulation, consents have been granted for the placing on the market of GMOs under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms <sup>(3)</sup>, it is necessary

to ensure that a unique identifier is or has been developed, assigned and appropriately recorded for each GMO covered by those consents.

- (6) In order to take account of and maintain consistency with developments in international fora, it is appropriate to have regard to the formats for unique identifiers established by the Organisation for Economic Co-operation and Development (OECD), for use in the context of its BioTrack product database and in the context of the Biosafety clearing house established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
- (7) For the purposes of the full application of Regulation (EC) No 1830/2003, it is essential that this Regulation apply as a matter of urgency.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS REGULATION:

## CHAPTER I

**SCOPE***Article 1*

1. This Regulation shall apply to genetically modified organisms, hereinafter 'GMOs', authorised for the placing on the market in accordance with Directive 2001/18/EC or other Community legislation, and applications for placing on the market under such legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Council Regulation (EEC) No 2309/93 <sup>(4)</sup>, or applications for authorisation under that Regulation.

## CHAPTER II

**APPLICATIONS FOR THE PLACING ON THE MARKET OF GMOs***Article 2*

1. Applications for the placing on the market of GMOs shall include a unique identifier for each GMO concerned.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 24.

<sup>(2)</sup> OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.

<sup>(3)</sup> OJ L 117, 8.5.1990, p. 15. Directive as last amended by Directive 2001/18/EC.

<sup>(4)</sup> OJ L 214, 24.8.1993, p. 1.

2. Applicants shall, in accordance with the formats set out in the Annex, develop the unique identifier for each GMO concerned, following consultation of the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with these formats.

#### Article 3

Where consent or authorisation is granted for the placing on the market of a GMO:

- (a) the consent or authorisation shall specify the unique identifier for that GMO;
- (b) the Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house;
- (c) The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

### CHAPTER III

#### **GMOs FOR WHICH CONSENT FOR THEIR PLACING ON THE MARKET HAS BEEN GRANTED PRIOR TO THE ENTRY INTO FORCE OF THIS REGULATION**

#### Article 4

1. Unique identifiers shall be assigned to all GMOs in respect of which, prior to the entry into force of this Regulation, consent has been granted under Directive 90/220/EEC for their placing on the market.

2. Relevant consent holders or where appropriate the competent authority that has taken the final decision on the original application shall consult the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with the formats set out in the Annex.

#### Article 5

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO and where a unique identifier has been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3 and 4 shall apply.

2. Each consent holder, or where appropriate the competent authority that has taken the final decision on the original application, shall within 90 days following the date of entry into force of this Regulation, communicate the following, in writing, to the Commission:

- (a) the fact that the unique identifier has already been developed in accordance with the formats set out in the Annex;
- (b) the details of the unique identifier.

3. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

4. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

#### Article 6

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO but where a unique identifier has not been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3, 4 and 5 shall apply.

2. Each consent holder or, where appropriate, the competent authority that has taken the final decision on the original application, shall develop a unique identifier for the GMO concerned in accordance with the formats set out in the Annex.

3. The consent holder shall, within 90 days following the date of entry into force of this Regulation, communicate the details of the unique identifier, in writing, to the competent authority granting consent, which in turn shall immediately transmit these details to the Commission.

4. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

5. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

### CHAPTER IV

#### **FINAL PROVISION**

#### Article 7

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

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

Done at Brussels, 14 January 2004.

*For the Commission*  
Margot WALLSTRÖM  
*Member of the Commission*

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## ANNEX

## FORMATS FOR UNIQUE IDENTIFIERS

The Annex below defines the format for the unique identifier for plants in Section A and for micro-organisms and animals in Section B.

## SECTION A

## 1. Overall format

This Annex provides details as to the format to be used for unique identifiers for GMOs pending or authorised for the placing on the market under Community legislation. The format consists of three components comprising a number of alphanumeric digits and providing reference to the applicant/consent holder, transformation event and a means for verification.

The format comprises nine alphanumeric digits in total. The first component represents the applicant/consent holder and comprises two or three alphanumeric digits. The second component comprises five or six alphanumeric digits and represents the transformation event. The third component provides for verification and is represented by a final numerical digit.

The following provides an example of a unique identifier developed using this format.

C	E	D	-	A	B	8	9	1	-	6
---	---	---	---	---	---	---	---	---	---	---

or

C	E	-	A	B	C	8	9	1	-	5
---	---	---	---	---	---	---	---	---	---	---

The following sections provide guidance as to how the three individual components of the unique identifier should be developed.

## 2. Applicant/consent holder component

The first two or three alphanumeric digits represent the applicant/consent holder (for example, the first two or three letters of the applicant/consent holder organisation name), followed by a dash, such:

C	E	D	-
---	---	---	---

or

C	E	-
---	---	---

Applicants may already have assigned alphanumeric digits to indicate their identity and these appear in the applicant's code table within the OECD BioTrack product database. These applicants should continue to use these digits.

Any new applicant that is not identified within the database will not be permitted to use the existing codes listed in the applicant's code table within the database. The new applicant should inform the national authorities, which should update the OECD BioTrack product database by including a new code (digits) that will be designed to identify the new applicant in the code table.

## 3. Transformation event component

The second set of five or six alphanumeric digits should represent the specific transformation event(s), which is the subject of the application for the placing on the market and/or consent, such as:

A	B	8	9	1	-
---	---	---	---	---	---

or

A	B	C	8	9	1	-
---	---	---	---	---	---	---

Clearly, an individual transformation event may occur in different organisms, species and varieties and the digits should be representative of the specific event in question. Again, applicants should, prior to formulating unique identifiers, consult the OECD BioTrack product database in terms of the unique identifiers that have been assigned to similar transformation events of the same organism/species in order to provide consistency and to avoid duplication.

Applicants should develop their own internal mechanism to avoid applying the same designation (digits) to a 'transformation event' if used in a different organism. Where similar transformation events are developed by two or more organisations, the 'applicant information' (see section 2) should enable applicants to generate a unique identifier for their own product, while at the same time ensuring its uniqueness from those generated by other applicants.

As regards new GMOs comprising more than one transformation event (often referred to as stacked-gene transformation events), applicants or consent holders should generate a novel unique identifier for such GMOs.

#### 4. Verification component

The final digit of the unique identifier is for verification, which shall be separated from the rest of the unique identifier digits by a dash, such as:

- 

6
---

or

- 

5
---

The verification digit is intended to reduce errors by ensuring the integrity of the alphanumeric identifier, entered by the users of the database.

The rule to calculate the verification digit is as follows. The verification digit is made up of a single numerical digit. It is calculated by adding together the numerical values of each of the alphanumeric digits in the unique identifier. The numerical value of each of the digits is from 0 to 9 for the numerical digits (0 to 9) and 1 to 26 for the alphabetical digits (A to Z) (see sections 5 and 6). The total sum, if made up of several numerical digits, will be further calculated by adding the remaining digits together using the same rule, in an iterative process, until the final sum is a single numerical digit. For example, the verification digit for the code CED-AB891 is calculated as follows:

step one:  $3 + 5 + 4 + 1 + 2 + 8 + 9 + 1 = 33$ ;

step two:  $3 + 3 = 6$ ; therefore the verification digit is 6.

Therefore, the final unique identifier then becomes — CED-AB891-6.

#### 5. Form of digits to be used in the unique identifier

0
1
2
3
4
5
6
7
8
9

**6. Form of alphabetic characters to be used, plus numerical equivalents for calculating verification digit.**

A=1
B=2
C=3
D=4
E=5
F=6
G=7
H=8
I=9
J=10
K=11
L=12
M=13
N=14
O=15
P=16
Q=17
R=18
S=19
T=20
U=21
V=22
W=23
X=24
Y=25
Z=26

Zero should be reflected by the symbol 0 to avoid confusion with the letter O.

**SECTION B**

The provisions of section A of this Annex shall apply to micro-organisms and animals unless another format for a unique identifier is adopted internationally and endorsed at Community level.

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**Appendix 9** – Commission Recommendation (2004/787/EC) on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003.

[http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2004/l\\_348/l\\_34820041124en00180026.pdf%20](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2004/l_348/l_34820041124en00180026.pdf%20)

## II

(Acts whose publication is not obligatory)

## COMMISSION

## COMMISSION RECOMMENDATION

of 4 October 2004

**on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003**

(Text with EEA relevance)

(2004/787/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, in particular the second indent of Article 211 thereof,

Whereas:

- (1) Regulation (EC) No 1830/2003 of the European Parliament and of the Council, of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC<sup>(1)</sup> sets up a system for the transmission and retention of information between operators at each stage of the placing on the market of products containing or consisting of genetically modified organisms, hereinafter 'GMOs', or food and feed products produced from GMOs, but does not require operators to sample and test products at each stage of the placing of the market for presence of GMOs or material produced from GMOs.
- (2) According to Article 9(1) of Regulation (EC) No 1830/2003, Member States are, however, required to ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with that Regulation.
- (3) In order to facilitate a coordinated approach for those inspections and control measures, Article 9(2) of Regulation (EC) No 1830/2003 requires that technical guidance on sampling and testing for GMOs and food and feed material produced from GMOs in products should be established.
- (4) This guidance should cover products that have received authorisations for their placing on the market but is without prejudice to Article 4(5) of Directive 2001/18/EC of the European Parliament and of the Council<sup>(2)</sup> with regard to GMOs which are not authorised in the European Union.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 24.

<sup>(2)</sup> OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.



- (5) The sampling and detection should be carried out using sound scientific and statistical protocols in order to achieve an appropriate level of confidence for detection of GMOs or material produced from GMOs.
- (6) In developing the guidance, the Committee set up by Article 30 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC has been consulted, and account has been taken of the work of the national competent authorities, the Standing Committee on the Food Chain and Animal Health and the Community Reference Laboratory.
- (7) Where lots of non-GM seed or other plant propagating material are required to comply with standards on adventitious or technically unavoidable presence of genetically modified seeds or other plant propagating material, a legally-binding protocol on sampling and testing for the presence of genetically modified seeds or other plant propagating material should be developed in the context of the specific legislation on seeds and other plant propagating material; whereby the elements provided in that protocol should also serve as a basis for sampling and testing of other GM crop species not covered by the abovementioned legislation, where appropriate,

HEREBY RECOMMENDS:

#### I. GENERAL PRINCIPLES

1. For the purpose of fulfilling the requirements set out in Article 9(1) of Regulation (EC) No 1830/2003, Member States should take account of:
  - (a) the past record of operators with respect to compliance with relevant legislation;
  - (b) the reliability of any controls that operators have already carried out;
  - (c) situations where non-compliance is suspected;
  - (d) using means proportionate to the desired specific objectives and particularly in the light of experience gained;
  - (e) the degree of heterogeneity and the point in the supply chain at which testing is being undertaken.
2. Official controls should be carried out without prior warning, except in cases where prior notification of an operator is necessary.
3. Official controls should be carried out at any stage of the production, processing, and storage, distribution of products that contain or may contain GMOs or food and feed produced from GMOs, including at the point of import<sup>(1)</sup>.

<sup>(1)</sup> In accordance with Article 9(3) of Regulation (EC) No 1830/2003 relevant information concerning GMOs which are not authorised in the EU should, where available, be placed on a central register.

4. Official controls should not differentiate between products intended for export outside the Community and products intended for placing on the market within the Community.
5. Operators whose products are subject to sampling and analysis should be entitled to appeal for a second opinion. Official bodies should collect a sufficient number of counter samples for enforcement and referee purposes in order to guarantee operators appeal right and have a second opinion, as required by national legislation.
6. Alternative sampling strategies to those recommended in this guidance may be applied.
7. Alternative testing strategies to those recommended in this guidance may be applied provided such methods are approved by the Community Reference Laboratory established under Regulation (EC) 1829/2003.
8. Without prejudice to specific requirements laid down in EU legislation concerning food, feed and other controls, and in particular Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition, Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feeding stuffs, Directive 89/397/EEC on the official controls of foodstuffs and Directive 93/99/EEC on the subject of additional measures concerning the official control on foodstuffs, Member States should ensure that official controls are carried out, so as to achieve the objectives of Regulation (EC) No 1830/2003.

## II. DEFINITIONS

- (a) Lot is defined as a distinct and specified quantity of material.

The following definitions take account of the type of material forming a lot and are in line with ISTA, ISO standards 6644 and 13690 and FAO (International Standards for Phytosanitary Measures):

seed lot: a specified quantity of seed, physically identifiable and uniform, not exceeding the maximum lot size as defined in the seeds Directives and forming the total or a part of a consignment;

other plant propagating material lot: a number of units of a single commodity identifiable by its homogeneity of composition, origin etc., not exceeding the maximum lot size as defined in the legislation on other plant propagating material, and forming the total or a part of a consignment;

food and feed products lot: quantity of product dispatched or received at one time and covered by a particular contract or shipping document.

- (b) Increment sample: small equal quantity of product taken from each individual sampling point in the lot through the full depth of the lot (static sampling), or taken from the product stream during a stated portion of time (flowing commodities sampling).
- (c) File increment sample: an increment sample that is retained for a specific period of time for further analysis.

- (d) Bulk sample: quantity of product obtained by combining and mixing the increments taken from a specific lot.
- (e) Laboratory sample: quantity of product taken from the bulk sample intended for laboratory inspection and testing.
- (f) Analytical sample: homogenised laboratory sample, consisting either of the whole laboratory sample or a representative portion thereof.
- (g) Counter sample: a sample retained for a specific period of time for enforcement or referee purposes.
- (h) Percentage of GM DNA: the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes.

### III. PRINCIPLES FOR SAMPLING PROTOCOLS

1. Member States should take account of the guidance on sampling protocols for products consisting of, containing or produced from GMOs when inspecting and controlling whether operators are complying with Articles 4 and 5 of Regulation (EC) No 1830/2003.
2. The Community Reference Laboratory established under Regulation (EC) No 1829/2003, and the nationally designated laboratories to the European Network of GMO Laboratories, hereinafter 'ENGL', will provide further guidance and assistance on the methods of sampling falling within the scope of this Recommendation.
3. Harmonised sampling procedures should be utilised for the purpose of estimating the presence of GMOs. These procedures should apply to seed and other plant propagating material, food, feed and agricultural commodity lots.
4. The following sampling procedures are defined in order to ensure that the samples collected and analysed are representative of the different types of commodities under investigation. Whereas sampling protocols for the presence of GM seeds and other plant propagating material in seed lots should be developed according to the specific legislation on seeds or other propagating material, sampling strategies for bulk commodities and food and feed products are addressed in separate sections that take into account commodity-specific properties.

### IV. SAMPLING PROTOCOLS

#### 1. **Sampling seed and other plant propagating material lots**

This section deals with the detection of genetically modified seeds or other plant propagating material in lots of seed or other plant propagating material of non-GM varieties or clones and the detection of GM seeds or other plant propagating material arising from a transformation event other than that designated for a lot of seed or other plant propagating material of a GM variety or clone.

Samples should be drawn in accordance with current international methods and where appropriate from lot sizes as defined in Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 92/34/EEC, 98/56/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC. The general principles and methods of sampling of seeds and other plant propagating material should be in accordance with the International Seed Testing Association (ISTA) rules and the associated ISTA Handbook on Seed Sampling.

The sampling and testing schemes to be used for seeds or other plant propagating material should meet the requirements indicated in the specific legislation on seeds and other propagating material as regards statistical risks. Seed or other plant propagating material lot quality level and its associated statistical uncertainty are defined in relation to thresholds for GMOs and relate to the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes.

## 2. **Sampling bulk agricultural commodities**

The sampling protocol is based on a two-step procedure that allows, if necessary, to obtain estimates of GMO presence levels, together with their associated uncertainty expressed as Standard Deviation (SD), without imposing any assumption on the possible heterogeneity of the GMOs.

In order to allow the estimation of SD, in the first instance, a bulk sample should be produced and the derived analytical sample analysed for the presence of GM materials. Where the obtained analytical result is close to the established threshold ( $\pm 50\%$  of its value), the analysis of the individual file increment samples is recommended to provide a measure of the associated uncertainty.

The following documents should be taken into account:

- (a) ISO standard 6644 (2002);
- (b) ISO standard 13690 (1999);
- (c) ISO standard 5725 (1994);
- (d) ISO standard 2859 (1985);
- (e) ISO standard 542 (1990).

### 2.1. *Protocol for sampling lots of bulk agricultural commodities*

It is recommended that sampling of bulk commodities (grains, oilseeds) takes place in accordance with the general principles and methods of sampling described in ISO standards 6644 and 13690. In case of flowing commodities, the sampling period should be defined, according to ISO standard 6644, as: total off-loading time/total number of increments. In case of static sampling, increments should be collected at specific sampling points. Such sampling points should be uniformly distributed throughout the lot volume, according to the principles described in ISO 13690. The number of increments or sampling points (where the increment samples for creating the bulk sample and the file increment samples are taken) is defined according to lot size, as follows:

Lot size in tonnes	Size of the bulk sample in kg	Number of incremental samples
≤ 50	5	10
100	10	20
250	25	50
≥ 500	50	100

In case of lots from 50 to 500 tonnes, the size of the bulk sample should be 0,01 % of the total lot size. In case of lots smaller than 50 tonnes, the size of the bulk sample should be 5 kg. In case of lots larger than 500 tonnes, the size of the bulk sample should be 50 kg. At each sampling interval (systematic sampling) or sampling point (static sampling) an increment of 1kg should be collected and split into two portions of 0,5 kg: one to be used as an increment for the production of the bulk sample, the other to be stored as a file increment sample.

Sampling of materials larger than grains (e.g. fruits, rhizomes, potatoes) should be carried out according to ISO standard 2859. Sampling of oilseed should be carried out according to ISO standard 542.

## 2.2. Protocol for the preparation of the analytical samples

A multiple-step protocol is recommended in order to minimise costs and maximise statistical power according to pre-defined acceptance levels.

Initially, the increment samples collected according to sub-section 2.1 are combined and mixed thoroughly, according to the procedures described in ISO standards 13690 and 6644, to form a bulk sample.

The bulk sample is used to create an analytical sample, according to the procedures described in ISO standards 13690 and 6644, and analysed for the presence of GMOs according to 'analytical test protocols/testing methods', as outlined in section V. If the result of the analysis is close to the established threshold (threshold  $\pm$  50 % of its value), an estimation of the associated uncertainty may be necessary (a protocol for estimating this uncertainty is foreseen in Article 2.3).

## 2.3. Protocol for estimating uncertainty

If there are 20 or fewer file increment samples, as in the case of smaller lots, all samples should be analysed individually and a decision as to labelling should be taken.

If there are more than 20 file increment samples, 20 samples should be randomly selected and individually analysed for the presence of GMOs. Analytical results from these 20 samples are used to estimate the GMO content of the lot and its associated uncertainty expressed as standard deviation (SD). If this uncertainty associated to the analysis of the 20 samples is acceptable, no additional analysis of the remaining file increment samples is necessary. If, instead, the level of associated uncertainty is not acceptable, additional analysis of the remaining file increment samples should be carried out.

The number of additional samples to be analysed should be established on a case-by-case basis, depending upon the level of uncertainty estimated from the initial 20 samples.

The sequential analytical process should stop when either or both of the following is the case:

- the estimated lot GMO content (mean GMO content of the analysed file increment samples) is above or below the established threshold  $\pm 50\%$  of its value,
- the uncertainty associated to the measured lot GMO content reaches an acceptable level ( $\pm 50\%$  of the mean analytical result).

Where all samples have been tested a decision as to labelling should be taken.

#### 2.4. *Protocol for sampling lots of food and feed products*

Sampling of pre-packaged food and feed products should be carried out according to the procedures described in ISO 2859.

Sampling of non pre-packaged food and feed products should be carried out according to the protocol described in sub-section 2.1.

### V. ANALYTICAL TEST PROTOCOLS/TESTING METHODS

1. The Community Reference Laboratory established under Regulation (EC) No 1829/2003, and the nationally designated laboratories to the ENGL, will provide further guidance and assistance on the methods of testing falling within the scope of this Recommendation.

#### 2. **Laboratory requirements**

Member States' laboratories carrying out the analyses in accordance with this Recommendation should be accredited according to EN ISO/IEC 17025/1999 or certified according to an appropriate scheme, and should regularly participate in proficiency testing schemes organised or co-ordinated by nationally or internationally recognised laboratories and/or by national, international organisations.

Foodstuffs submitted for analysis in accordance with this Recommendation should be submitted to laboratories complying with the provisions of Article 3 of Directive 93/99/EEC.

The analytical investigation of the samples should be carried out in accordance with the general laboratory and procedural requirements from the draft European standard prEN ISO 24276:2002.

#### 3. **Analytical sample preparation**

When taking samples, the aim is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination. Member States should use the draft European standard prEN ISO 24276:2002 and prEN ISO 21571:2002 that indicate strategies for the homogenisation of the laboratory sample, the reduction of the laboratory sample to the test sample, the preparation of the test sample and the extraction of target analyte.

Obtaining samples of seeds should be done according to the ISTA International Rules for Seed Testing. Obtaining plant-propagating material samples should be done according to current international methods, in so far such methods exist.

#### 4. **Analytical testing**

The current scientific knowledge does not allow for the detection and quantification of all GMOs or food and feed material produced from GMOs that have been approved for the placing on the market by using a single method.

Several testing approaches are likely to provide equally reliable results. These may include one or a combination of the following:

- (a) qualitative methods, that may be event-specific, construct-specific or genetic element-specific;
- (b) quantitative methods, that may be event-specific, construct-specific or genetic element-specific.

It may be appropriate to start with a screening method to test whether GMOs are present or not. If a positive result is obtained, specific methods for a genetic construct and/or transformation event should be carried out. If different GMOs containing the same genetic construct are present on the market, an event specific method is strongly recommended. The results of quantitative analysis should be expressed as the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes. Whenever possible, laboratories should use a method validated according to internationally recognised criteria (e.g. ISO 5725/1994 or IUPAC harmonised protocol), and include the use of certified reference material.

An up-dated list of validated methods, including validated methods reported to *Codex Alimentarius*, is available in (<http://biotech.jrc.it>).

#### 5. **Absence of validated methods**

If a situation arises where no validated method exists, for instance to test whether GMOs are present or not, Member States' laboratories should carry out an in-house validation of the method according to internationally recognised criteria. If no validated method is available for the matrix under analysis, it is recommended to select from the database available on <http://biotech.jrc.it> a method that has been validated on a similar matrix or raw material. Before adoption, the performance of such method should be tested on the matrix of interest.

#### 6. **Expression and interpretation of the results of the analyses**

In case of qualitative methods, the limit of detection (LOD) is the lowest level of analyte that can be reliably detected, given a known number of target taxon genome copies.

In case of quantitative methods, the limit of quantification (LOQ) is the lowest level of analyte that can be reliably quantified, given a known number of target taxon genome copies. Results of quantitative analysis should be expressed as GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes. If the GM target sequence content is below the limit of quantification (LOQ), the results shall only be expressed qualitatively.

It is recommended to interpret the results according to the instructions given in the draft European standard prEN ISO 24276:2002.

**VI. FINAL PROVISIONS**

Sampling and detection methodology, including relevant protocols and documents, should continue to be developed and up-graded taking account of any change in thresholds and threshold values established under Articles 12, 24 and 47 of Regulation (EC) No 1829/2003, Article 21(2) and (3) of Directive 2001/18/EC and under other Community legislation, the report under Article 12 of Regulation (EC) No 1830/2003 concerning the implementation of that regulation, advances in technology and developments in international fora.

Done at Brussels, 4 October 2004.

*For the Commission*  
Margot WALLSTRÖM  
*Member of the Commission*

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