

Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

The Manual was published by Earthscan/Routledge from 2010 to 2012. It was designed as an on-line interactive reference work and annual printed versions were also produced.

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The Manual should be cited as follows:

Farmer, A.M. (2012) (Editor). Manual of European Environmental Policy. 1043pp. Routledge, London.

Genetically modified organisms: Food and feed

Formal references	
Regulation (EC) No 1829/2003 (OJ L268 18.10.2003)	Regulation on genetically modified food and feed
Proposed 25.7.2001 COM(2001)425	
Amended proposal 8.10.2002 COM(2002)559	
Regulation (EC) No 641/2004 (OJ L102 7.4.2004)	Commission Regulation on detailed rules for the implementation of Regulation (EC) No 1829/2003
Regulation (EC) No 298/2008 (OJ L 097 9.4.2008)	Regulation amending 1829/2003 on genetically modified food and feed , as regards the implementing powers conferred on the Commission
Regulation (EC) No 619/2011 (OJ L 166, 25.6.2011)	Regulation laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired
Legal base	Articles 37, 95 and 152
Binding dates	
Entry into force	7 November 2003
Applies from	18 April 2004
Commission to report	7 November 2005

Purpose of the Regulation

This Regulation seeks to establish the basis for a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to the use of genetically modified organisms (GMOs) in food and feed. It thus extends existing rules on the use of GMOs in research, [teaching and commercial development](#) (see section on GMO deliberate release), by laying down Community procedures for the authorization and supervision and for the labelling of GM food and feed. In doing so it further ensures common procedures for the functioning of the internal market. These measures are to be seen in the context of those on the [traceability and labelling](#) and on the [transboundary movement of GMOs](#).

Summary of the Regulation

The Regulation aims to achieve its purpose by laying down Community rules for the authorization, supervision and labelling of genetically modified food and feed. Chapter II of the Regulation establishes the authorization, supervision and labelling requirements applied to genetically modified food while Chapter III sets up parallel procedures for genetically

modified feed. Chapter IV lays down common provisions for both food and feed. The Regulation establishes also a Community register of genetically modified food and feed authorized by this Regulation available to the public and sets down a threshold for adventitious or technically unavoidable presence of GM material in food and feed products, under a number of restrictions.

Definitions

For the purposes of the Regulation ‘genetically modified food or feed’ is food or feed containing, consisting of or produced from GMOs; similarly ‘GMO for food or feed use’ means a GMO that may be used as food or as source material for the production of food. The definition of a GMO is taken from Article 2(2) of Directive 2001/18/EC on the [deliberate release of GMOs](#).

Genetically modified food

The scope of Chapter II is defined in Article 3. It applies to:

- GMOs for food use;
- food containing or consisting of GMOs;
- food produced from or containing ingredients produced from GMOs.

More specifically, food additives containing, consisting or produced from GMOs fall within the scope of the safety assessment of the genetic modification although authorization is to be granted under Directive [89/107/EEC](#) on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption. Flavourings that contain GMOs also will need a safety assessment.

Authorization procedure for genetically modified food

Article 4 establishes that a GMO product cannot be introduced in the market for food use unless it is covered by an authorization in accordance with the Regulation. To obtain the required authorization the genetically modified food is to meet the following requirements:

- Not having an adverse effect on human health, animal health or the environment;
- Not misleading the consumer;
- Not differing from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

The application for authorization shall be made in accordance with the provisions laid down in Article 5. Article 5 also obliges the Commission to establish specific implementing rules for application of this procedure and the European Food Safety Authority (EFSA) (herein after Authority) to publish detailed guidance to assist applicants in preparing and presenting applications. Commission Regulation (EC) [No 641/2004](#) amongst others provides detailed rules for the application for authorization. The application procedure consists of the following steps:

- The applicant shall submit an application to the national competent authority accompanied by:

- details of the applicant and the food product, including the designations and specification of the food and the product transformation events used including the method of the production and manufacturing where applicable;
- information, where applicable, relating to compliance with Annex II of the [Cartagena protocol](#);
- studies, independent where possible, to demonstrate that the product meets the requirements specified in Article 4(1);
- analysis showing either that the characteristics of the product do not differ from its conventional counterpart or a proposal for labelling the food in accordance with Article 13 (see below);
- either a reasoned statement that the food does not give rise to ethical and religious concerns or a proposal for labelling;
- where appropriate, conditions for placing on the market the food or foods produced from it;
- methods for detection, sampling and identification of the transformation event and for the detection and identification of the transformation event in the food and/or in foods produced from it;
- samples of the food and their control samples and information as to the place where the reference material can be accessed;
- a proposal for post-market monitoring regarding use for human consumption, where appropriate;
- in the case of GMOs or food containing or consisting of GMOs the application also shall be accompanied by the complete dossier supplying the information required by Annexes III and IV to Directive [2001/18/EC](#) and information and conclusions about the risk assessment (see section on GMO deliberate release);
- where a GMO has been authorized already under the earlier Directive a copy should be supplied of the monitoring plan for environmental effects conforming with Annex VII to Directive [2001/18/EC](#), including a proposal for the duration of the monitoring plan.
- The national competent authority shall acknowledge receipt of the application to the applicant within 14 days of receipt in written form and inform the Authority without delay, making available the application and any supplementary information.
- The Authority shall inform without delay other Member States and the Commission of the application making available all the information supplied to them a summary of the dossier prepared by the applicant is to be made available to the public.

The Authority is to ‘endeavour’ to give its opinion within six months after receiving the application, although this period can be extended if the Authority needs supplementary information. To prepare its opinion the Authority:

- shall verify the conformity of the documents submitted with the application procedure and with the requirements defined in Article 4 and examine whether the food complies with the criteria;
- may ask the appropriate food assessment body of a Member State to carry out a safety assessment. For seeds and similar material a national body may be asked;
- may ask a competent authority under Article 4 of Directive [2001/18/EC](#) to carry out an environmental risk assessment;

- shall forward to the Community reference laboratory the methods for detection, sampling and identification of the transformation event and the samples of the food specified in the application procedure for its validation;
- shall verify that the characteristics of the food to be authorized are not different from its conventional counterpart.

For GMOs or food containing or consisting of GMOs the environmental safety requirements referred to in Directive 2001/18/EC shall be assessed. For this purpose the Authority shall consult the national competent authority designated by each Member State under Directive 2001/18/EC. They have three months to respond.

The Authority is to forward its opinion to the Commission, Member States and the applicant, including a report explaining its assessment. In the event of a favourable opinion the Authority shall include any conditions or restrictions imposed on the product regarding placing on the market the food labelling proposal, validation of the detection and identification methods and the monitoring plan for environmental effects, where applicable. Taking into account the confidentiality requirements laid down by Article 30, the Authority shall make its opinion public, enabling the public to make comments to the opinion within 30 days from its publication.

The Commission will submit a draft Decision of its own to the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) [No 178/2002](#), on general principles and requirements for food law and procedures on food safety, within three months after receiving the opinion of the Authority, taking its views and other factors into consideration. The final Decision is to be adopted in accordance with the procedures for the exercise of implementing powers conferred on the Commission, as specified in Articles 5 and 7 of Decision [1999/468/EC](#). Details of the Decision shall be published in the *Official Journal of the European Union* and the application is to be informed.

It is specified that the granting of an authorization ‘shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned’ (Article 7.7).

The authorization holder shall submit reports to the Commission in those cases in which a post-market monitoring regarding the use of food for human consumption is needed. The same applies if a plan for monitoring environmental effects has been required. Any modification of the terms of the authorization requires the submission of another application following the conventional procedure. Authorized foods are to be entered in a new Community register of genetically modified food and feed which is to be available to the public.

The authorization granted by this procedure is valid for ten years but it can be renewed for ten-year periods by application one year before the expiry date of the authorization. Renewals require submitting the authorization, together with any additional information such as reporting on monitoring if specified, new information available and proposals for amendments or complementing the conditions of authorization. If no Decision is taken before the expiry date, the period of authorization shall automatically be extended until a Decision is taken.

The Authority, by his own initiative or following a request from any member State or the Commission, can issue an opinion regarding the modification, suspension or revocation of

authorizations. The Commission shall examine this opinion taking appropriate measures if necessary.

Status of existing genetically modified food products

Products falling within the scope of the Regulation but placed on the market before its entry into force in accordance with previous legislation may remain on the market by way of derogation from Article 4(2), provided that they meet the following conditions:

For products placed on the market under Directive 90/220/EEC (repealed by Directive [2001/18/EC](#)) or Regulation (EC) [No 258/97](#) operators shall notify the Commission of the date on which they were first placed on the market in the Community. They shall further submit the same documentation that is necessary for the authorization procedure for new applications summarized above. Within nine years, but not earlier than three years from the date of application of this Regulation, operators shall submit an application for the renewal of the authorization.

For products not covered by the above mentioned legislation, operators shall notify the Commission about their placement on the market within six months of the date of application of this Regulation, accompanying this with the same documentation as for a new application. Application for renewals shall be submitted within three years of the application of this Regulation.

Once the information about these products has been submitted and verified, including the testing and validation of the detection and identification method by the Community reference laboratory and within a year of this Regulation's application, the products concerned will be entered in the Register. Products may be withdrawn from the market if they are found not to be in compliance with the requirements specified by this Regulation. In accordance with Commission Regulation (EC) No 641/2004, the Commission has to publish and maintain a list of genetically modified material that has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the 18 April 2004. This [list](#) has subsequently been published.

Labelling

Those products containing, consisting of, or produced from GMOs to be delivered as such to the final consumer or mass caterers in the Community need to comply with the labelling rules set up by the Regulation (Article 12.1). Labelling is not necessary for foods, which contain, consist of or are produced from GMOs in a proportion no higher than 0.9 per cent for each ingredient (Article 12.2), although operators need to demonstrate that this presence is adventitious or technically unavoidable. They must be able to supply evidence that they have taken appropriate steps to avoid the presence of such material. Lower thresholds may be established in particular regarding foods containing or consisting of GMOs in order to take into account advances in science and technology.

Labels of products falling within the scope of the Regulation shall explain clearly the presence of the genetically modified material in the product, meeting the visibility requirements laid down by the Regulation. The label must explain also any other characteristic or property of the product in the following cases (Articles 13 and 25):

- if the food is different from its conventional counterpart in composition, nutritional value or nutritional effects, intended use or implications for health of certain sectors of the population;
- if the product may raise ethical or religious concerns.

Detailed rules for the implementation of this section are to be drawn up by the Commission, including rules for the information to be provided by mass caterers.

Genetically modified feed

The scope of Chapter III is defined in Article 15. It applies to:

- GMOs for feed use;
- feed containing or consisting of GMOs;
- feed produced from GMOs.

More specifically, feed materials containing, consisting of or produced from GMOs will fall within the scope of the Regulation and not Council Directive [82/471/EEC](#) on certain products used in animal nutrition. Feed additives containing or produced from GMOs will also fall within the scope of this Regulation, in addition to the authorization procedure in Directive [70/524/EEC](#) concerning additives in feeding-stuff.

Genetically modified feed is subject to the same authorization procedure followed by genetically modified food, as well as similar labelling requirements. In addition to the requirements set down for genetically modified food, genetically modified feed to be placed in the market for animal consumption must not harm or mislead the consumer by impairing the distinctive features of animal products (Article 16.1(c)).

Article 27 specifies that products to be used indistinctively as both food and feed need to submit one single application that will raise one opinion from the Authority and one Community decision.

Public access and confidentiality

Applications for authorization, supplementary information, opinions from competent authorities, monitoring reports and any other information provided by the applicant shall be accessible to the public, excluding potentially significant amounts of confidential information (Article 29). The public can also intervene during the authorization process, by submitting comments on the opinion of the Authority during a period of 30 days after the opinion is made publicly available (Articles 6.7 and 18.7).

The applicant, as specified by Article 30.1, can indicate which information in the application shall be treated as confidential. The following information shall not be treated as confidential:

- name and composition of the GMO;
- general description, applicant, physical, chemical and biological characteristics of the GMO;
- effects of the GMO on human and animal health, on the environment or on the characteristics of animal products and its nutritional characteristics;
- methods for detection and information on waste treatment and emergency response.

The information provided cannot be used for the benefit of other applicants unless the ten-year period has expired, as long as the new applicant can demonstrate that the food or feed for which they are seeking authorization is essentially similar to food or feed already authorized.

Other evaluation and consultation institutions

The authorization procedure includes a role for the Community reference laboratory which is specified in the Annex as the Commission's Joint Research Centre. It is responsible for a range of tasks including samples, validation of the detection method and evaluation of the applicant's data (Article 32 and Annex). It shall submit proposed evaluation reports to the Authority as well as play a role in dispute settlements between Member States. The 'European Network of GMO laboratories', consisting of a consortium of national reference laboratories, will assist it in its tasks. Applicants for authorization of genetically modified food and feed shall contribute to supporting the costs of the Community reference laboratory and the European Network of GMO laboratories. Detailed implementing rules may be established.

The Commission may also consult the European Group on Ethics in Science and New Technologies, making these opinions available to the public (Article 33). The Standing Committee on the Food Chain and Animal Health shall also assist the Commission in its final decision.

Any review of the administrative procedure and the functioning of the Authority may be reviewed by the Commission under its own initiative or in response to a request from any Member State or person directly and individually concerned.

Penalties

Member States shall lay down the rules on penalties for infringements of the provisions of this Regulation, notifying them to the Commission six months after the Regulation entry into force.

Transitional measures and review

Article 47 determines that 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 per cent does not require authorization to be placed in the market, subject to certain premises: The presence of the GMO must be technically unavoidable, the genetic material must have a favourable opinion from the Community Scientific Committee or the Authority before the date of application of the Regulation, the application for its authorization must not have been rejected and detection methods must be publicly available. Operators need to demonstrate that they have taken appropriate measures to avoid the presence of such materials.

This threshold may be lowered in particular for GMOs sold directly to the final consumer. In addition, the Commission is to forward to the Parliament and the Council a report on the implementation of this Regulation and in particular of Article 47 no later than 7 November 2005 accompanied by suitable proposals. Article 47 is to be applicable for a period of 3 years after the date of application of the Regulation.

Amendments to existing legislation

The following table outlines the legislation repealed or amended by this Regulation:

EU legislation modified by Regulation (EC) No 1829/2003	
Repeals	<ul style="list-style-type: none"> • Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from GMOs of particulars other than those provided for in Directive 79/112/EEC on labelling, presentation and advertising of foodstuffs. • Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from GMOs of particulars other than those provided for in Directive 79/112/EEC. • 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 GMOs.
Amendments	<ul style="list-style-type: none"> • Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. • Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition. • Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species. • Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine. • Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs and repealing Council Directive 90/220/EEC – Commission Declaration (see section on GMOs – deliberate release).

This Regulation amends Articles 12a and 26a of Directive [2001/18/EC](#). The new Article 12a introduces transitional measures for the adventitious or technically unavoidable presence of GMOs that have benefited from a favourable risk evaluation. The new Article 26a states that Member States may take appropriate measures to avoid the unintended presence of GMOs in other products, while the Commission shall coordinate the information and develop guidelines for this co-existence.

Any authorization, renewal, modification, suspension or revocation of the authorization shall be notified to the Parties to the [Cartagena protocol](#).

The following Transitional Measures are established by the Regulation:

Requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be considered as applications for genetically modified food authorization provided that:

- the initial assessment report to be provided under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission; or
- an additional assessment report is needed in accordance with Articles 4 and 6 of the Regulation concerned.

Otherwise those applications are to continue under the provisions of Regulation (EC) No 258/97.

Products do not need to apply the labelling requirements drawn by Regulation (EC) No 1829/2003 if the manufacturing process has begun before the date of application of this Regulation and those products are labelled in accordance with the legislation applicable before the date of application of this Regulation. Notifications concerning products to be used as feed submitted under Article 13 of Directive 2001/18/EC before the date of application of the Regulation that have not submitted the assessment report under Article 14 of the Regulation shall be transformed into applications for the genetically modified feed authorization as specified before. Detailed rules for the notification of existing products are contained in Regulation (EC) No 641/2004.

Requests submitted for feed produced from GMO under Article 7 of Directive 82/471/EEC before the date of the application of the Regulation shall be transformed into applications for genetically modified feed authorization. Requests submitted for feed consisting of, containing or produced from GMOs under Article 4 of Directive 70/524/EEC shall be supplemented by applications submitted for those products for the genetically modified feed authorization.

Development of the Regulation

The original proposal was based on in the concept in the Commission's White Paper on Food Safety [COM\(1999\)719](#) of bringing together a range of regulations pertinent to genetically modified food. In addition to the authorization and monitoring procedure, an appropriate labelling system for GMO food and feed was regarded as one of the key issues in ensuring greater acceptance of the application of gene technology in the agro-food sector. The proposal was to extend the existing labelling provisions to all GMO food and feed, covering a number of foodstuffs such as highly refined oils from GMO origin, for the first time. The European Commissioner for Health and Consumer Protection David Byrne said at the European Parliament that:

- ‘The proposal ensures a high level of protection requiring genetically modified food and feed, including food and feed produced from GMOs, to undergo a scientific risk assessment prior to the placing on the market;
- The proposal enables the consumer to exercise a freedom of choice by reinforcing current labelling requirements; and
- The proposal provides for improved, transparent and streamlined Community level procedures for authorization, involving the European Food Authority’.

The first reading at the European Parliament raised a number of issues including the scope of the proposal, the environmental assessment required and the thresholds for the adventitious or technically unavoidable presence of GMO material in non-GM products. The Commission adopted 54 out of the 111 amendments proposed by the Parliament.

The debate on the scope of the proposal was vigorous both inside and outside Europe. Senior US government officials raised their concerns about the proposal after American food industry interests sent a letter to the US Secretary of State. The Commission proposal was to include products produced from a GMO but not products produced with the aid of a GMO (with processing aids such as GMO enzymes). The US food industry alleged that this would discriminate against American products produced from GMOs, while to make a distinction between the two was virtually impossible. The United Kingdom delegation at the EU said that ‘the measure of traceability and labelling requirements in relation to products derived from GMOs but containing no detectable genetically modified material is unenforceable and potentially risks consumer confidence’. The Commission accepted the Parliament amendments to extend the scope of the proposal to processing aids and animal products derived from animals fed on GM feed and to restrict the scope of the proposal to products derived from GMOs, which contain transgenic DNA or protein. However, the Commission did not accept amendments to include in the scope of the Regulation products produced from GM processing aids not present in the final product or products from animals fed with GM feed. Regarding labelling, the Commission proposed mandatory labelling of food, food ingredients and feed produced from GMOs, even when transgenic DNA is not present in the final product arguing that this was needed, to ensure that consumers receive all the necessary information. The Commission did not accept ‘GM-free’ or ‘non-GM’ as alternative labels to the mandatory labelling of GM-derivatives. However it accepted their use as a form of complementary and voluntary labelling.

On the issue of risk assessment, the Commission rejected the amendments challenging the suggestion that the EFSA should carry out the environmental risk assessment as part of the overall assessment of a GM food or feed. Several other amendments regarding the issue of transparency were adopted, however.

On the highly sensitive thresholds issue, the original proposal was amended by the Parliament to include a threshold of 0.5 per cent (rather than the 1 per cent). The Commission did not agree with this and suggested instead that, following the principle established by Directive 2001/18/EC, the threshold for the presence of an unauthorized GMO in food and feed could be fixed through a comitology procedure, taking into account technological and scientific progress.

The majority of delegations at the Council had a fairly open approach to the thresholds issue. The Presidency supported the 1 per cent tolerance level set down in the proposal, but during a transitional period of three years. The Council adopted its common positions by qualified majority (Luxemburg, Austrian and the United Kingdom voting against), taking into account some of the amendments made by the Parliament, including the following:

- A threshold of 0.5 per cent for the maximum acceptable presence of GMOs traces in a food or feeding stuff above which a market authorization would be needed, subject to the following strict conditions:
 - The GMOs concerned must have received a favourable opinion from a Community scientific authority already;
 - The threshold may, if necessary, be lowered under a committee procedure.
- A higher threshold of 0.9 per cent was set under which food or feed containing GMOs did not need to be labelled.

The United Kingdom maintained that 1 per cent was the lowest level that could be reliably detected and that the text agreed by the Council did not meet the obligations arising from the [Cartagena protocol on Biosafety](#).

The European Parliament adopted nine amendments and left unchanged the Council's labeling threshold of 0.9 per cent for each ingredient. Eventually the Commission accepted these changes as a compromise package to facilitate the final adoption of the proposal. One of the amendments accepted refers to co-existence measures in Member States. The Regulation enables Member States to take appropriate measures to avoid the unintended presence of GMOs in other products and invites the Commission to develop guidelines in order to provide Member States with a framework to put it into practice. The Commission accepted also amendments regarding deleting the provisions specifying that GMOs for release under Part B of Directive 2001/18/EC and GMOs and genetically modified micro-organisms for contained use activities are excluded from the definition of 'placing on the market'.

The Council approved those amendments at second reading when the Regulation was adopted by qualified majority, with Austria, Denmark, Luxembourg and the United Kingdom voting against it.

Implementation of the Regulation

The Commission published its first implementation report ([COM\(2006\)626](#)) on Regulation No 1829/2003/EC on 25 October 2006. The report covers implementation in Member States, and summarizes additional measures and clarifications of the Regulation which have been introduced by the Commission. However, since the Regulation had only been applied since 2004, limited conclusions concerning the effectiveness of the Regulation could be drawn from the report. Until the beginning of July 2006, 34 authorization applications had been received by the EFSA via Member State competent authorities. However, only six overall EFSA opinions had been finalized since the application of the Regulation. There was a limited number of food products labelled as GM food on the European market. On the other hand, GM labelled feed has a significant presence on the European market, largely due to the extensive global production and low cost of GM soy. In relation to Member States' monitoring responsibilities some shortcomings were found in terms of lack of sampling controls and lack of capabilities for determining the presence of GMOs in food and feed. Moreover, six Member States did not take action in all cases where they discovered relevant traces of GMOs in seed consignments. Three different unauthorized GM products had entered the European market: unauthorized GM papaya from Hawaii (last time in July 2005); unauthorized GM maize Bt10 from the US (March 2005); and GM rice LL601 in US rice shipments to Europe (2006). The Commission indicated that these cases illustrate that it cannot be excluded that similar accidents will happen again, and although the existing alert system has proven effective it would consider whether specific actions were needed. The second implementation report was foreseen 'after a sufficient period of time allowing more insight into the different aspects of the implementation of the Regulation'.

In March 2008 the Regulation was amended by (EC) Regulation No 298/2008, to incorporate changes to the comitology procedure as required by the regulatory procedure with scrutiny. The Commission, in accordance with the regulatory procedure with scrutiny, will:

- define whether a type of food or feed falls within the scope of Regulation (EC) No 1829/2003;
- lower the thresholds for the labelling of the adventitious and technically unavoidable presence of material which contains, consists of or is produced from GMOs and for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk assessment in food and feed; and
- adopt measures regarding certain labelling and information requirements incumbent on operators and mass caterers.

Regulations (EC) No 1829/2003 and (EC) No 152/2009 did not set a minimum threshold for the presence of GM varieties not authorized for food or feed in the EU, and a de facto ‘zero tolerance policy’ was assumed. However, as the cultivation of GM varieties has expanded in South America, particularly in Brazil and Argentina, whilst detection methods have improved, feed importers are finding it increasingly difficult to import feed with no detectable GM contamination. In addition, the EU authorization for MON810 maize, one of the most widely cultivated GM varieties, has expired and is still pending reauthorization. In response to pressure from feed importers, the Commission proposed a new Regulation, which details EU-wide standards for analysis, as validated by the European Union Reference Laboratory, and sets a threshold for unauthorized GM material in feed.

Commission Regulation (EU) No [619/2011](#) of 24 June 2011 states that imports of animal feed will be allowed to contain traces of unauthorised genetically modified (GM) material below a threshold of 0.1 per cent, without needing labelling or authorization. This corresponds to the most widely accepted margin of error in test results. Member States initially rejected the Commission's proposal, until it was agreed that the 0.1 per cent limit would only apply if 1) the GM variety involved has previously been authorised in at least one non-EU country, 2) the European Food Safety Authority (EFSA) has received an import authorisation request for the GM variety at least three months before the import, and 3) the EFSA has provided an assessment that the presence of GM material of 0.1 per cent is not detrimental to health and the environment. The current solution refers to feed imports only, whereas imports destined for the food supply will still operate under the zero tolerance policy.

Authorizations and Decisions

In September 2003, the Commission issued a Decision ([2006/601/EC](#)) to ban EU imports from the United States of certain rice products. The Decision confirmed a provisional ban which was implemented as an emergency measure in August 2003 following the discovery by US authorities that the non-authorized GMO LL Rice 601 had been found in US rice products, some of which may have been imported to the EU. The measures require importers to certify that imported rice does not contain LL Rice 601 and Member States to carry out random sampling and analysis. On 7 November 2006 the Commission strengthened the rules concerning controls of imported rice (Decision [2006/754/EC](#)). This included a requirement on Member States to ensure that official sampling and analysis of each consignment of rice products (which falls under the scope of the Decision) are carried out to demonstrate that it does not contain GM rice LL601. In March 2007, the Commission decided to lift a compulsory certification requirement on imports of maize products from the US to avoid contamination with the non-authorized GM maize Bt10 (Decision [2007/157/EC](#)). The requirement was introduced following the contamination of a shipment of maize from the US in early 2005.

On 3 March 2006, the European Commission authorized the first GMO under Regulation 1829/2003. The authorization Decision concerns a GM maize (*Zea mays* L. line 1507) for marketing as food, food ingredients or derived products on the European market. The 1507 maize was also subject to the new [labelling and traceability rules](#) introduced in 2003. Regulation (EC) No 1829/2003 uses a slightly different Decision procedure to Directive 2001/18/EC, under which a number of GMOs have been authorized since [mid-2004](#). However, both cases included a controversial comitology procedure, which required the Commission to approve the product if the Council cannot reach a qualified majority. Since Member States are divided on the issue of GMOs, the Council time after another fails to reach a qualified majority in GMO votes. In practice, this means that all GMOs judged safe by the EFSA and consequently proposed for authorization by the Commission, will be granted authorization. This was also the case with the 1507 maize, as the Council failed to either approve or reject the Commission's authorization proposal in December 2005.

In April 2008, the Commission issued a Decision ([2008/289/EC](#)) which introduced emergency measures regarding the unauthorized GMO Bt 63 in rice products originating from China, in consideration to the continuing alerts and the lack of sufficient guarantees from the Chinese competent authorities. That Decision required that prior to placing on the market, operators should submit an analytical report to the relevant Member State competent authorities demonstrating that the consignment of rice products was not contaminated with genetically modified rice Bt 63. Additionally, that Decision provided Member States to take appropriate measures, including random sampling and analysis carried out using a specific method described therein, concerning products presented for importation and on the market. In 2008 and 2011 the Food and Veterinary Office conducted inspections in China with the objective to evaluate the implementation of the Directive, which indicated there was a high risk of further introductions of unauthorized GMOs in such rice products. In light of these findings and the numerous Rapid Alert System for Food and Feed (RASFF) notifications concerning unauthorised genetically modified rice events, the scope of the measures provided by the Decision were extended to broaden it to all genetically modified organisms found in rice products originating in or consigned from China ([Decision 2011/884/EU](#)).

Enforcement and court cases

In Case [C-442/09](#), 6.9.2011, the European Court of Justice ruled that GM pollen present in honey is to be considered an ingredient 'produced from GMOs', and therefore honey with any detectable level of GM material is subject to the regulations and directives on authorisation and marketing of GM food. Previously, the Commission had argued that honey is exempt because pollen is a natural component of honey, and not an ingredient. As bees can forage in a radius of up to 5 kilometres from their hives, honey can be subject to a range of possible GM contamination if GM crops are grown within that area. The issue of crop contamination by GMOs and thresholds for their presence continues to be widely contested by environmentalists and stakeholders concerned about the use of GMO products.

Further developments

As part of the continuous process of reviewing the existing legislation and the improvement of its implementation, the Commission published, in October 2011, an independent report on the evaluation of the legislative framework on GM food and feed. The main goal was to collect facts and opinions, particularly from stakeholders and competent authorities, to assess

the effectiveness and efficiency of the legislative processes and formulated options for the improvement and adjustment of the system.²

Related legislation

The following legislation and policy has a strong interaction with Regulation (EC) No 1829/2003 on genetically modified food and feed:

- Directive [2001/18/EC](#) on the deliberate release into the environment of GMOs.
- Regulation (EC) No [1946/2003](#) on the transboundary movements of GMOs.
- Regulation (EC) No [1830/2003](#) concerning the traceability and labelling of GMOs and the traceability of food and feed products from GMOs.
- [Common Agriculture Policy](#) and related legislation.

This Regulation extends the rules laid down by Directive 2001/18/EC on the deliberate release of GMOs. In addition, its applications for authorization for GM food must comply with provisions under Regulation (EC) No 1946/2003 on transboundary movements. GMOs covered by this Regulation may also be subject to the labelling and traceability rules introduced by Regulation (EC) No 1830/2003. In addition, there is a strong interaction with the Common Agriculture Policy, concerning issues such as co-existence between conventional, organic and GM crop production, and food security.

References

1 European Commission (2011) EU Committee Endorses Proposal to Harmonize Testing for GMO Traces in Feed. Press release issued on 22.02.2011, European Commission, Reference: MEX/11/0223

<http://europa.eu/rapid/pressReleasesAction.do?reference=MEX/11/0223&format=HTML&aged=0&language=EN&guiLanguage=en>

2 European Commission (2011) Evaluation of the EU legislative framework in the field of GM food and feed.

http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf