
INFORMATION NOTE

Genetically Modified Food Labelling in the European Union

1. Background

1.1 The purpose of this information note is to provide the Panel on Food Safety and Environmental Hygiene with information regarding the regulation of genetically modified (GM) food labelling in the European Union (EU)¹. New regulations have been introduced in the European Parliament in July 2003 to enhance the regulatory framework on GM food labelling.

2. Regulatory authority

2.1 The European Commission (Commission) is the body responsible for establishing rules for the assessment and authorization of genetically modified organisms (GMOs)² and GM food in EU whereas the responsibilities of adopting, implementing and enforcing the legislation fall on the governing authorities of the member states.

¹ The member states of EU are Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Luxembourg, the Netherlands, Austria, Portugal, Finland, Sweden, and the United Kingdom. Within EU, there are five institutions, each playing a specific role: the European Parliament (elected by the peoples of the member states), the Council of the European Union (representing the governments of the member states), the European Commission (the driving force and the executive body of EU), the Court of Justice (ensuring compliance of the member states with the law), and the Court of Auditors (controlling sound and lawful management of the EU budget).

² GMOs are organisms in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination.

3. Regulatory framework

3.1 A regulatory framework on GMOs has been in place since the early 1990s as the first legislation which authorized experimental release and marketing of GMOs in EU was implemented on 23 April 1990 under EU Directive 90/220/EEC. Since then, the regulatory framework has been extended and refined. GM food labelling has been made mandatory to indicate the presence of GMOs in a product since 1997. In January 2000, the Commission adopted two regulations relating to the labelling of GM food products:

- (a) under Regulation (EC) 49/2000, the Commission introduced a 1% *de minimis* threshold for DNA and protein resulting from genetic modification to address the problem of adventitious contamination of GM materials in food products. Labelling is not required if the GM content is below the threshold, and if operators can demonstrate that they have used appropriate steps to avoid the presence of GM materials in the food product; and
- (b) under Regulation (EC) 50/2000, labelling is required for food and food ingredients containing additives and flavourings that have been genetically modified or have been produced from GMOs.

3.2 On 17 October 2002, Directive 90/220/EEC was repealed by Directive 2001/18/EC, which provided a more complete framework on GM food labelling by introducing the following measures:

- (a) a more detailed environmental risk assessment;
- (b) mandatory monitoring requirements including long-term effects on human health associated with the interaction with other GMOs and the environment;
- (c) mandatory information to the public, including information relating to:
 - (i) the specifics of GMOs;
 - (ii) the conditions of the release of GMOs and the receiving environment; and
 - (iii) the interactions between GMOs and the environment;

- (d) first approval for the release of GMOs to be limited to a maximum of 10 years;
- (e) mandatory consultation with the Scientific Committee(s)³;
- (f) an obligation to consult the European Parliament on decisions to authorize the release of GMOs; and
- (g) the possibility for the Council of the European Union to adopt or reject a Commission proposal for authorization of a GMO by qualified majority⁴.

3.3 On 2 July 2003, the European Parliament adopted two proposals for regulation of GM food labelling to enhance the existing regulatory framework. Details of the regulations are being drawn up. The two proposals are:

- (a) regulations concerning traceability⁵ and labelling of GMOs and traceability of food and feed products produced from GMOs; and
- (b) regulations of GM food and feed products.

3.4 On 22 July 2003, the Council of the European Union also adopted the two proposals, and the proposed regulations will be formally published in the Official Journal by the end of the year. The Commission is drafting details of the regulations, the precise form of which is critical to the practical implication of the proposals.

³ Under the Commission, there are eight Scientific Committees, namely the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Committee on Animal Health and Animal Welfare, the Scientific Committee on Veterinary Measures relating to Public Health, the Scientific Committee on Plants, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, the Scientific Committee on Medicinal Products and Medical Devices, and the Scientific Committee on Toxicity, Ecotoxicity and the Environment.

⁴ A qualified majority is the number of votes required in the Council of the European Union for a decision to be adopted when issues are being debated. Until 1 November 2004, the threshold for the qualified majority is set at 62 out of 87 votes.

⁵ Traceability refers to the means to trace the movement of GM products throughout the production and distribution chains.

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

3.5 The proposed regulations on traceability and labelling require business operators, when using or handling GM products, to transmit and retain information from the production to delivery of GM products to the market. The proposed regulations impose careful separation of GM crops from non-GM crops and a detailed paper trail from the fields to food stores. Information concerning the presence of GMOs in products must be transmitted throughout the commercial chain and retained for five years. The industry has to ensure that systems are in place to identify to whom and from whom GM products are made available.

3.6 After promulgation of the regulations, there will be a three-month transition period to give operators time to adjust to the new rules before their full application.

Regulations of genetically modified food and feed products

Threshold of labelling

3.7 Minute traces of GMOs in conventional food and feed products can arise during cultivation, harvest, transport and processing. In the past, the presence of approved GM materials did not have to be labelled if it was below 1% and if it could be shown to be adventitious and technically unavoidable. The proposed regulations lower the threshold to 0.9%. For unapproved but risk-assessed GM varieties⁶, the threshold is set at 0.5%. The latter provision will expire after three years, at which time the threshold will drop to 0%. Food producers and distributors have six months to comply with the new procedures after promulgation of the regulations.

GM food products

3.8 The proposed regulations require the labelling of all food products produced from GMOs irrespective of whether there is DNA or protein of transgenic origin in the final product. In the past, labelling provisions only covered food produced from GMOs if traces of DNA or protein from the genetic modification were detectable in the final product. The proposed regulations also extend the current labelling requirements to cover food ingredients produced from GMOs. Pre-packaged products produced from GMOs should indicate "*This product contains genetically modified organisms*" or "*... produced from genetically modified [name of organism]*".

⁶ A number of GMOs have already been assessed by the Scientific Committees under the Commission as not posing any danger to the environment and health, but their final approval is still pending.

GM feed products

3.9 The proposed regulations introduce for the first time comprehensive labelling requirements of GM feed products based on the same principle for GM food products. In the past, there were no labelling requirements in place for feed products produced from GMOs.

4. Negative Labelling

4.1 The Commission does not have specified policies on negative labelling. The view of the Commission is that voluntary "*GMO-free*" (or similarly phrased) schemes are beset by a number of technical and commercial difficulties. The Commission considers that consumers in the European community are primarily interested in knowing whether their food is produced from GMOs or contains ingredients produced from GMOs, and they prefer to be informed what is in products, and not what is not in products.⁷ In addition, GMO-free products have already been supplied under the organic production scheme, which excludes the use of GMOs in the whole production chain on a very strict basis. A second "*GMO-free*" labelling scheme is therefore considered by the Commission to be confusing for consumers and potentially misleading.

5. Enforcement

Authorization

5.1 In the proposed regulations, scientific risk assessment of GM food is carried out by the European Food Safety Authority⁸, whose opinion is available to and open for comment by the public. On the basis of this opinion, the Commission drafts a proposal for granting or refusing authorization. The proposal is approved through qualified majority by the member states within a Regulatory Committee⁹. Thereafter, authorized products are entered into a public register of GM-food and feed products. The authorization is granted for a period of 10 years, subject to a post-market monitoring plan, where appropriate. The authorization is renewable for subsequent 10-year periods.

⁷ World Trade Organization, "Response from the European Commission to Comments Submitted by WTO Members under Either or Both G/TBT/N/EEC/6 and G/SPS/N/EEC/149", G/SPS/GEN/337 and G/TBT/W/179, 26 July 2002.

⁸ The European Food Safety Authority is an independent EU body whose core task is to provide independent scientific advice and support on food safety issues and other related matters at the request of the Commission, the European Parliament and individual member states as a basis for risk management decisions.

⁹ A Regulatory Committee is a decision-making body consisting of representatives of the member states. The Standing Committee on the Food Chain and Animal Health is the Regulatory Committee responsible for food safety policies in the Commission.

Testing

5.2 To facilitate a co-ordinated approach for inspection and control by the member states, the proposed regulations stipulate that the Commission will develop technical guidelines on sampling and testing methods prior to the application of the regulations on traceability and labelling.

5.3 Operators are obliged to provide detection methods to the Commission within six months of entry into force of the proposed regulations on GM food and feed products. The proposed regulations also establish the Joint Research Centre (JRC) of the Commission as the new Community Reference Laboratory which will have the main task of validating detection methods. JRC will work with the European Network of GMO Laboratories¹⁰.

Violation

5.4 At present, those member states which violate the EU legislation may face trials in the European Court of Justice. For instance, in July 2003, the Commission decided to refer France, Luxembourg, Belgium, the Netherlands, Germany, Italy, Ireland, Greece, Spain, Austria and Finland to the European Court of Justice for failing to adopt national legislation to implement Directive 2001/18/EC relating to the deliberate release of GMOs in the environment.

6. Views of the European Commission and the public

6.1 The European Health and Consumer Protection Commissioner, David Byrne, welcomes the new regulations. He states that *"consumer will have a clear choice of products to buy as GM food will now be clearly labelled. Europe will now have a comprehensive and transparent system of authorization and labelling that can only enhance business and consumer confidence."*

6.2 The European Environment Commissioner, Margot Wallstrom, considers that the new regulations *"will enforce the national credibility and will certainly help in building public confidence in new technologies. By ensuring that GMOs can be traced at all stages in the production and marketing chain, we provide a robust safeguard system and the foundation for a comprehensive labelling system. In this way, we address the most critical concerns of the public regarding the environment and health effects of GMOs and enable consumers to choose."*

¹⁰ The European Network of GMO Laboratories consists of more than 45 control laboratories chaired by the Commission. It is responsible for the analysis of food, feed, seed and environmental samples to determine the presence of GMOs. This network aims at harmonizing pan-European test methods, sampling strategies and analytical techniques by exchanging information between experts, developing robust testing methods and producing reference materials.

6.3 International organizations, including Greenpeace and Friends of the Earth, support the regulations. Friends of the Earth states that *"this gives countries the power to impose strict restrictions on GM crops"* in order to protect organic and conventional crops from the unintended presence of GMOs. Greenpeace takes a harsher stance, calling it *"a slap in the face of the US administration which thought by bullying, Europe and eventually others would swallow its GMO policy."*

6.4 The European Environment Bureau (EEB), a non-governmental lobby group consisting of 134 organizations in 25 countries, further calls for the member states in EU to create GMO-free zones. Head of EEB, Mauro Albrizio, states that *"the right to eat GM-free food will be severely compromised if GM crops are grown on a large scale. The Commission must accept that no one wants GM foods and that public authorities have every right to protect their consumers and environment."*

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