

**GETTING READY FOR EU LABELING & TRACEABILITY REGULATIONS**

**AN NFPA OVERVIEW – April 5, 2004**

## **Part 1: – Fact Sheet**

### **Introduction**

Legislation concerning the safety assessment, authorization, commercialization, labeling and traceability of foods and feeds produced from, or foods containing genetically modified organisms have been finalized. Regulations have been published in the Official Journal of the European Communities. These regulations are:

**Regulation (EC) No. 1829/2003** of the European Parliament and the Council (September 22, 2003) on genetically modified food and feed (Official Journal No. L268/ P.1, 18.10.2003).

**Regulation (EC) No. 1830/2003** of the European Parliament and the Council (September 22, 2003) concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products from genetically modified organisms and amending Directive 2001/18/EC (Official Journal No. L268/ P.24, 18.10.2003).

### **Key Provisions Of The New Regulations**

- The regulations introduce an obligation to inform customers when marketing a GMO or food containing a GMO ingredient as well as the obligation to maintain a system to trace the GMO in the food chain.
- The current criteria for labeling is changed from one of “detectable DNA and/or protein” to require labeling for all GM foods/feeds or foods containing GM ingredients regardless on the presence or absence of “detectable DNA and/or protein.” Labeling is based on genetic origin. This impacts ingredients like refined sugars and oils from GM grains and plants that must now be labeled. Under current rules, only GM foods with detectable GM DNA and protein require labeling.
- Labeling of animal feed is to indicate GM components becomes mandatory.
- The new threshold for labeling is “if > 0.9% GM material.” Therefore, labeling is now required for non-GM foods if the level of “adventitious presence” of GM material exceeds 0.9%.
- A threshold is also set for GM events “not-yet approved by the EC,” but which has passed an EC safety evaluation. If a food (or food ingredient) contains >0.5% not approved adventitious material, the food (or ingredient) must not be placed on the market.
- The new regulations do not apply to medicinal products for human and veterinary use.
- Labeling language shall be “genetically modified” or “produced from genetically modified ‘soy’” immediately following the ingredient concerned. The indications may appear in a foot not but shall be printed in at least the same size font as in the list of ingredients. Where there is no list of ingredients, the words shall appear clearly on the label.
- If a food is different from a conventional counterpart with regards to composition, nutrition value, intended use, has implications for the health of certain populations or gives rise to ethical or religious concerns, appropriate information shall also appear on the label.

### **Implementation Schedule**

- The 1830/2003 rules on food and feed apply 90 days after the publication in the Official Journal (January 18, 2004) on April 18, 2004.
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- The 1829/2003 rules will also come into effect on April 18, 2004. Processed products made before April 18th (even if in distribution) will not require labeling under the "new" labeling regulations: the old rules still apply. However, products made on/after the 18th must comply with the "new" labeling regulations.

## **Food Processors And Suppliers Are Subject To The New Rules And Are Required To:**

- Label GM foods, or foods containing GM ingredients, sold in the EC for GM presence and content.
- Trace the GM event in foods while the food is a “viable” organism (living modified organism – LMO). Once the organism is not viable, tracing the unique event further in the food chain is no longer necessary.
- Trace the GM content one step back and one-step forward so the final product can be labeled accurately. Retain tracking records and documents for 5 years.
- Maintain food chain and production control so that a non-GM food does not become mixed with GM materials at a level greater than 0.9%. If this occurs, labeling and traceability is required for the GM material.
- Maintain food chain and production conditions so that any food does not become mixed with unapproved (but with a positive safety assessment) GM materials at a level greater than 0.5%.
- Biotech companies will be guided by the European Food Safety Authority (EFSA) safety assessment procedures, to seek authorization for environmental release from the Commission with approvals for food and feed, providing detection methods and reference materials.
- Biotech companies will notify the Commission about GMOs, and food and feed products to be placed on the market that have received a favorable authorization.
- Biotech companies can assist with information about the unique identifier code for their products.
- Biotech supplier companies also need to re-authorized GM products already on the market as well as follow-up on future re-authorizations (authorization is for a 10 year period).

## **Part 2: EC Labeling and Traceability – Questions and Answers**

**Question:** When do I have to begin labeling for products sold in EU markets?

**Answer:** After April 18, 2004, GM products or products made with GM ingredients must be labeled.

**Question:** Will the product have the “unique identifier code” on the label as well as the fact that it contains GM ingredients?

**Answer:** No, products will never have the unique code on the label. Only agricultural, manufacturing, and production records will keep track of the code.

**Question:** Will processors have to keep track of the code throughout the food chain?

**Answer:** The code is for tracing the event through the food chain – from seed up to the point of non-viability. Once a viable GM organism (living modified organism -LMO) becomes non-viable, tracing the code from that point forward is no longer necessary. Only the fact that the material contains genetically modified XYZ (e.g. soy or corn) is important.

**Question:** Who handles the notification of foods or feed to be placed on the market?

**Answer:** Following a positive authorization (safety assessment, etc.), the biotech companies notify the Commission that genetically modified food or feed will be placed on the market and the notification includes the scope of the food/ feed involved.

**Question:** What are some examples of acceptable & unacceptable label statements?

**Answer:** Use the terms like: genetically modified [name of organism] or contains [name of ingredient] produced from genetically modified [organism]. Examples are:

1. For pre-packaged foods/ ingredients: This product contains genetically modified organisms; genetically modified maize; flour (contains flour produced from genetically modified maize). An asterisk with a footnote approach for ingredients is possible.
2. For foods with no ingredient statement: This product contains genetically modified organisms; rice (genetically modified); bread produced from genetically modified wheat; this product contains genetically modified tomatoes.
3. Avoid statements like: may contain genetically modified [organism]; contains GMOs; GM Free or Non-GM

**Question:** What food substances are excluded from labeling?

**Answers:**

- a) Animals fed GM feed do not require labeling as to GM content, neither do the animal products from those animals. So the meat, milk or eggs produced by these animals do not need to be labeled.
- b) The regulation covers food or feed produced “from” a GMO but not food or feed produced “with” a GMO. Some additives (used during processing and that serve no technical function in the finished product) are excluded from labeling. These include: processing aids, (carry-over) additives, carriers for flavorings or additives, and extraction solvents. For example, processing aids (like enzymes) where the food is “made with” the substance, do not require labeling of the processing aid

(examples, cheese & butter made with GM enzymes). Other additives, such as lecithin from GM soybeans, must be labeled.

- c) Fermentation products, such as those derived from GM feed stocks, are now being categorized as to their labeling requirements (the UK is the first to clarify a position). The GM labeling trigger is (1) use of a GM microorganism (GMM) and (2) GM substrate ends up in the finished product. For examples, see the chart provided by the UK (Page 7 of this Fact Sheet). We believe, at this time, that ingredients derived through fermentation processes (like ethanol and citric acid from GM corn or certain gums and other organic acids and alcohols) where a non-GM microbe is used would be exempt from labeling. The rationale is that they are changed on a molecular basis by a non-GMM and not just a fractional part of the original grain or plant. Also, one could say that the corn or grain is “fed” to non-GM microorganisms and that this is analogous to the feeding of animals where the animal products don’t require labeling, therefore the fermentation by-products don’t require labeling either. Key points of distinction as to labeling requirements involve considering the process, the microorganism and the presence in the final product.

**Question:** Is food sold by mass caterers or restaurants exempt from these traceability and labeling regulations?

**Answer:** Yes, food service products and restaurants are not required to trace or label biotech products. (**Note!** The UK and/or other States interpret this differently and may require mass catering outfits to label).

**Question:** Will refined GM foods like oils and sugars contain detectable GM DNA or GM protein?

**Answer:** While these GM foods or ingredients require labeling, it is reported (some literature is available) that they will not have detectable GM DNA or GM protein. One of the justifications for traceability requirements recognizes this inability to confirm GM origin of these foods using testing and therefore the need to keep records as to the GM origin and/or content is part of the regulation.

### **Part 3: EU Resource Materials Available Regarding Labeling and Traceability**

#### Q & A On the Regulation of GMOs in the EU - October 2003

This is a good review of the regulations in a two part document - A) legislation in force and B) new legislation on traceability & labeling (attached)

#### Regulation No. 1829/2003 and Regulation No. 1830/2003:

[http://www.europa.eu.int/servlet/portail/RenderServlet?search=RefPub&lg=en&nb\\_docs=25&domain=&in\\_force=NO&year=2003&month=10&day=18&coll=JO&nu\\_jo=&page=](http://www.europa.eu.int/servlet/portail/RenderServlet?search=RefPub&lg=en&nb_docs=25&domain=&in_force=NO&year=2003&month=10&day=18&coll=JO&nu_jo=&page=)

#### Unique Identifier Information:

Establishing a system for the development and assignment of unique identifiers for genetically modified organisms (Contact NFPA for a copy)

#### Authorization and Notification Rules Explanations:

On detailed rules for the implementation of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council as regards the preparation and the presentation of the application for the authorization 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 favorable risk evaluation (Contact NFPA for a copy).

#### Sampling and Detection Guidance:

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 (Contact NFPA for a copy).

#### Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed:

[http://www.europa.eu.int/comm/food/fs/sc/ssc/out327\\_en.pdf](http://www.europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf)

#### U.K. Guidance Notes and Compliance Draft Regulations

<http://www.foodstandards.gov.uk/foodindustry/Consultations/consulteng/gmosconsulteng>

Labeling chart from the UK guidance notes:

Appendix 6 – Examples of labelling requirements under EC Regulation No. 1829/2003 for authorised GMOs

GMO-type	Example	Labelling required from 18 April 2004
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
Fermentation products produced for food (GMM and non-GM substrate)	Beer, yoghurt	Yes
Food from animals fed GM animal feed	Meat, milk, eggs	No
Fermentation products produced for food (non-GMM and GM substrate)	Beer, yoghurt	No (providing no GM substrate remained in the final product)
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, Vitamin B2 (Riboflavin)	Yes
Feed additive produced from a GMO	Vitamin B2 (Riboflavin)	Yes
Fermentation products produced for food use (GMM and GM substrate)	Beer, yoghurt	Yes
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
Feed products produced by fermentation process (non-GM substrate and GMM)	Vitamins, enzymes	Yes
Feed products produced by fermentation process (GM substrate and non-GMM)	Vitamins, enzymes	No
Feed products produced by fermentation process (GM substrate and GMM)	Vitamins, enzymes	Yes
Food containing GM ingredients which are sold in catering establishments		Yes. However, we are aware that the Commission is seeking advice from lawyers on the interpretation of the wording in Regulation No. 1829/2003

GM – genetically modified  
GMM – genetically modified micro-organism

**Please note:** This overview is intended to raise awareness about the upcoming EU labeling and traceability regulations. It is not a comprehensive “how to” labeling guide and represents our best information to date. We expect some changes in interpretation to occur as the regulations are implemented. The EU has not yet provided implementing guidelines for these labeling regulations. Also, the various nations of the EU may interpret certain elements of the regulations slightly differently when they incorporate these regulations into their own regulatory and compliance schemes.

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