GM Guidelines for the European Food and Drink Industries

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1 - INTRODUCTION AND BACKGROUND DOCUMENTATION

These Guidelines seek to explain the requirements introduced by EC legislation[1] on genetically modified organisms, and aim to assist food and drink manufacturers with their practical application. They focus exclusively on food products. The relevance of the legislation for feed materials is not subject to these guidelines.

Two EC Regulations constitute the legal regime relating to the authorisation, labelling and traceability of genetically modified food and feed.

These are:

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ No L268/1, 18.10.2003)

and

- 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 from genetically modified organisms and amending Directive 2001/18/EC (OJ No L.268/24, 18.10.2003)

The previous legislation on the authorisation and placing on the market of genetically modified food, namely Regulations (EC) No 1139/98, 49/2000 and 50/2000, was replaced by the application of the aforementioned Regulations.

Regulation (EC) No 258/97[2], the Novel Foods Regulation, only applies to those novel foods whose novelty is not attributable to genetic modification.

Entry into force

Regulations (EC) 1829 and 1830 entered into force on 7 November 2003, and have applied since 18 April 2004. [3]

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[1] http://europa.eu.int/eur-lex/en/archive/2003/l_26820031018en.html

[2] *Regulation (EC) No. 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel food and novel food ingredients*
http://www.biosafety.be/GB/Dir.Eur.GB/FF/258_97/258_97.html

[3] i.e. 90 days after publication in the OJ of *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*
http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_010/l_01020040116en00050010.pdf

2 - DEFINITIONS

Conventional

By “conventional” food products, CIAA means food products to which the GM traceability/labelling obligations of Regulations (EC) 1829/2003 and (EC) 1830/2003 do not apply.

Ingredient

Article 2.13 of Regulation (EC) 1829/2003 refers to the term “ingredient” as defined in Directive 2000/13/EC[4]. Article 6.4 of Directive 2000/13 defines “ingredient” as:

“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”.

Substances not considered to be ingredients are listed under Article 6.4 of Directive 2000/13/EC (see Chapter 6.2 of these Guidelines).

GMO (Genetically Modified Organism)

Article 2.5 of Regulation (EC) No 1829/2003 refers to the definition of the term “genetically modified organism” used in Directive 2001/18/EC[5]. Article 2.2 of Directive 2001/18/EC defines “genetically modified organism” as:

“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”

Organisms obtained through the techniques listed in Annex I A Part 1 of Directive 2001/18/EC are considered to be genetically modified.

Organisms obtained through the techniques listed in Annex I A Part 2 are not. Organisms obtained through a technique listed in Annex I B are excluded from the definition.

A GMO (e.g. grain) is distinguished from a food or a food ingredient produced from GMOs (e.g. maize flour) by the fact that the former may reproduce and transfer its genetic material.

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[4] *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*
http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en_2000L0013_do_001.pdf

[5] *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*
http://europa.eu.int/eur-lex/en/consleg/pdf/2001/en_2001L0018_do_001.pdf

Traceability

Article 3.15 of Regulation (EC) No 178/2002[6] defines traceability as the:

"ability to trace and follow a food, feed, food-producing animal or substance… through all stages of production, processing and distribution".

Article 3.3 of Regulation (EC) No 1830/2003 defines the traceability of GMOs as:

"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".

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[6] *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*
http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

3 - MAIN PROVISIONS

3.1 - Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

In relation to the authorisation of Genetically Modified Organisms which should be placed on the market as food or feed products, the Regulation contains the following main provisions:

- It introduces a centralised procedure through EFSA (the European Food Safety Authority) for the safety assessment of genetically modified food and feed (Article 5 and 6, Recital 3);
- A “one door - one key” approach is adopted allowing for authorisation of the Genetically Modified Organism for its approval for food and feed use, as well as for products produced from the GM event (Article 27 and 4.4);
- Applicants (in other words, GM-event owners) will be required to provide detection and sampling methods, including samples, as part of the dossier (Article 5.3);
- Re-authorisation will be required after 10 years. This requirement also applies to existing products (Article 7.5 and 11.1).

With regard to labelling, the Regulation:

- Shifts the basis for labelling from presence/detection of genetically modified DNA or protein, to apply to any products produced or derived from GM material, regardless of the presence/detectability of genetically modified material (Article 12.1, Recital 21);
- Sets a threshold for adventitious and technically unavoidable presence of genetically modified material at 0.9% for authorised GM material (Article 12.2).

3.2 - Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms:

This Regulation provides for:

- Harmonised systems and standardised procedures for the documentation required to account for and identify GMOs, as defined by Directive 2001/18/EC, and products produced from GMOs, throughout the supply chain, with the objective of facilitating labelling, monitoring and, if necessary, withdrawal from the market;
- The obligation of suppliers to forward the information to purchasers that a food contains, consists of or is produced from a genetically modified organism (Article 5.1 and 4.1-2).

4 - SCOPE

Regulation (EC) No 1829/2003, Article 3.1 states that authorisation and supervision requirements apply to:

(a) GMOs for food use;
(b) Food containing or consisting of GMOs;
(c) Food produced from or containing ingredients produced from GMOs.

Regulation (EC) No 1829/2003, Article 12.1 states that labelling requirements apply to products which:

(a) Contain or consist of GMOs; or
(b) Are produced from or contain ingredients produced from GMOs.

Regulation (EC) No 1830/2003, Article 2.1 states that traceability and labelling requirements apply 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.

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5 - AUTHORISATION

5.1 -Requirements

GMOs covered by the scope (Article 3.1) of Regulation (EC) No 1829/2003 must undergo an authorisation procedure. The formal conditions hereto are laid down in Article 5 of the Regulation.

Each application for authorisation of a GM event must be accompanied by:

- Safety studies;
- Methods for detection and sampling;
- Samples of the food and their control samples.

and other information as stated in the article.

In the case of GMOs or food containing or consisting of GMOs, a technical dossier for those GMOs containing documentation on an environmental risk assessment and a monitoring plan also has to be provided (Article 5.5b), either in the form of a consent obtained under Directive 90/220/EEC or 2001/18/EC, or a full dossier with the purpose of obtaining the consent, as outlined in Regulation (EC) No 1829/2003.

5.2 -Products excluded from the scope of authorisation

5.2.1 - Processing Aids

Processing aids are excluded from the scope of authorisation, since, according to Article 6.4 of Directive 2000/13/EC, they are not "ingredients". This exclusion is further explained in Recital 16 of Regulation (EC) 1829/2003, which reads:

"…Processing aids which are only used during the food or feed production process are not covered by the definition of food and feed and, therefore, 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…"

The main examples of processing aids which are made with the help of GMOs are food enzymes. All food enzymes are used as processing aids, except two (invertase and lysozyme, which are authorised as additives and are not made with the help of a GMO).

5.2.2 - Food products from animals fed with GM-feed or treated with GM medicinal products

These are excluded, according to Regulation (EC) No 1829/2003, Article 3.1, because they are produced with, not from a GMO. This is further confirmed by Recital 16, which reads:

"…*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 the labelling requirements referred to in this Regulation...*".

5.2.3 - Foods produced by fermentation using GMMs (genetically modified micro-organisms) not present in the final product.

Examples of such food are products made with GMMs such as vitamins, amino acids, certain additives and flavours.

The record of the Standing Committee on the Food Chain and Animal Health, section on Genetically Modified Food and Feed and Environmental Risks of 24 September 2004[7] states the following:

"…..the Council did not intend the scope of Regulation No; 1829/2003 to include food produced by fermentation using GMMs ….. "

5.3 - Authorisation Procedure

5.3.1 - The role of EFSA (European Food Safety Authority)

The procedure under EFSA constitutes a centralised evaluation procedure (Recital 3 of Regulation (EC) No 1829/2003).

EFSA and its scientific panel are responsible for the safety assessment of applications for authorisation of GMOs and products produced from GMOs (Article 5 of Regulation (EC) No 1829/2003).

In order to prepare its opinion, EFSA may ask an appropriate food assessment body of a Member State to carry out the safety assessment of the food.

Likewise, a competent national authority may carry out the environmental risk assessment.

In the case of GMOs to be used as seeds or other plant propagating material, an environmental risk assessment must be carried out by a competent national authority (Article 6.3 of Regulation (EC) No 1829/2003).

5.3.2 - Steps of the authorisation procedure

The steps of the authorisation procedure, according to Regulation (EC) No 1829/2003, Article 5 - 7, are as follows:

1) The manufacturer (= GM event owner) sends an application to a national competent authority which subsequently forwards the application to EFSA;

[7] (Document no. 6780/03 ADD1; Inter-institutional file 2001/0173 (COD); adoption of a Common Position with a view to the adoption of a Regulation of the European Parliament and of the Council on genetically modified food and feed COMMON GUIDELINES; Statements to be entered into the Council minutes)

2) EFSA prepares an opinion, which is forwarded to the Commission, the Member States and the applicant, and which - after deletion of confidential information - is made public;
3) The Commission submits its draft decision to the Standing Committee on the Food Chain and Animal Health, taking into account EFSA's opinion and the data provided in support of the application;

The final decision is adopted according to the Comitology procedure.

5.3.3 - Duration of the authorisation

The authorisation will be valid throughout the Community for 10 years (Article 7.5 of Regulation (EC) No 1829/2003) and is renewable for ten-year periods.

To obtain renewal, the operator must apply at least one year before the expiry date of the current authorisation.

5.4 -Applications: Who does what?

5.4.1 - Notification of existing products

Operators responsible for placing existing products on the market (GMOs and their derivatives) which were legally on the EU market prior to the date of application of Regulation 1829/2003, namely as a result of authorisations under Directive 2001/18/EC or 90/220/EEC (deliberate release) or Regulation (EC) No 258/97 (novel foods) were invited to notify such products to the Commission with a reference to the date when they were first placed on the market (Article 8 of Regulation (EC) No 1829/2003).

The purpose of this was to maintain legal situations prevailing prior to the GM food and feed Regulation, until re-evaluation.

This notification took place between April 2004 and October 2004, ie during a 6-month time-period starting from the date of application[8] of the GM food and feed Regulation. GM-event owners have coordinated with relevant trade associations with a view to cover GM-events in question and all products produced from them. These products have been entered in the register of GM food and feed.

5.4.2 - Lists of existing products

A list of GMOs authorised in the EU prior to the entry into force of the Regulation 1829/2003 Regulation is available. See the DG Sanco website:
http://ec.europa.eu/food/food/biotechnology/authorisation/258-97-ec_authorised_en.pdf

[8] The determination of this date, and in general of periods, dates and time limits, is governed by Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, Official Journal L 124 , 08/06/1971 P. 0001 - 0002. English special edition: Series I Chapter 1971(II) P. 0354.

- For GMOs evaluated positively by an EU scientific committee before 18 April 2004 but not yet authorised, the provisional threshold of 0.5% was applicable until 18 April 2007.
  See DG Sanco website, section "Tolerance levels of adventitious presence of unauthorised material"
  http://ec.europa.eu/food/food/biotechnology/gmfood/tolerance_en.htm

  Following Commission Decisions 2007/304-308 of 25 April 2007, five genetically modified organisms (GMO), authorised in the EU for human and animal foods, were withdrawn from the market at the end of April 2007. This involves two varieties of maize (BT 176 and GA21xMON810) and three varieties of rapeseed (Ms1Rf1, MS1Rf2 and Topas 19/2).

- For GMOs authorised in third countries, see the OECD database: *http://www2.oecd.org/biotech/*

5.4.3 - Applications for authorisation of GMOs since 18 April 2004

Since 18th April 2004, GM event owners have applied for authorisation for food and feed uses, a procedure in which food operators are not obliged to be involved.

5.4.4 - Transitional measures

Where the genetically modified material has benefited from a favourable opinion from the EU Scientific Committee(s) or EFSA before 18 April 2004 (Article 47.1 of Regulation 1829/2003), and its prerequisites (e.g. publicly available detection methods) are fulfilled, the adventitious or technically unavoidable presence of this GM material below 0.5% is allowed in food. This transitional measure will remain applicable until 18 April 2007.

6 - LABELLING

6.1 -General labelling requirements

Community general labelling rules apply to all foods delivered to the final consumer or mass caterer in the Community (as described in Directive 2000/13/EC, Article 1.1-1.2 and 3 and Directive 2003/89/EC)[9]. The general labelling requirements also apply to products containing, consisting of or produced from genetically modified organisms.

6.2 - Products exempted from the scope of general labelling requirements

According to the Community general labelling requirements, the following categories are excluded from general labelling requirements because they are not considered "ingredients" as defined by Article 6.4 of Directive 2000/13/EC.

[9] *Directive 2003/89/EC of the European Parliament and of the Council of 10th November 2003, amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs*: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_308/l_30820031125en00150018.pdf

These exclusions also apply in the case of products containing, consisting of or produced from GMOs:

"(i) The constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(ii) Additives:
- Whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product;
- Which are used as processing aids;

(iii) Substances used in the quantities strictly necessary as solvents or media for additives or flavouring."

(iv) In addition, Directive 2003/89/EC, Article 1c, applicable since 25 November 2005, exempts from the labelling requirements:

"Substances which are not additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in altered form."

6.3 - Specific labelling requirements for GMOs and foods produced from GMOs

6.3.1 - Requirements

The scope of Regulations 1829/2003 and 1830/2003 is described in Chapter 4 of these Guidelines.

Requirements for GM-labelling will apply regardless of the presence/detectability of GM material (see Chapter 3 of these Guidelines).

Since 18 April 2004, labels must state for each ingredient whether it contains, consists of, or is produced from a GMO.

Any special characteristics or properties of the food or food ingredient specified in the authorisation of the GMO must be mentioned (Article 13.2 of Regulation (EC) No 1829/2003) as follows:

(a) Where the 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;

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

Foods which do not have a conventional counterpart must give "appropriate information in writing" about the nature and characteristics of the food concerned.

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6.3.2 - Products excluded from GM - labelling requirements

The following product categories are not subject to GM-labelling requirements:

- Products excluded from the scope of the GM Regulations (see Chapter 5.2 of these Guidelines);
- Products which are excluded from the definition of "Ingredients" in Article 6.4 of Directive 2000/13/EC (see point 6.2);
- Conventional products: products which contain, consist of or are produced from GMOs in a proportion no higher than 0.9 % of the ingredients considered individually or consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable (Article 12.2 of Regulation 1829/2003),[10]
  - The labelling threshold of 0.9% applies to each individual ingredient. It does not relate to the inclusion level of the food ingredient in the finished product, (Article 12.2 of Regulation (EC) No 1829/2003).
    Example: If a dish contains a sauce with soy flour in it, it is the soy flour which must contain less than 0.9% GM-material in order to avoid labelling, not the sauce or the entire dish.

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For which the supplier is able to demonstrate to the authorities that he has taken appropriate steps to avoid the presence of GM-material (Article 12.3, Article 47.2). CIAA has prepared Principles regarding "appropriate steps" to avoid the presence of material which contains, consists of or is produced from GMOs according to Articles 12, 24 and 47 of Regulation (EC) No 1829/2003 on genetically modified food and feed. See Annex B.

[10] With reference to Article 47.1 of Regulation 1829/2003, conventional products are also products that contain, consist of or are produced from GMOs in a proportion no higher than 0.5%, provided that the presence is adventitious or technically unavoidable, that the GM material has benefited from a favourable opinion from the Community Scientific Committee(s) or EFSA before the date of application of the GM Food and Feed Regulation, that the application for its authorisation has not been rejected in accordance with the relevant Community legislation, and that the detection method is publicly available.

- The Directive 2000/13/EC on labelling does not stipulate any requirements for labelling of products with their possible contents of foreign material, and therefore, by derogation, such requirements also do not apply for genetically modified material. CIAA considers therefore that Regulation 1829/2003 should be interpreted as taking into account, for the application of the 0.9% threshold, the presence of GM impurities only when they are of the same botanical origin as the food, ingredient or feed material at stake.

CIAA reads this as follows: conventional wheat flour, for example, may be found to contain traces of other botanical origin, including genetically modified plants, but the product is still only required to be labelled "wheat flour".

6.4 - How to label

6.4.1 - Wording

Article 13 of the Regulation (EC) No 1829/2003 specifies the wording to be used on the label as follows:

(a) Where the food consists of more than one ingredient, the following wording must follow immediately after the ingredient concerned, in brackets: “genetically modified” or “produced from genetically modified [name of ingredient]” (Article 13.1a) of Regulation (EC) No 1829/2003). A compound ingredient with a constituent X which is produced from a GMO Y must be labelled “contains X produced from genetically modified Y” (Article 6.8 of Directive 2000/13/EC as amended by Directive 2003/89/EC).

Example: a biscuit containing soya flour derived from GM-soya must be labelled “contains soya flour produced from genetically modified soya”.

(b) Where the ingredient is designated by the name of a category, the following wording must be used in the list of ingredients: “contains genetically modified [name of organism]”; or “contains [name of ingredient] produced from genetically modified [name of organism]”.

Example: For vegetable oils containing rape oil produced from genetically modified rape, the reference “contains rape oil from genetically modified rape” must appear in the list of ingredients (Article 13.1b of Regulation (EC) No 1829/2003).

(c) Where there is no list of ingredients, the words ‘genetically modified’ or‘ produced from genetically modified [name of organism]’ must appear clearly on the labelling (Article 13.1c of Regulation (EC) No 1829/2003).

Example 1: “A spirit containing caramel produced from genetically modified maize.”

Example 2: “Genetically modified sweet maize.”

(d) If the product consists of or contains a GMO, e.g. GM sweet maize in a Mexican salad, the label must state “genetically modified sweet maize”.

The designations in (a) and (b) may appear in a footnote to the ingredients list, provided that they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, printed clearly on the labelling.

6.4.2 - "Non-GM", "GM free" and similar terms

There is no EU legislation[11] which defines "non-GM", "GM free" and similar terms or lays down their use on food labels. As there is no clear definition of what this means and as it would be very difficult to achieve – and substantiate –"non-GM" or "GM free" in any commercially produced complex food product, CIAA advises against the use such terms.

6.4.3 - Non-pre-packaged foods and small containers

Where the food is offered non-pre-packed to the final consumer, or in small containers, of which the largest surface area is 10 cm^2 the information in writing specified above must be displayed as follows (Regulation (EC) No 1829/2003, Article 13):

Specifically:

- The reference to the GMO origin must be displayed on the display unit or within the immediate proximity in a legible manner (Article 13.1e) of Regulation (EC) No 1829/2003) or on the packaging itself.

  Example: "Bread produced from genetically modified maize".

6.5 - Using traceability to apply labelling requirements

Manufacturers use a large number of ingredients, sourced from many different suppliers. Since it is not always possible for manufacturers to know the precise origin of their ingredients, in order to fulfil labelling requirements in a correct manner, traceability is relied upon for all practical purposes (see Chapter 8 of these Guidelines).

CIAA interprets the requirements as follows:

- If the information in writing received from the supplier of the ingredient makes reference to the fact that the "ingredient is produced from genetically modified […]", this ingredient will have to be labelled accordingly.
- If the information in writing received from the supplier of the ingredient makes no reference to its GM-origin, the ingredient is considered as not consisting of, containing or having been produced from a GMO, and therefore, no GM-labelling is required.
- GM traceability requirements only apply to those products which have to be labelled according to Regulations (EC) No 1829/2003 and 1830/2003.

6.6 - Transitional measures

Article 46 of Regulation (EC) No 1829/2003 outlines the transitional measures to be taken.

[11] National legislation currently exists in several Member States.

Two important terms, "products" and "manufacturing processes" are used in Article 46.2 of the Regulation, which states that GM labelling requirements:

> *"...shall not apply to products, the manufacturing process of which has commenced before the date of application of this Regulation (18th April 2004), provided that these products are labelled in accordance with the legislation applicable to them before the date of application of this Regulation".*

The term "products" is broader than merely "ingredients". As a consequence, CIAA considers that GM-labelling is neither required nor possible for products for which GM-labelling was not required under previous legislation, if produced after 18 April 2004 using ingredients produced before 18 April 2004. The reason for this is that no traceability requirements had to be applied to GMOs or products produced from GMOs before 18 April 2004 (see Article 46.2 of Regulation (EC) No 1829/2003).

Likewise, "manufacturing processes of products" covers more than "manufacturing processes of ingredients". CIAA interprets that "manufacturing processes", as described in the Article, includes all products and therefore also the very first stage of processing.

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7 - METHODS OF ANALYSIS

Methods for detection and sampling are part of the requirements for each authorisation (see Chapter 5 of these Guidelines).

For validation of methods of detection, a Community reference laboratory has been established, the Joint Research Centre (JRC) (Article 32 of Regulation (EC) No 1829/2003).

See http://www.jrc.cec.eu.int

- Limits linked to the materials analysed

The detection and quantification of GMOs only has to be carried out on ingredients containing DNA or proteins.

Therefore, GMO analyses must be carried out upstream on a raw material before it is processed to possibly separate protein/DNA.

Example: Soya beans prior to crushing.

- Limits linked to the methods themselves

The methods of detection and quantification, the relevance of an analysis and choice of a provider laboratory must be taken into account by both authorities and food operators.

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8 - TRACEABILITY

8.1 -General requirements

Article 18[12] of Regulation (EC) No 178/2002, which lays down the requirement and provisions for traceability applies to all food products, with effect from 1 January 2005. It is generally interpreted as a) Information to be gathered as to whether the food/food ingredient contains or consists of GMOs. It is the responsibility of the food processor to know the origin of the product and its destination, and b) The unique identifiers for the GMOs (in accordance with Regulation 1830/2003) must be given. In general, the traceability rules in Regulation 178/2002 require knowledge "one step up, one step down", for example. This indicates a shared responsibility along the food chain, starting with the operator that first places the product on the market.

Operators should have in place systems which allow for traceability information to be made available to the authorities on demand. Food intended to be placed on the market should be adequately labelled or identified to facilitate its traceability through relevant documentation.

Since 1 January 2005, all food products face traceability requirements. CIAA recommends that documentation is kept by operators for the duration of the product's shelf life plus a reasonable period of time (typically 6 months).

8.2 – Specific requirements for GM food and feed and products produced from GMOs

Additional traceability requirements also apply to products produced from GMOs. (Article 13 of Regulation (EC) No 1830/2003).

Operators must retain traceability information in writing for a period of 5 years (Regulation (EC) No 1830/2003, Article 4.4).

8.2.1 - Requirements specific to products containing or consisting of GMOs

According to Article 4.1-2 of Regulation (EC) No 1830/2003 for products consisting of or containing GMOs, information in writing must be transmitted throughout all stages of the supply chain.

This traceability information must state that the product:

a) Contains or consists of GMOs, and
b) Must give the unique identifiers for the GMOs (in accordance with Regulation (EC) No 65/2004).

Example: Since 18 April 2004, bags of e.g. GM soya beans have had to be marked "genetically modified soya" and have had to mention the relevant unique identifiers.

[12] CIAA has developed Industry Guidelines for the application of Article 18 of Regulation 178/2002.

8.2.2 - Requirements for products produced from GMOs

Traceability requirements also apply to products produced from GMOs. (Article 5.1a, b and c of Regulation (EC) No 1830/2003). Information regarding which ingredients are produced from GMOs must be transmitted in writing. Information on unique identifiers is not required for products not containing or consisting of GMOs.

Example: Since 18 April 2004, bags with e.g. soya flour have had to be marked "produced from genetically modified soya," but they have not had to be marked with unique identifiers.

Information about traceability is of particular importance in the case of products produced from GMOs which do not contain detectable DNA or protein.

For products sourced in the EU, CIAA considers that in the event that the "information transmitted in writing" received from a supplier does not indicate GM content or origin of the product, it is reasonable, assuming the application of quality management in purchasing decisions and supply chains, to assume that the material or ingredient is of conventional origin.

Manufacturers who intend to maintain conventional supply chains will wish to take steps to satisfy requirements including the provisions set out in Article 18 of Regulation (EC) No 178/2002.

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9 - ANNEX A

MODEL LETTER TO SUPPLIERS FOR ANY PURCHASE FROM CONVENTIONAL SOURCES (WITH REGARD TO THE GMO ISSUE)

N.B: It is suggested that the CIAA guide be shared between customers and suppliers.

In this document, the term "conventional product" refers to a product which does not have to carry the statutory labelling as a product produced from GMOs within the framework of the requirements defined in Regulations (EC) No 1829/2003 and 1830/2003.

1 -The European Regulations concerning GMOs

Two Regulations were published in the Official Journal of the European Community on 18 October 2003:

- Regulation (EC) No 1829/2003 of the European Parliament and of the European Council on genetically modified food and feed. This has applied since 18 April 2004.
- Regulation (EC) No 1830/2003 of the European Parliament and of the European Council on the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. This has applied since 18 April 2004[13].

The main rules they introduce are the following:

- Each link in the food chain must inform its client in writing (for example via commercial documents such as delivery notes) when it passes on a GMO, a product containing a GMO or a product produced, totally or partially, from a GMO.
- Each link in the food chain must retain for 5 years the information in writing concerning such products and their "GMO" status: that provided by the supplier (“n-1”) and that provided to the clients ("n+1"). This is referred to as the obligation of GMO traceability.
- Products which are not GMOs or produced from GMOs, and which contain more than 0.9% adventitious GM-material are also covered by the scope. Thus, each link (operator) should know whether an ingredient contains more than 0.9% adventitious GM-material.
- Products which are not GMOs or produced from GMOs, and which contain less than 0.9% adventitious GM-material are also covered by the scope if it cannot be demonstrated that the presence of such material was indeed adventitious or technically unavoidable.
- Thus, in order to fall outside the scope, the supplier must be able to demonstrate to the competent authorities that it has implemented, at its level, adequate measures to avoid the presence of GMOs and products produced thereof.

[13] This entered into force on the 90th day following publication of *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*.

Other details concerning the GM rules:

- As in previous regulations, the labelling concerns the ingredients "produced from GMOs" and not products obtained "with GMOs". This means that, for instance, products from animals fed on GMOs do not need to be labelled.
- Since 18th April 2007, the provisional tolerance threshold of 0.5% for GM-material which has been favourably assessed but not yet approved, is no longer applicable.
- Following the withdrawal from the market of Bt-176 maize, a maize hybrid known as GA21/MON810, and three GMO rapeseeds: Ms1Rf1, Ms1Rf2 and Topas 19/2, the presence of material which contains or consists of GM events in food or feed products notified under Article 8(1)(a) and Article 20(1) of the Regulation will be tolerated until five years after the date of notification of the Decisions, (a) provided that this presence is adventitious or technically unavoidable; and (b) in a proportion no higher than 0,9 %.

Temporary measures:

- Since 18 April 2004, the labelling rules of the previous regulations (Regulations (EC) No 1139/98, 49/2000 and 50/2000), including the exemptions, no longer apply to products where food processing started.

2 - GMO policy of Company X

Company X (or “for its product Y, Company X”) does not want to find itself in the position of having to label its products (or "its product Y") as a GMO or as produced from GMOs.

3 - Consequences for the supplier

The policy of Company X states that its suppliers must only sell it conventional ingredients in the above sense of the term.

As a result of the application of the Regulations referred to above, if a product is sold with information in writing that does not mention its GMO status (on the label or on the accompanying documents), the product will be deemed to be conventional. In the event that their product contains less than 0.9% (0.5%) GM-material, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken, at their level, appropriate steps to avoid the presence of such material, and that any such presence is therefore adventitious and/or technically unavoidable.

9 - ANNEX B

PRINCIPLES REGARDING "APPROPRIATE STEPS" TO AVOID THE PRESENCE OF MATERIAL WHICH CONTAINS, CONSISTS OF OR IS PRODUCED FROM GMOS ACCORDING TO ARTICLES 12, 24 AND 47 OF REGULATION (EC) NO 1829/2003 ON GENETICALLY MODIFIED FOOD AND FEED

1 - Introduction

Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003 on genetically modified food and feed contain specific labelling requirements for genetically modified food (Articles 12 and 13) and feed (Articles 24 and 25). Article 47 of Regulation (EC) No 1829/2003 regulates "transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation".

Both the labelling provisions mentioned above and the transitional measures according to Article 47 contain so called "threshold provisions" intended to accommodate the possibility of material from GMOs being present in food and feed despite the fact that operators have tried to avoid the presence of such material.

The "threshold provisions" of Articles 12(2) and (3), 24(2) and (3) and 47(1) and (2) recognise the fact that such material may be present in traces in conventional food and feed as a result of adventitious or technically unavoidable "contamination" during seed production, cultivation, harvest, transport or processing. In the interest of the practicability and feasibility of the application of the Regulation, these "threshold provisions" foresee that, provided the thresholds are not exceeded, neither the labelling requirements nor the authorization requirements of the Regulation apply.

In order to establish that the presence of such 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 (Articles 12(3); 24(3) and 47(2)). Discussions on the scope and content of such "appropriate steps" within the food industry have led CIAA to agree on the principles you find hereafter. It is shown what may or may not be "appropriate steps" for operators to take in order to demonstrate that the presence of GM material is adventitious and technically unavoidable, has to be decided individually on a case –by-case basis.

2 - Adventitious or technically unavoidable presence according to articles 13(2) and (3), 24(2) and (3) and 47(1) and (2) of Regulation (EC) No 1829/2003

The experience gained on the issue under Regulation (EC) No 1139/98 should be taken into account in the forthcoming discussions, as according to Article 2(2) of Regulation (EC) No 1139/98, the possibility of adventitious presence of GM material in conventional food has been acknowledged and accepted ever since the introduction of this provision by Commission Regulation (EC) No 49/2000.

However, it has to be stressed that experience gathered in applying Regulation (EC) No 1139/98 to soy and maize products can and may not be directly transposed and applied to Regulation (EC) No 1829/2003 for the following reasons:

- Regulation (EC) No 1829/2003 on genetically modified food and feed is much broader in scope as it is not restricted to products that may contain genetically modified DNA or proteins, but covers all food and feed produced from GMOs.

- Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and products thereof has introduced an entirely new obligation to transfer information on genetically modified organisms and food and feed produced from them along the chain whenever they are placed on the market and, in addition, to put into place systems and procedures to secure that information.
- Regulation (EC) No 1829/2003 recognises that the presence of GM material may not only result from adventitious "contamination", but may also be "technically unavoidable", thereby broadening the scope of the threshold provisions to "contaminations" that are, whilst not adventitious, still unavoidable for technical reasons. Hereby the Regulation acknowledges the practical limitations to avoid the presence of traces of GM-derived material throughout seed production, cultivation, harvest, transport or processing (throughout the supply chain). Hence, the Regulation tolerates presence that is inherent because of the nature and geographical origin of the crop, the current structure of the supply chain, current industrial practices and premises, as far as the regulatory thresholds are met.

Regulations (EC) No 1829/2003 and 1830/2003 have therefore set a new legal background against which to assess whether the presence of GM material may be regarded as "adventitious or technically unavoidable" and what steps are considered to be "appropriate to avoid the presence of such material".

In particular, the obligation to inform operators throughout the food chain, at all stages of placing on the market of GMOs and products thereof, about the GM origin of those products in the interests of traceability, has had a direct effect on the "appropriateness of steps" to avoid foods and food ingredients from GM origin. Under the terms of the Regulations, operators can in all cases where no such information is distributed conclude that the foods and food ingredients concerned are not GM-derived. This has not been the case hitherto and will therefore have to be taken into account when assessing what, or, as the case may be, what additional "steps" will be necessary and appropriate.

"Appropriate steps"

The appropriateness of steps taken to avoid adventitious or technically unavoidable presence of GM material in conventional food or feed will depend very much on, inter alia, the origin, nature and composition of the food or food ingredient in question. In addition, the food business operator's position in the chain has to be taken into account. (i.e. the questions an operator should raise when doing his risk assessment are different if he is a 1st transformation industry, a compound ingredient manufacturer or a finished food manufacturer). Certainly, there is not a "one size fits all" system or method, because origins, nature and composition of food and feed may vary to such a degree that measures taken in relation to one may be superfluous or irrelevant in relation to another food or feed.

What measures are deemed appropriate therefore have to be decided on a case-by-case basis. Contractual specifications will be a core measure to avoid the presence of GM material. In many instances they will suffice and no other steps will be necessary, because they would not serve any purpose and therefore not be appropriate. If there is, for example, no GM-variety of an ingredient on the market or being cultivated where the ingredient is sourced, it would seem inappropriate to ask for additional measures to be taken to avoid the presence of GM-material. However, in other cases, those contractual specifications may or may not have to be

complemented by other means or steps, which may or may not include, for example, sampling, analysis, measures of segregation, traceability, identity preservation or other specific quality systems for segregation, or auditing, either to be taken by the supplier or buyer.

In addition, the measures mentioned above, which may or may not be part of the appropriate steps, will inevitably themselves need to be individually tailored and "appropriate" for the food or feed in question depending on contractual obligations which may be very general (e.g. "no GM derived products requiring labelling") or may be more specific. The design of sampling and analysis measures may depend on such factors as the origin of a product, its transport and storage conditions, the manner and degree of the changes it undergoes during the possibly many production stages, the analytical sensitivity and reliability of the method used which are of influence on how homogenous and/or representative sampling and analysis can be. Not least, such measures will be based on strategic decisions taking into account the differing risks of unintentional presence and/or the evolving product value along the supply chain. Finally, segregation and/or traceability or identity preservation systems of differing nature may or may not depend on the factors just mentioned, especially on the contractual obligation and the specifics of the product in question.

3- Appropriateness of steps according to individual "risk" assessment

The appropriateness of steps taken to avoid the adventitious or technically unavoidable presence of GM material in conventional food or feed essentially depends on the risk – in a non-technical (food safety) sense – of such presence in a given food or feed. Hence, it is the individual risk assessment concerning such presence which is crucial in deciding what steps need to be taken and regarded as appropriate in relation to an individual food, feed or ingredient.

That individual risk assessment may for example be based on the following criteria:

- The "botanical source or origin" of a food, feed or ingredient has to be assessed. If there is no GM or GM-derived variety on the market, there is little to no risk of adventitious or technically unavoidable presence of such material, and consequently, no additional "steps" would be necessary or appropriate.
- The "geographical source or origin" of a food, feed or ingredient has to be assessed. If there is no GM variety of a given product grown or processed in a defined geographical area, the source will not be GM and consequently no additional "steps" would be necessary or appropriate.
- If there is indeed a "risk" of sourcing a GM variety of a food, feed or ingredient or that risk cannot be excluded, the appropriateness of measures to avoid the presence of GM material has to be decided on the individual risk assessment. Design and scope of measures may vary, depending on the following:
    - The actual market situation for each crop;
    - Detectability of GM origin of product. Hence, measures may or may not include analysis, and a control plan may or may not be appropriate;
    - The contractual specification that the operator is trying to achieve for his customer as to the "GM-status" of a product, for example "no labelling". Accordingly, what needs to be done first is an individual "risk" analysis on the basis of the criteria just mentioned. This analysis will then lead to individual "appropriate steps" to be defined by each individual operator. Those steps are aimed at limiting the risk of unintentional presence of GM material as defined on that individual basis.

CONCLUSION

There is no “one size fits all” system or method of appropriate steps to avoid the adventitious or technically unavoidable presence of GM material in conventional food. Guidance can therefore only be given in terms of drawing up an inventory of the many factors to be observed and the many different steps and options to be considered, thereby aiming at enabling operators to choose the “steps” appropriate to their situation and product range.

The design of measures depends on the origin of raw materials and ingredients, transport and storage conditions, the manner and degree of the changes they undergo during the possibly many production and processing stages, the analytical sensitivity and reliability of the method used which are of influence on how homogenous and/or representative sampling and analysis can be, and not least on strategic decisions taking into account the differing risks of unintentional presence and/or the evolving product value along the supply chain.

CIAA is the voice of the EU food and drink industry – the largest industrial sector, major employer and exporter in the EU. CIAA represents the food and drink industries’ interests at the level of the European and international institutions, in order to contribute to the development of a European and international legislative and economic framework addressing and respecting the environment.

CIAA membership is made up of 25 national federations, including 3 observers from Central and Eastern Europe and the European Economic Area (EEA), 30 European sector associations and 20 major food & drink companies producing in Europe.

The permanent secretariat of the CIAA, based in Brussels, maintains close contact with European and international institutions on food-related developments and co-ordinates the work of experts, grouped in committees and working groups around the following three themes:

- Trade and Competitiveness
- Food and Consumer Policy
- Environment

Through these committees and expert groups, manufacturers from all the countries of the European Union provide broad and in-depth expertise. They contribute to establishing CIAA positions on key issues which, once approved, are communicated to European and international decision makers.

As a result of its longstanding work in the European and international field, CIAA has become a favoured partner of Community and international institutions on horizontal food issues such as food quality and safety, nutrition and health, novel foods, labelling, sustainable development and respect for the environment, the Common Agricultural Policy, international trade issues and enlargement.

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