
EFFA Guidance Document on the interpretation of GMO Legislation in the EU in relation to flavourings

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Introduction

Within the EU the use of genetically modified organisms (GMOs) in food and feed is regulated via various Regulations and Directives. This Guidance Document provides EFFA's understanding of the main GMO Regulations that are relevant for foods including flavourings for foods, namely Regulations (EC) 1829/2003 and 1830/2003. It replaces EFFA Position Paper FL/03/141.

Scope

This document covers:

1. The use of GMOs that are authorised to be marketed in the EU
2. 'Business to Business' traceability and labelling requirements for GMOs, products containing GMOs and products produced from GMOs as found in Regulations (EC) 1829/2003¹ and 1830/2003².

A clear distinction is made between products that are within the scope of these Regulations, and products that fall outside the scope of these Regulations. Elementary are the concepts 'produced from' *versus* 'produced with' which are explained by various examples.

1. Definitions of GMO

The definition of GMO is found in Directive 2001/18/EC 'on the deliberate release of GMOs into the environment'³. The definitions of 'Genetically modified food/feed' and 'produced from GMOs' are found in Regulation (EC) No 1829/2003.

Article 2(2) of Directive 2001/18/EC Definition 'GMO': 'genetically modified organism (GMO)' means 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; Within the terms of this definition:

- genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;
- the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

Art 2.6 of Regulation 1829/2003 Definition 'genetically modified food': 'genetically modified food' means food containing, consisting of or produced from GMOs

Art 2.7 of Regulation 1829/2003 Definition 'genetically modified feed': 'genetically modified feed' means feed containing, consisting of or produced from GMOs

Art 2.10 of Regulation 1829/2003 Definition 'produced from GMOs': 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs'

2. Regulation (EC) No 1829/2003 on genetically modified food and feed

Regulation (EC) No 1829/2003 was published on October 18, 2003 and concerns genetically modified food and feed. It needs to be read in conjunction with Regulation (EC) No 1830/2003 on GMO-traceability and labelling (See chapter 3).

2.1 Objective

The objective of Regulation (EC) No 1829/2003 is three-fold:

- The protection of 'life, health, welfare and consumer interests' whilst ensuring an effective internal market.
- The introduction of authorisation procedures and supervision.
- The introduction of provisions for labelling of GM Food and Feed.

2.2 Scope of the Regulation

The scope of the Regulation is found in articles 3.1 and 15.1. The Regulation applies to:

- GMOs for food/feed use,
- Food/feed containing or consisting of GMOs,
- Food/feed produced from or containing ingredients produced from GMOs.

2.3 Clarification of the scope: produced from versus produced with

Recital 16 provides explanations and further clarity on the scope of the Regulation: Food and feed *produced from* a GMO are covered.

Recital 16: “This Regulation should cover food and feed produced ‘from’ a GMO but not food and feed ‘with’ a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.”

Flavourings for use in foodstuffs also fall within the scope of this Regulation. This is clearly expressed in recital 13:

Recital 13: “..... flavourings for use in foodstuffs and to source materials for their production which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.”

In recital 16 it is explicitly mentioned that food and feed *produced with* a GMO do not fall within the scope of the Regulation. Also materials that are neither food nor feed (e.g., processing aids, medicinal products) do not fall by definition within the scope. The same applies to food and feed *produced with* the help of genetically modified processing aids. Illustrations of EFA’s understanding of what is in scope *versus* what is out of scope are provided in the table below.

in scope	out of scope
GMOs for food and feed use	Food and feed <i>produced with</i> a ‘GMO’
Food and feed containing or consisting of GMOs	Processing aids*
Food and feed <i>produced from</i> or containing ingredients <i>produced from</i> GMOs	Food and feed produced by fermentation using genetically modified micro-organisms
	Medicinal products*
	Food and feed from animals fed with GMO feed
	Food and feed from animals treated with medicinal GMO products

Table 1: list of materials in scope and out scope

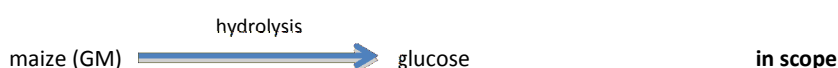
* processing aids and medicinal products are by definition out of scope

2.4 Examples

With publication of Regulation (EC) No 1829/2003 a number of questions came up on the interpretation of the scope which were addressed by the Standing Committee on the Food Chain and Animal Health (SCoFAH) and the UK Food Standards Agency (FSA). Some further explanation is provided by the examples below.

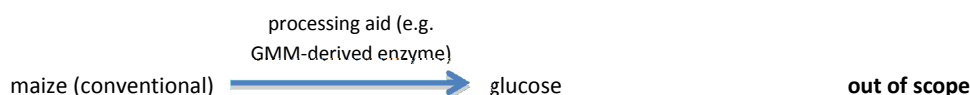
Use of GM source materials

In the case of a plant derived food ingredient, e.g. soya oil produced from genetically modified soya beans, there is no discussion on the interpretation of *produced from*. The genetically modified soya bean is the source of the food ingredient. Another example is glucose when obtained from genetically modified maize.

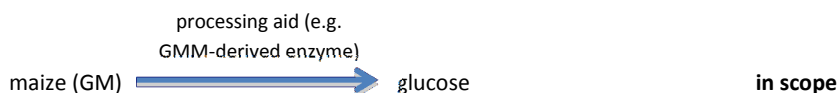


Use of processing aids such as enzymes

Many food or feed ingredients are produced with the help of *processing aids* like enzymes. Since *processing aids are by definition out of scope* these food or feed ingredients are out of scope. The status of these processing aids – GM derived or not – is not relevant.



If however the Source Material is GM-derived the end product is in the scope.



Use of Genetically Modified Micro-organisms

Food ingredients that are *produced with* genetically modified micro-organisms (GMMs) are in principle out of scope. These GMMs are used as processing aids. As outlined in recital 16 “*the determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed.*” In their meeting of September 24, 2004⁴ SCoFAH discussed food and feed (including flavourings) produced by fermentation using a GMM and reached the following consensus:

SCoFAH consensus on GMMs and fermentation: “Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is

- kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No 1829/2003. These food and feed have to be considered as having been **produced with** the GMM, rather than from the GMM.
- present in the final product, totally or partially, whether alive or not, are **included in the scope** of Regulation (EC) No 1829/2003, in regard of both authorisation and labelling.”

maize (conventional) $\xrightarrow{\text{GMMs}}$ glucose **out of scope**

maize (conventional) $\xrightarrow{\text{GMMs}}$ glucose + detectable GMM-material **in scope**

If however the Source Material is GM-derived the end product is in the scope:

maize (GM) $\xrightarrow{\text{GMMs}}$ glucose **in scope**

Use of GM-substrates/GM-feed

Micro-organisms require a substrate to grow and to perform their desired task (fermentation). *“Where a GM substrate is used, the final products will not require labelling providing there is no detectable material from the GM substrate in the final product.”* This interpretation was shared in January 2005 by the UK Food Standards Agency in a letter to interested parties⁵.

It perfectly aligns with the example provided in recital 16: *“Products obtained from animals fed with GM feed will be subject neither to the authorisation requirements nor to the labelling requirements.”*

GM-substrate $\xrightarrow{\text{yeast}}$ Ethanol (contains no detectable GM-material from the substrate) **out of scope**

GM-feed $\xrightarrow{\text{cow}}$ Milk (contains no detectable GM-material from the “substrate”) **out of scope**

3. Traceability and labelling

3.1 Traceability

The definition of ‘traceability’ in the context of GMO is found in article 3.3 of Regulation (EC) No 1830/2003.

Article 3.3 of Regulation (EC) 1830/2003 Definition ‘Traceability’: ‘Traceability’ means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains.’

The specific traceability requirements for products consisting of or containing GMOs are found in article 4.A.

Article 4.A of Regulation (EC) 1830/2003 'Specific Traceability Requirements':

1. *At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product: (a) that it contains or consists of GMOs; (b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.*
2. *At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.*
3. *In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.*
4. *Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.*
5. *Paragraphs 1 to 4 shall be without prejudice to other specific requirements in Community legislation.*

Under Article 4.A each operator in the supply chain is obliged to transmit information in writing to indicate both the presence and the unique identifiers of all GMOs in their products.

This implies that where no information is received from a supplier it can be assumed that the product falls outside the scope of Regulation (EC) 1829/2003 and therefore it does not contain or consist of GMOs as defined by the Regulation.

EFA recommends that for due diligence reasons members ask their suppliers about the status of purchased products in relation to Regulation (EC) No 1829/2003.

3.2 Labelling

The supplier/producer of flavourings has the obligation to inform his customer about the presence of ingredients produced from GMOs.

It is up to the customer to conclude on the labelling of the final food, taking into account the following elements:

- For foods that contain flavourings with flavouring ingredients from GMO it is always required that the words '*produced from genetically modified (name of the ingredient)*' shall appear in the list of ingredients of the final food, immediately following the flavouring concerned.
- For foods that contain flavourings with non-flavouring ingredients from GMO (e.g., carriers, additives) which do not have a technological function in the final food no labelling is required according to the legislation.

Flavourings intended for sale to the final consumer need to be labelled according to Art. 17 of Regulation (EC) No 1334/2008 and according to the GMO-labelling requirements.

3.3 Exemption from the traceability and labelling requirements

Exempted from these labelling and traceability requirements are *“Foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable”*. Recital 24 of the same Regulation provides further information: *“The marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.”* In fact the recital introduces the additional requirement that the 0,9 per cent exemption only applies for GMOs that are authorised to be marketed in the EU.

Operators might need to demonstrate to the competent authorities that they have taken adequate measures to avoid the presence of GMO material.

No threshold is set for non-authorised GMOs.

End notes / references

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

² Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

³ 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

⁴ Standing Committee on the Food Chain and Animal Health, Section on Genetically Modified Food and Feed and Environmental Risk, Summary record of the 3rd meeting – 24 September 2004.

⁵ Food Standards Agency, Letter to interested parties. Regulation (EC) No 1829/2003: GM FOOD AND FEED REGULATION, reference NFU 475, date January 4, 2005.

Disclaimer

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