Interpreting the prohibition of using genetic engineering in the production and for the processing of organic food

1. Background

The use of genetic engineering in organic food products is legally prohibited. The new EU Eco regulation **(Council Regulation (EEC) No. 834/2007)** which enters into force in early 2009, the prohibition of using GMOs described in the former Eco regulation is defined more precisely by, among other things, reference to the EU labelling regulation **(Regulation (EC) No. 1829/2003)** which also applies to conventional production.

2. Objective

It is the objective of this interpretation to contribute to the common understanding of the prohibition of using genetic engineering for producing and processing food according to the Council Regulation (EEC) No. 834/2007.

3. Basis

With the Regulation 834/2007, the revised version of the Council Regulation on Organic Agriculture, the EU has also reformulated the exclusion of GMOs and products produced from or by GMOs.

> THE COUNCIL OF THE EUROPEAN UNION – [...]
>
> Whereas:
>
> (9) | Genetically modified organisms (GMOs) and products produced from or by GMOs are incompatible with the concept of organic production and consumers' perception of organic products. They should therefore not be used in organic farming or in the processing of organic products.
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> (10) | The aim is to have the lowest possible presence of GMOs in organic products. The existing labelling thresholds represent ceilings which are exclusively linked to the adventitious and technically unavoidable presence of GMOs.

The regulatory authority states that the use of GMOs and products produced from or by GMOs in the production of organic food does not meet consumers' expectations. The authority concludes that GMOs and products produced from or by GMOs must not be applied for the production of organic food and that the presence of GMOs from contaminations for which neither organic farmers nor processors of organic food are responsible should be reduced to a minimum.

4. Horizontal scope of the prohibition of use

1. In Article 9, para. 1, the basic Regulation on Organic Agriculture defines the conventional resources, ingredients and additives concerned by the prohibition of the use of genetic engineering.

> **Article 9 Prohibition on the use of GMOs**
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> 1. GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals in organic production.

2. This requirement defines the 'system' of organic food production which is submitted to the inspection system recognised by community law for organic farming. It describes the areas the prohibition relates to and excludes other areas like detergents, veterinary medicinal products, commodities, fuels, etc.

3. Article 4 (a) (iii) clarifies once more that the use of veterinary medicinal products which are an GMO or were produced from or by GMOs is allowed in organic farming.

> **Article 4 Overall principles**
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> Organic production shall be based on the following principles:
>
> (a) the appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:
>
> (iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products;

4. Within the framework of inspections and accreditations for organic food, the chain from farming to the final product is considered. On all levels of this production chain it is excluded that GMOs or substances produced from or by GMOs are applied to biologic processes. Accordingly, this requirement is of practical relevance particularly in those areas where conventional products enter the organic food production system.

The implementing rules list the **permitted conventional resources, ingredients and processing aids** which are relevant in this context according to Article 9, 1.

5. Vertical scope of the prohibition of use

(1) None of the substances listed in Article 9, 1. must be a GMO. The definition in Article 2 (t) stipulates what a GMO is:

> **Article 2 Definitions**
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> (t) the definition of 'Genetically modified organism (GMO)' is that given in 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 (9) and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive;

Here, **GMO** is only understood to be an organism capable of replication and of passing on its genetic information. If it loses its capability of replication, for example through comminution, drying or heating, a substance produced 'from a GMO' is created.

A transgenic maize grain is a GMO as long as a new maize plant can be grown from it; as soon as it loses this quality, it turns into a substance 'from a GMO'.

2. None of the substances according to Article 9, para.1, and corresponding regulations in the implementing rules must be produced from or by GMOs. Article 2, para. (u) and (v) defines what a product manufactured 'from' or 'by' GMOs is:

Article 2 Definitions

(u) 'produced from GMOs' means derived in whole or in part from GMOs but not containing or consisting of GMOs;

(v) 'produced by GMOs' means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;

Accordingly, substances 'produced **from** GMOs' are products which were a part of a GMO.

Substances 'produced **by** GMOs' are usually substances produced with genetically modified microorganisms by way of biotechnological methods. To assess each of the substances according to Article 9, para. 1 (resources, ingredients, and processing aids) as a substance produced 'from' or a substance produced 'by' GMOs, the production process is **observed in a backward process from the final product to the point where an organism capable of replication is first encountered** and from which the substance originates or which has produced the substance (by). If this substance is not a GMO, the respective substance is suitable for organic farming.

(3) **Substances like additives, feeds, plant care products, or processing aids which are used to produce the conventional products approved for organic production according to Article 9, para. 1, and which are not components of the substances according to Article 9, 1., need not be considered.** This results from the fact that the conventional resources, ingredients and processing aids are not produced 'from or by' the processing aids. Accordingly, the field of consideration is defined.

6. Composite products

For composite products (formulations) it is necessary that each component (ingredient, carrier, co-formulant, etc.) meets the requirement to be free from GMOs and from products produced from or by GMOs. Technically unavoidable residues are not taken into consideration. If culture media are a component of a composite product, all other components must also be considered, for example in case of fluid cultures which are sold in the culture medium.

7. Providing evidence

1. Article 9, 2. and 3. describes how an organic enterprise has to provide evidence of not using GMOs and/or products produced from or by GMOs.

Article 9 Prohibition on the use of GMOs

2. For the purpose of the prohibition referred to in paragraph 1 concerning GMOs or products produced from GMOs for food and feed, operators may rely on the labels accompanying a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed (14) or Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

Operators may assume that no GMOs or products produced from GMOs have been used in the manufacture of purchased food and feed products when the latter are not labelled, or accompanied by a document, pursuant to those Regulations, unless they have obtained other information indicating that labelling of the products in question is not in conformity with those Regulations.

Here it is explicitly pointed out that the labelling according to the Regulation EC 1829/2003 within the scope of this inspection should be reliable. In this context, Articles 12 and 24 of this Regulation are particularly relevant.

Article 12 Scope

1. This Section shall apply to **foods** which are to be delivered as such to the final consumer or mass caterers in the Community and which:

(a) contain or consist of GMOs; or

(b) are produced from or contain ingredients produced from GMOs.

2. This Section shall not apply to 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.

3. In order to establish that the presence of this 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.

Article 24 Scope

1. This Section shall apply to **feed** referred to in Article 15(1).

2. This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this 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 materials.

According to Article 12, the labelling requirements on which an enterprise may rely in the inspection refer to all foodstuffs including their ingredients.

Concerning **feeds,** the information relates to the substances defined in Article 15, para. 1.

Article 15 Scope

1. This Section shall apply to:

(a) GMOs for feed use

(b) feed containing or consisting of GMOs;

(c) feed produced from GMOs

2. This level of consideration deals with the conventional substances according to Article 9, para. 1 (Regulation 834/2007) which are allowed to enter into the system of organic food; consequently substances which were used for production but do not remain in the product need not be considered (refer to 5, 3.)

3. For substances according to Article 9, para. 1 of Regulation 834/2007 like processing aids, plant protection products, fertilisers and soil conditioners which might have been produced from GMOs or might contain GMOs but which are not subject to labelling according to the Regulation 1829/2003, a compliance agreement to the prohibition of GMOs must be obtained (Article. 9, para. 3) which states clearly that the product intended for use in organic food production is not a GMO and was not produced from GMOs. According to Article 69 of the implementing rules, the compliance agreement may follow the template suggested for use in Appendix XIII of the implementing rules.

Article 9 Prohibition on the use of GMOs

3. For the purpose of the prohibition referred to in paragraph 1, with regard to products not being food or feed, or products produced by GMOs, operators using such non-organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs.

(4) Substances which might have been 'produced by GMOs' are not subject to the labelling requirements of the Regulation 1829/2003. Thus, a compliance agreement (Article 9, para. 3) should be obtained for all substances which might have been produced by GMOs according to Article 9, para. 1 of the Regulation 834/2007 to state clearly that the product intended for use in organic food production was not produced by GMOs. The Regulation 889/2008 suggests formulations for such compliance agreements in Appendix XIII.

8. Contaminations

The Regulation 834/2007 creates a link to the labelling requirements of Regulation 1829/2003. This Regulation stipulates that all GMOS or food and feed produced from GMOs must be labelled as such. There is an exception concerning adventitious or technically unavoidable contamination up to a maximum of 0.9%, which need not be labelled. According to the requirements of Article 12, para. 3 and Article 24, para. 3 of the Regulation 1829/2003, operators must be able to demonstrate that they have taken appropriate steps to avoid the presence of such materials if they do not label GMO contaminations below 0.9%.

In the opinion of Waiblinger et al. (2007)[1], the current state of technology makes it normally possible to avoid contaminations significantly below 0,9 % in the food products sector. The GMO thresholds[2] which, as a rule, are presently met by most of the market partners are less than approx. 0.1% for maize and less than approx. 0.2% for soy. From this it follows that, for products which are contaminated with GMOs above these thresholds but were not labelled, suppliers must prove specifically which measures they have taken to avoid this and that these measures usually have the desired effect.

Article 9 Prohibition on the use of GMOs

2. [...] Operators may assume that no GMOs or products produced from GMOs have been used in the manufacture of purchased food and feed products when the latter are not labelled, or accompanied by a document, pursuant to those Regulations, unless they have obtained other information indicating that labelling of the products in question is not in conformity with those Regulations.

From the requirement of Article 9, para. 2, second clause, it follows that an operator who supplies a batch of raw materials exhibiting a GMO contamination which, according to the state of technology, is above the usually avoidable level but has not been labelled as a genetically modified product must be able to prove that he has taken all relevant measures to prevent this contamination. The operator must also be able to demonstrate that the existing contamination is technically unavoidable or adventitious.

If a buyer detects a GMO contamination in non-labelled raw materials which is above the level to which the contamination can be reduced according to the state of technology, he should request the supplier of the goods to provide evidence that the existing contamination is technically unavoidable or adventitious. This way he can ensure that the raw materials do not have a negative impact on the GMO labelling status of his products.

[1] H. U. Waiblinger, N. Graf, D. Mäde and K. Woll (2007): Der Begriff „technisch nicht zu vermeiden“ – Ansätze zur Interpretation bei der Kontrolle gentechnisch veränderter Lebensmittel. Published in Deutsche Lebensmittel- Rundschau, Vol. 3, 2007.

[2] The mentioned thresholds can be applied exclusively to authorised GMOs. There is zero tolerance for unauthorised GMOs.

9. Derogation

Legislation provides for the possibility that substances produced by GMOs may be used in organic products subsequently to permission granted by the Article 37 Commission. For this, four conditions need to be fulfilled:

- The substance must not be available on the market in conventional quality.
- The use of the substance in foods or feeds is mandatory because of other legal provisions.
- The substance must be authorised for the use in organic products independent of the production process.
- The commission has to agree to the use of the substance in GMO quality.

Article 22 Exceptional production rules

2. Exceptions as referred to in paragraph 1 shall be kept to a minimum and, where appropriate, limited in time and may only be provided for in the following cases: [...]

(g) where it is necessary to use food additives and other substances as set out in Article 19(2)(b) or feed additives and other substances as set out in Article 16(1)(d) and such substances are not available on the market other than produced by GMOs;

10. Examples

A feed mill supplies a feed mix which contains 1.5% of an authorised construct that is genetically modified in its soy component. There is a proportion of 5% of soy in the mixture. The feed must not be sold as organic because one single component exceeds the **labelling threshold** of the Regulation 1829/2003. The feed may only be sold with the statement 'contains GMOs'.

A farmer supplies maize with GMO traces of MON 810 in the range of 0.05% to a mill. The product can be used as an organic product. Traces under 0.1% are considered to be unavoidable or adventitious.

A feed mill is offered organic soy with a content of 0.7% GMOs. The mill must only use this raw material if the supplier can reasonably demonstrate that the GMO contamination was technically unavoidable or adventitious; otherwise, the product must be labelled 'contains GMOs' and must not be used for organic production. xxx It must be guaranteed that the microorganism which produced the vitamin was not genetically modified.

When checking a sample, a processing enterprise detects that a batch of maize (without GMO labelling) is contaminated with 0.6% of GMOs. According to the current state of technology there are grounds for suspecting that the contamination was avoidable. The supplier is requested to provide evidence that all appropriate measures have been taken to protect the batch from contamination. In case the pre-supplier can furnish substantial proof of this, the product can be further processed without having an impact on the GMO labelling status. Otherwise the processed products must be labelled accordingly but cannot be declared to be an organic product.

A processing enterprise buys vitamin C/ascorbic acid for its organic production. As additives are not subject to legal labelling requirements with reference to their GMO status, a GMO compliance agreement is to be obtained. It must be guaranteed that the microorganism which produced the vitamin was not genetically modified.

If starch is obtained 'from' maize and the maize was GMO maize, the starch is a product obtained 'from GMOs'. If lecithin is obtained from soy as a by-product of oil processing and the soy was genetically modified, then the lecithin is produced 'from GMOs'. The fertilisers, sprays or used processing aids like, for example, enzymes, which were applied for the production of the maize

or soy are not to be considered for the assessment of the substance was produced ‘from GMO‘.

If, for example, a vitamin is biotechnologically produced by means of a genetically modified microorganism, then this vitamin is produced ‘***by GMOs*’*.*** For this, the organism that was last used in the production chain of the vitamin is to be considered. The components of the substrate used as a culture medium and the processing aids used during reprocessing are not to be considered for the assessment whether the substance was produced ‘***by GMOs***’.