

Interpretation of the ban on the use of genetic engineering in the production and processing of organic food

1. Background

The use of genetic engineering in organic food products is legally prohibited. In new **EU regulation on organic production No. 2018/848** which is into force since 1st January 2022, 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 (EU) No. 2018/848.

3. Basis

With the new version of EU organic regulation by regulation no. 2018/848, the EU has recast the exclusion of GMOs and products made from or by GMOs.

Article 11 Prohibition of the use of GMOs

(1) GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms or animals in organic production.

(2) For the purposes of the prohibition laid down in paragraph 1, with regard to GMOs and products produced from GMOs for food and feed, operators may rely on the labels of a product that have been affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council ⁽¹⁾ or Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾ or any accompanying document provided pursuant thereto.

(3) Operators may assume that no GMOs and no products produced from GMOs have been used in the manufacture of purchased food and feed where such products do not have a label affixed or provided, or are not accompanied by a document provided, pursuant to the legal acts referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those legal acts.

(4) For the purposes of the prohibition laid down in paragraph 1, with regard to products not covered by paragraphs 2 and 3, operators using non-organic products purchased from third parties shall require the vendor to confirm that those products are not produced from GMOs or produced by 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 prohibition of use

In Article 11, paragraph 1, the basic organic regulation defines to which conventional inputs, ingredients and auxiliary substances of agricultural or non-agricultural origin the prohibition on the use of genetic engineering applies to.

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.

Article 5 (f) (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 5 General principles

Organic production is a sustainable management system that is based on the following general principles:

- a) respect for nature's systems and cycles and the sustainment and enhancement of the state of the soil, the water and the air, of the health of plants and animals, and of the balance between them;
- b) the preservation of natural landscape elements, such as natural heritage sites;
- c) the responsible use of energy and natural resources, such as water, soil, organic matter and air;
- d) the production of a wide variety of high-quality food and other agricultural and aquaculture products that respond to consumers' demand for goods that are produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare;
- e) ensuring the integrity of organic production at all stages of the production, processing and distribution of food and feed;
- f) the appropriate design and management of biological processes, based on ecological systems and using natural resources which are internal to the management system, using methods that:
 - i) use living organisms and mechanical production methods;
 - ii) practice soil-related crop cultivation and land-related livestock production, or practice aquaculture which complies with the principle of the sustainable exploitation of aquatic resources;
 - iii) exclude the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products;
 - iv) are based on risk assessment and the use of precautionary measures and preventive measures, where appropriate;

g) the restriction of the use of external inputs; where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, the external inputs shall be limited to:

- i) inputs from organic production; in the case of plant reproductive material, priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic agriculture;
- ii) natural or naturally-derived substances;
- iii) low solubility mineral fertilisers;

h) the adaptation of the production process, where necessary and within the framework of this Regulation, to take account of the sanitary status, regional differences in the ecological balance, climatic and local conditions, stages of development and specific husbandry practices;

i) the exclusion from the whole organic food chain of animal cloning, of rearing artificially induced polyploid animals and of ionising radiation;

j) the observance of a high level of animal welfare respecting species-specific needs.

In the context 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 for consideration according to Article 11.

5. Vertical scope of prohibition of use

None of the substances listed in Article 11 must be a GMO. The definition in Article 3 (58) stipulates what a GMO is:

Article 3 Definitions

(58) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council ⁽³⁾ which is not obtained through the techniques of genetic modification listed in Annex I.B to 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'.

None of the substances according to Article 11 and corresponding regulations in the implementing rules must be produced from or by GMOs. Article 3 defines what a product manufactured 'from' or 'by' GMOs is.

Article 3 Definitions

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

(60) '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 biotechnological methods.

In order to assess each of the substances according to Article 11 (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.

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 11, and which are not components of the substances according to Article 11, 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. This defines the scope of consideration.

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. Nachweisführung

Article 11 describes how an organic enterprise has to provide evidence of not using GMOs and/or products produced from or by GMOs.

Article 11 Prohibition of the use of GMOs

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(3) Operators may assume that no GMOs and no products produced from GMOs have been used in the manufacture of purchased food and feed where such products do not have a label affixed or provided, or are not accompanied by a document provided, pursuant to the legal acts referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those legal acts.

It is explicitly pointed out that this verification can be based on the labeling according to Regulation EC 1829/2003. In this context, Articles 12 and 24 of this Regulation are particularly relevant.

Article 11 Prohibition of the use of GMOs

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8. Contaminations

The Regulation 2018/848 represents a reference 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 prove that they have taken appropriate steps to avoid the presence of such materials if they do not label GMO contaminations below 0.9%.

According to 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 thresholds² 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. 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.

As per requirement of Article 11, an operator who supplies a batch of raw materials having 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 explain 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. So 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. 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 state 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.

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.

(1) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

(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 (OJ L 268, 18.10.2003, p. 24).

(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 (OJ L 106, 17.4.2001, p. 1).

(4) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

(5) 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 (OJ L 268, 18.10.2003, p. 24).
