

Guideline on withdrawal of unauthorised genetically modified food and feed

This Guideline is designed for use by food and feed sector operators and control authorities. Evira has not been conferred legislative competence in this matter and cannot therefore issue binding regulations. The interpretations presented in this Guideline constitute Evira's views on how legislative regulations should be applied. Issues pertaining to the application of legislative regulations are in the last instance settled by a court of law. The European Union has not yet initiated the preparation of a common application guide. Should the European Commission issue instructions pertaining to this matter, Evira will revise this Guideline accordingly.

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Pursuant to Article 4 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, the safety of foods and feeds containing, consisting of or produced from genetically modified organisms (GMO) must be assessed before they are placed on the market within the Community. For this reason they may not be placed on the market until their safety has been assessed and they have been authorised.

If a food or feed contains unauthorised GMO, the product will be withdrawn from the market. If food or feed placed on the market is found by authorities in a control inspection or by the food business operator himself to contain unauthorised GMO, or if information of this is received through the RASFF system (Rapid Alert System for Food and Feed), the operator must take immediate action. Depending on the situation, the operator must discontinue the sales of the product from stock and initiate procedures to withdraw the food or feed from the market. The operator shall also inform competent authorities about the matter. Evira informs the other member states of the EU about the matter through the RASFF system. The further processing of food and feed withdrawn from the market shall be agreed on with the control authority.

The procedure to be followed in case a food or feed contains unauthorised GMO is described in the following:

- 1. The product contains unauthorised GMO, but an application has already been submitted for the authorisation of that GMO**
 - ***If EFSA has issued a positive opinion on the safety of the GMO***
→ The food or feed business operator must withdraw the product from the market, i.e. from retail stores and from production. The food or feed need not be recalled from consumers or feed users.
 - ***If EFSA has not issued an opinion on the safety of the GMO***
→ The product must be withdrawn from the market and the consumers or feed users must be informed of the withdrawal, and products already supplied to them must be recalled (General Food Law Regulation (EC) No 178/2002¹, Articles 7 and 19).
- 2. The product contains GMO about to be removed from the market (authorisation has expired and the operator has not applied for re-**

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council 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

² Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

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authorisation, but the Commission's decision defines a transitional period for the removal of the product from the market, and the maximum content of the GMO)

- ***If the maximum content is not exceeded***

→ No action required during the transitional period.

- ***If the maximum content is exceeded***

→ The food or feed business operator must withdraw the product from the market, i.e. from retail stores and from production. The food or feed need not be recalled from consumers or feed users.

3. The product is found to contain unauthorised GMO for which an authorisation application has not been submitted

→ The product must be withdrawn from the market and the consumers or feed users must be informed of the withdrawal, and products already supplied to them must be recalled, because the safety of the GMO has not been assessed (General Food Law Regulation (EC) No 178/2002¹, Articles 7 and 19).

4. The product is suspected to contain unauthorised GMO for which an authorisation application has not been submitted

→ Sales from stock must be discontinued temporarily until the composition of the product has been established.

→ If the suspicion proves correct:

→ Sales from stock must be discontinued for good.

→ The product must be withdrawn from the market and the consumers or feed users must be informed of the withdrawal, and products already supplied to them must be recalled (General Food Law Regulation (EC) No 178/2002¹, Articles 7 and 19).

In individual cases the authorities can apply this Guideline on a risk-informed basis and according to the proportionality principle (Administrative Act 434/2003 Section 6, Control Regulation (EC) No 882/2004² Article 54). According to the proportionality principle, the extent of regulatory action must be in keeping with the severity of the violation and the possible risks caused by the product.

This Guideline replaces previous guidelines on the withdrawal of genetically modified food and feed (17015/2 and REHU 810/1).

Revisions to previous version:

- A paragraph about the binding force of the Guideline added at the beginning
- A paragraph about the proportionality principle added at the end
- Feed user added
- References to regulations made more explicit and consistent
- Minor revisions of word order and phrases

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council 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

² Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules