These guidelines are intended for food and feed business operators and control authorities. Finnish Food Authority has not been conferred legislative competence in this matter and cannot therefore issue binding regulations. The interpretations presented in these guidelines constitute the views of the authority in charge of food and feed control on how legislative regulations on food and feed should be applied. Issues pertaining to the application of legislative regulations are in the last instance settled by a court of law. Should the European Commission issue guidelines pertaining to this matter, Finnish Food Authority will revise these guidelines accordingly.

Guideline on withdrawal of unauthorised genetically modified food and feed

Pursuant to Article 4 of Regulation (EC) No 1829/2003[1], the safety of foods and feeds containing, consisting of or produced from genetically modified organisms 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. Genetically modified materials that have and have not been authorised in the EU can be checked from the register maintained by the Commission.

If a food is found to contain unauthorised genetically modified material, the product will be withdrawn from the market. Pursuant to Commission Regulation (EU) No 619/2011[2], in feed, the tolerance level for unauthorised genetically modified material is 0.1 % if the EU authorisation procedure of the genetically modified feed material is pending or its authorisation has expired. The same applies in the case of genetically modified material authorised in third countries for which the EU authorisation procedure is currently in progress. If the concentration of such genetically modified material is 0.1 % or higher or any other unauthorised genetically material is found from the feed, the feed must be withdrawn from the market.

If a food or feed placed on the market by the company is found by authorities in a control inspection or by the food business operator himself to contain unauthorised genetically modified material, or if information to this effect is received through the RASFF (Rapid Alert System for Food and Feed) system, the operator must take immediate action. Depending on the situation, the operator must discontinue the sales of the product concerned from its stocks and initiate procedures for withdrawing the food or feed from the market. The operator is also required to inform competent authorities about the matter. Finnish Food Authority will inform the other EU Member States of the matter

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

[2] Commission Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired

through the RASFF system. The further processing of food and feed withdrawn from the market must be agreed upon with the regulatory authority.

The procedure to be followed in the case that a food or feed contains unauthorised genetically modified material is described below:

1 The product contains unauthorised genetically modified material for which an application for authorisation has already been filed

- If the European Food Safety Authority (EFSA) has issued a favourable opinion on the safety of the material
  → The food business operator must withdraw the product from the market, i.e. from retail stores and from production. The product need not be recalled from consumers.
  → The feed business operator must determine the genetically modified ingredient involved and the concentration thereof. If the concentration of the genetically modified material is low (< 0.1 %) and it falls under the scope of Commission Regulation (EU) No 619/20111, the feed may be used. Otherwise, the above procedure instructed for food business operators applies.
- If EFSA has not issued an opinion on the safety of the genetically modified material
  → The product must be withdrawn from the market and consumers or feed users must be informed of the withdrawal, and care must be taken to ensure that any products already supplied to them are recalled (General Food Law Regulation (EC) No 178/2002[3], Articles 7 and 19).

2 The product contains genetically modified material about to be removed from the market (authorisation has expired and the operator has not applied for re-authorisation, but the Commission's decision defines a transitional period for the removal of and the allowed maximum content for the product concerned)

- If the maximum content is not exceeded
  → No action required during the transitional period.
- If the maximum content is exceeded

[3] 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

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

3 The product is found to contain unauthorised genetically modified material for which an application for authorisation has not been filed

→ The product must be withdrawn from the market and consumers or feed users must be informed of the withdrawal, and care must be taken to ensure that any products already supplied to them are recalled, because the safety of the genetically modified material has not been assessed (General Food Law Regulation (EC) No 178/2002[4], Articles 7 and 19).

4 The product is suspected of containing unauthorised genetically modified material for which an application for authorisation has not been filed

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

- If the suspicion proves correct:
  → Sales from the stocks must be discontinued permanently.
  → The product must be withdrawn from the market and consumers or feed users must be informed of the withdrawal, and care must be taken to ensure that any products already supplied to them are recalled (General Food Law Regulation (EC) No 178/2002, Articles 7 and 19).

The authority may apply this guideline a case-by-case basis on a risk-informed basis and according to the proportionality principle (Administrative Procedure Act 434/2003, Section 6, Control Regulation (EC) No 882/2004[5], 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.

Coming into force

This guidance has come into force on 15.5.2020 and it replaces the previous version (The Finnish Food Safety Authority Evira's guidance 10019/2, published on 7.3.2017).

[4] 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
[5] 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

Updates in version 5

The guidance has been converted from The Finnish Food Safety Authority Evira's instruction to that of the Finnish Food Authority.