

Product Safety Unit

Instructions for withdrawal of unauthorised novel foods from the market

This Guideline is designed for use by food 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 the views of the authority supervising food control 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.

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Novel foods refer to foods and food ingredients which have not prior to the year 1997 been used for human consumption to a significant degree within the European Union. Pursuant to Regulation (EC) No. 258/97 on Novel Foods, authorisation is required for placing foods classified as novel foods on the market and to obtain the authorisation, the food shall pass a safety assessment. New processes, such as foods produced using nanotechnology, also fall under the Novel Food Regulation.

There are no comprehensive lists of novel foods or authorised products. Under the Food Act (23/2006, Section 16), operators in the food sector are responsible for their products being safe and compliant with food regulations. As far as novel foods are concerned, the operators are also responsible for establishing and, if necessary, proving the history of use and the novel food status of the food. Particularly with respect to plants, which are not commonly known for their use as food (such as exotic plants from non-EU countries or wild plants with no known prior use as food), the operators shall verify that they have had significant history of commercial use as food within the EU prior to the adoption of the Novel Food Regulation (15 May 1997).

Only authorised novel foods may be placed on the market. If unauthorised novel foods are found on the market, they will have to be withdrawn, because the safety of the product as food has not been verified. Finnish Food Safety Authority Evira will inform authorities in other countries, if necessary, through the RASFF alert system about an unauthorised food.

Information on novel foods is available on Evira's website at

<https://www.evira.fi/en/foodstuff/manufacture-and-sales/common-requirements-for-composition/novel-foods/>

and on the website of the Commission at

http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm.

Examples of food products and food ingredients, which have been classified as novel foods but have not been authorised for placing on the market under the Novel Food Regulation

- Leaves of the Stevia plant (*Stevia rebaudiana*) and food containing them
- *Hoodia gordonii* cactus
- Nangai nuts (*Canarium indicum*)

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Revisions over previous version:

The guide has been updated according to the Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods