

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 If unauthorised novel foods are found on the market, they will have to be withdrawn, because the safety of the product as food has not been verified.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 http://www.evira.fi/portal/en/food/manufacture_and_sales/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 them¹⁾
- *Hoodia gordonii* cactus²⁾
- Products containing betaine. The use of betaine and betaine hydrochloride is permitted in food supplements, however³⁾
- Nangai nuts (*Canarium indicum*)⁴⁾
- Yacon or *Smallanthus sonchifolius*⁵⁾

Product Safety Unit

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- 1) Commission Decision 2000/196/EC refusing the placing on the market of *Stevia rebaudia* plants and dried leaves as a novel food or novel food ingredient. Authorisation was granted as of 2 December 2011 pursuant to EU regulations on additives to using steviol glycosides produced from the leaf extract of the Stevia plant as sweetener.
- 2) Opinion of novel food authorities on Hoodia cactus (Cafab 9/03/2004) and RASFF notifications.
- 3) Commission Decision 2005/580/EC refusing the placing on the market of betaine as a novel food or novel food ingredient. Instead, betaine and betaine HCl have been used in food supplements prior to the year 1997 and thus their use is authorised in food supplements.
- 4) Commission Decision 2001/17/EC refusing the placing on the market of nangai nuts as a novel food or novel food ingredient.
- 5) Yacon or *Smallanthus sonchifolius* is according to the Commission's Novel Food Catalogue considered to be a plant with no known history of use as food within the EU prior to 15 May 1997; in other words, it is considered to be a plant that requires novel food authorisation
http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/mod_search/index.cfm?action=mod_search.details&seqfce=259.

Revisions over previous version:

- The word "unauthorised" added in the heading
- New text added about e.g. food produced using nanotechnology and about the responsibilities of operators in the food sector
- The text has been reformulated and re-paragraphed
- The examples have been updated