

## Instructions on withdrawal of novel foods from the market

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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.

## Instructions on withdrawal of novel foods from the market

Operators in the food processing industry must ensure that foods and food ingredients that have not been used for human consumption to a significant degree within the European Union, and which fall under the categories listed in the Novel Food Regulation (258/97) Article 1 are in accordance with the legislation on novel foods before placing products on the market.

Information on novel foods is available on the Finnish Food Safety Authority Evira's website at [http://www.evira.fi/portal/en/food/information\\_on\\_food/novel\\_foods/](http://www.evira.fi/portal/en/food/information_on_food/novel_foods/) and on Commission's website [http://ec.europa.eu/food/food/biotechnology/novelfood/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm). The websites also include a list of applications for novel foods within the EU and related decisions and notifications in accordance with the Novel Food Regulation (258/97, Articles 4.2 and 7).

There is no comprehensive list of food ingredients regarded as novel foods. With exotic ingredients in particular, the company must always ensure that the ingredients have been significantly used for human consumption within the European Community before the Novel Food Regulation came into force in May 1997. If it is possible to prove reliably that the food ingredient has been used before that, it is not classified as a novel food. Instead, if the food or food ingredient is classified as a novel food, it cannot be placed on the market before it has been authorized under Regulation 258/97.

### Example of a defect that leads to withdrawal of the product:

*If a food or food ingredient that is regarded as a novel food has not been authorized under the Novel Food Regulation, and if it has not undergone the single safety assessment through a Community procedure before being placed on the market within the European Community.<sup>i</sup>*

The defect is serious and will lead to the withdrawal of the product since its safety as a food has not been confirmed.

The Finnish Food Safety Authority Evira informs the EU RASFF alert system of withdrawals of novel foods.

### Examples of food ingredients and products regarded as novel foods but use of which as a food is prohibited within the EU

- Extracts, capsules and powders made of noni (*Morinda citrifolia*). Only noni juice and leaves as well as puree and concentrate made of noni<sup>ii</sup> that have been given a safety assessment and authorization can be placed on the market.

Product Safety Unit

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- Foods containing stevia (*Stevia rebaudiana*) and marketing of the plant for use as a food<sup>iii</sup>
- *Hoodia gordonii* cactus<sup>iv</sup>
- Products containing betaine. Only the use of betaine hydrochloride in nutrition supplements is permitted<sup>v</sup>
- Nangai nuts (*Canarium indicum*)<sup>vi</sup>
- Clinoptilolite<sup>vii</sup>

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<sup>i</sup> Placing novel foods on the market is subject to licence. Novel foods require an approved safety assessment in accordance with the Novel Food Regulation (258/97) and a Community decision before being placed on the market.

<sup>ii</sup> Commission Decision 2003/426/EC authorizes the noni juice of Morinda Inc., and dozens of other similar noni juice brands have been authorized since then (see the Finnish Food Safety Authority Evira's list on novel foods). A favourable novel food decision has also been issued on the leaves of the plant *Morinda citrifolia* (2008/985/EC) and on puree and concentrate made of noni (2010/228/EU). Other food products made from noni may not be brought onto the market. Noni products have caused several RASFF notifications (August 11, 2006 no 2005.858; December 21, 2005 no 2005.959; January 11, 2006 no 2006.ACU; February 28, 2006 no 2006.AOV; May 8, 2006 no 2006.BCM; May 15, 2006 no 2006.0313; November 22, 2006 no 2006.CRS; December 15, 2006 no 2006.CWI).

<sup>iii</sup> Commission Decision 2000/196/EC prohibits the placing on the market of '*Stevia rebaudiana* Bertoni: plants and dried leaves' as a food or novel food ingredient. RASFF notification January 11, 2006 no 2006.ACS and August 7, 2006 2006.AXN.

<sup>iv</sup> The statement of the authorities for novel food on the use of Hoodia cactus (Cafab 9/03/2004) and RASFF notifications (November 8, 2005 no 2005.791; January 11, 2006 no 2006.0031).

<sup>v</sup> Commission Decision 2005/580/EC prohibits the placing on the market of betaine as a food or novel food ingredient. RASFF 2006.0314add03.

<sup>vi</sup> Commission Decision 2001/17/EC prohibits the placing on the market of nangai nuts (*Canarium indicum* L) as a food or novel food ingredient.

<sup>vii</sup> The decision of UK authorities prohibits clinoptilolite from being placed on the market (3 september 2008).

### Revisions over previous version:

- Link to Evira's web site updated
- Link to Commission's web site on novel foods added
- Decision 2010/228/EU on noni puree and concentrate added in the example