

## Permitted vitamins and minerals in fortified foods, and their sources

By virtue of Article 3 of the Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (1925/2006/EC, hereinafter Fortification Regulation) only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods.

By way of derogation from the aforesaid, until 19 January 2014, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

- a) the substance in question is used for addition to foods marketed in the Community on 19 January 2007

and

- b) the European Food Safety Authority EFSA has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food, on the basis of a dossier supporting use of the substance in question submitted to the Commission by the Member State not later than 19 January 2010.

### Practice in Finland

The use of vitamins and minerals not listed in Annex I (e.g. boron), or in the forms not listed in Annex II (e.g. chromium picolinate) for addition to foods is allowed until 19 January 2014, provided the aforementioned conditions are fulfilled.

Operators wishing to use vitamins and minerals not listed in Annex I (e.g. boron), or in the forms not listed in Annex II (e.g. chromium picolinate) for addition to foods manufactured by or for the operators shall submit to the Finnish Food Safety Authority by **15 December 2009**:

1. A clarification to the effect that the substance in question has been used for addition to foods marketed in the Community prior to the enforcement of the Fortification Regulation (19 January 2007).
2. The dossier required for the evaluation of safety in compliance with the guidelines issued by the Scientific Committee on Food of the European Commission on 11 July 2001 (Guidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods). The guidelines are available at [http://ec.europa.eu/food/fs/sc/scf/out100\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out100_en.pdf). The dossier shall also include a summary document that can be separated.

The dossier shall be submitted to the following address:

Finnish Food Safety Authority Evira  
Mustialankatu 3  
00790 Helsinki  
Finland

or by e-mail to:  
kirjaamo@evira.fi

The Finnish Food Safety Authority will submit the dossier to the Ministry of Agriculture and Forestry for forwarding to the Commission.

A company wishing to import a food to which vitamins and minerals not listed in Annex I, or in the forms not listed in Annex II have been added shall verify that the manufacturer of the product has submitted or is about to submit the required dossier, via the national authority in the country of the manufacturer, to the Commission or that the required dossier is submitted by the Finnish importer to Evira (by 15 December 2009) for forwarding, via the Ministry of Agriculture and Forestry, to the Commission.

The dossier need not be submitted if EFSA has already in connection with evaluations of nutritional substances related to food supplements expressed an opinion on the suitability of the substance to fortified foods. EFSA's opinions are published on the Internet at

[http://ec.europa.eu/food/food/labellingnutrition/supplements/food\\_supplements.pdf](http://ec.europa.eu/food/food/labellingnutrition/supplements/food_supplements.pdf) .

If a dossier, which also pertains to fortified foods, has been submitted to EFSA in connection with evaluations of nutritional substances related to food supplements, the dossier need not be submitted again. However, if the operator has any new evidence related to the matter (research, etc.), Evira recommends that such evidence be submitted to EFSA using this procedure.

The use of vitamins and minerals not listed in Annex I, or in the forms not listed in Annex II will be prohibited as of 1 February 2010, unless the required dossier on the use of such vitamins and minerals in fortified foods has been submitted to the EU Commission no later than 19 January 2010.

More information about the evaluation procedure of nutritional substances is available at

[http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm\\_guidance\\_safety\\_substances\\_en.pdf](http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf).