

Guidelines for withdrawal of fortified foods from market

Public authority action shall be based on legislative competence conferred to the authority and public authority action shall be consistent with legislation. Authoritative guidelines are not, by their legal nature, binding on other authorities or operators. Issues pertaining to the application of legislative regulations are in the last instance settled by a court of law.

These Guidelines present both direct quotations from legislation and interpretations on the application of legislation. Legal quotations are clearly distinguished from the rest of the text. The interpretations presented in these Guidelines constitute Evira's views on how legislative regulations should be applied.

Fortification of foods refers to the addition of nutrients, usually one or several vitamins and/or minerals, to the food in conjunction with manufacture. Foods fortified with nutrients are regulated by Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (the Fortified Food Regulation).

Pursuant to Article 3 of the Fortified Food Regulation, only vitamins and minerals listed in Annex I to the Regulation may be added to fortified foods, and they must be in the forms listed in Annex II to Regulation 1170/2009. Further, pursuant to Article 17(1) of the Fortified Food Regulation, the vitamins and minerals referred to in Item f) of the Community Register (Article 9) may be used in fortified foods, provided an unfavourable opinion has not been given in respect of their use. The adding of other vitamin formulations and mineral substances is forbidden, because they have not been considered suited for adding to foods or no safety evaluation has been carried out on them.

The fortification of products included within the scope of the Fortified Food Regulation* with vitamin formulations and mineral substances other than the aforesaid is a severe violation, which will result in the withdrawal of the food from the market.

The operator shall in such a case instigate action to remove the foods from the market. General principles for the removal of foods from the market are presented in Evira's Guidelines for withdrawal:

http://www.evira.fi/portal/en/food/manufacture_and_sales/guidelines_on_withdrawal_of_products/

If proven necessary by a risk assessment, the operator shall take withdrawal action also as a result of other fortification errors, if food safety could be endangered or consumers are being essentially misled. Examples:

- due to a dosage error, the amount of nutrient added to food is so high that it could endanger the safety of consumers
- the vitamin or mineral is not present in the food in a significant amount even after fortification

More information about fortification is provided on Evira's web site at:

http://www.evira.fi/portal/en/food/manufacture_and_sales/addition_of_nutrients_to_food/

* The provisions of the Fortified Food Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC. This Regulation shall apply without prejudice to specific provisions laid down in Community legislation concerning: a) foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended; b) novel foods and novel food ingredients; c) genetically modified food; d) food additives and flavourings; e) authorised oenological practices and processes.