Guide on withdrawal of fortified foods

1 Introduction

Fortification of foods is the addition of nutrients, or most commonly one or several vitamins and/or minerals to food in conjunction with manufacturing. The rules for fortified foods are laid down 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 Regulation on Fortified Foods).

The actions of an authority must be based on the powers granted to it by legislation, and the laws must be strictly adhered to in activities performed as a public authority. By their legal nature, instructions issued by authorities are not binding on other authorities or operators. Issues pertaining to the application of legislation are ultimately settled in a court of law.

This Guide includes both direct quotations from the legislation and interpretations of the application of the legislation. Legislation is clearly separated in the text. The interpretations presented in this Guide are the Food Authority's opinion of how the legislation should be applied.

2 Accepted vitamins and minerals and their forms in fortification and prohibited or restricted substances in EU

Accepted vitamins and minerals

According to article 3 in the Regulation on Fortified Foods only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods. It is prohibited to add other vitamin and mineral compounds.

The provisions of the Regulation on Fortified Foods regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC. The 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.

Prohibited or restricted substances

Under article 8 in the Regulation on Fortified Foods, the addition of substances other than vitamins and minerals to food can also be prohibited if the use of the substances have been identified as having a harmful effect on health. These substances are included in annex III to the regulation, parts A-C, as follows:

- Part A: Prohibited substances
- Part B: Restricted substances
- Part C: Substances under Community scrutiny

More information related to prohibited, restricted or substances under scrutiny from the Finnish Food Authority's web site.

3 When the operator must take measures concerning fortified foods?

The product must be withdrawn if

- products that are covered by the Regulation on Fortified Foods have been fortified with vitamin and mineral compounds other than mentioned above or
- the product contains substances that are prohibited according to annex III part A, or if the product is in breach of the restrictions in part B

In these cases, the operator must take measures to withdraw the product from the market. The general principles for withdrawal of food from the market are presented in the Food Authority's guide on withdrawal of food.

Based on their risk assessment, the operator must take measures to withdraw the product also due to other errors in fortification, if the food safety may be endangered or the consumer is being significantly misled. If for example:

- due to a dosage error such a large amount of a fortified nutrient has been added to the food that it exceeds the tolerable upper intake level (UL) and endangers the consumer's safety or
- the vitamin or mineral added to the food does not result in the presence of at least a significant amount after fortification

If the tolerable upper intake level (UL) has exceeded, the actions to manage the health risk shall be considered specifically in each case depending on the circumstances. Examples of possible risk management measures are for example:

- the reduction of the level of the nutrient in question in the product,
- changing the instructions for use so that the UL value is not exceeded in the recommended dose,
- a warning statement on the labelling, or
- some other action that will ensure the food is safe for consumers.

If the above-mentioned actions are not possible to implement or if the food is targeted at vulnerable consumer groups and / or the levels of consumption are high (e.g. beverages), an excessive content of a vitamin or mineral is a severe safety risk and must result in the withdrawal of the product from the market.

For more information on fortified foods,

- From the website of the Food Authority
- Guidelines for the control of fortified foods (The Finnish Food Authority's guide 6538/04.02.00.01/2021).

4 Coming into force

This guidance has come into force on 15.11.2021 and it replaces the previous version (The Finnish Food Authority's guidance 17051/3, published on 19.12.2019).

Updates in this version:

The guide has a correction to a reference to the updated Food Authority's guidelines for the control of fortified foods.