

Commission Implementing Regulation (EU) No 489/2012 of 8 June 2012 establishing implementing rules for the application of Article 16 of 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 489/2012

of 8 June 2012

establishing implementing rules for the application of Article 16 of 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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods<sup>(1)</sup>, and in particular Article 16 thereof,

Whereas:

- (1) Article 16 of Regulation (EC) No 1925/2006 establishes that the Commission shall submit, by 1 July 2013, a report to the European Parliament and the Council on the effects of implementing that Regulation. With regard to this, the Member States shall provide the necessary relevant information to the Commission.
- (2) The necessary relevant information to be provided by the Member States should relate to the evolution of the market in foods to which vitamins and minerals have been added, including data demonstrating trends in the market since harmonisation at Union level of the addition of vitamins and minerals to foods.
- (3) Such information should include consumption patterns of foods to which vitamins and minerals have been added and information on intake of vitamins and minerals by the population and by specific population groups if appropriate. This should include information that demonstrates changes in dietary habits since harmonisation of the addition of vitamins and minerals to foods.
- (4) The relevant information to be provided by the Member States should also relate to the addition of substances other than vitamins or minerals to foods, including food supplements, as defined by Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements<sup>(2)</sup>. Such information should include information on the consumption of such foods and the amounts of the substances added, and on any national measures whether legislative or not, that have been taken so as to restrict or prohibit the use of certain other substances in foods.

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- (5) It is necessary by way of these implementing rules to establish a list of the relevant information that Member States should collect and provide to the Commission, and to set a common format for presenting this information.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

### *Article 1*

#### **Subject matter**

This Regulation establishes implementing rules for the application of Article 16 of Regulation (EC) No 1925/2006 and in particular on the provision of the necessary relevant information by the Member States to the Commission for the purpose of evaluating the effects of implementation of the Regulation (EC) No 1925/2006.

### *Article 2*

#### **Relevant information**

1 Member States shall by 1 July 2012 provide to the Commission the necessary relevant information in particular concerning the following:

- a evolution of the national market in foods to which vitamins and minerals have been added since the date of application of Regulation (EC) No 1925/2006;
- b consumption patterns of foods to which vitamins and minerals have been added;
- c intake levels of vitamins and minerals by the population;
- d the addition of substances other than vitamins or minerals to foods, including food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC and the information on the consumption patterns of such foods as well as the amounts of these substances added to foods and food supplements.

2 The necessary relevant information to be provided by the Member States to the Commission referred to in paragraph 1 shall include at least the information specified in Annex I to this Regulation.

The necessary relevant information and details thereof shall be submitted to the Commission in the format laid down in Annex II to this Regulation.

3 A Member State shall inform the Commission if any of the information specified in Annex I is not available or cannot for any other reason be provided to the Commission by 1 July 2012.

### *Article 3*

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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Done at Brussels, 8 June 2012.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX I

### **Necessary relevant information to be provided by the Member States for the purpose of evaluating the effects of implementation of Regulation (EC) No 1925/2006**

A. Information concerning the evolution of the national market in foods to which vitamins and minerals have been added shall include the following:

1. general information on the national market including the market share of specific foods or food categories;
2. information on trends in the evolution of the national market.

The information referred to in points 1 and 2 shall include the information for the foods which contain the most commonly added vitamins and minerals and information on the amounts of vitamins and minerals added to foods. Such information may be obtained from commercially available market reports, national monitoring measures and other relevant and defined sources.

B. Information on consumption patterns of foods to which vitamins and minerals have been added shall include the following:

1. information on the consumption patterns of specific foods or food categories to which vitamins and minerals have been added for the population and if appropriate, for specific population groups, including such information for the foods which contain the most commonly added vitamins and minerals and information on the amounts of vitamins and minerals added to foods;
2. information obtained from nationally representative dietary consumption surveys, data from academic studies and other relevant and defined sources, including the information on the dietary survey methodology, such as the dietary assessment methodology, and the population subgroups and age groups assessed;
3. information on any observed changes in overall dietary habits and trends in the consumption of foods to which vitamins and minerals have been added, in particular those changes that may be associated with the date of application of the Regulation (EC) No 1925/2006. Member States shall provide the details for the basis of these observed changes, including details on the base-line data used to compare past and current consumption of foods to which vitamins and minerals have been added.

C. Information on the intake levels of vitamins and minerals shall include the following:

1. information on the intake levels for vitamins and minerals for the population and, if appropriate, for specific population groups. This information shall be obtained from the data sources referred to in point B.2 of this Annex;
2. information on any observed changes in intake levels for vitamins and minerals including trends in the levels of intake that may be associated with the date of application of Regulation (EC) No 1925/2006. Member States shall provide the details for the basis of these observed changes, including details on the base-line data used to compare intake levels of vitamins and minerals prior to and after the date of application of Regulation (EC) No 1925/2006.

D. Information on the addition of substances other than vitamins or minerals to foods shall include the following:

1. information on the national market in foods to which certain other substances have been added, including the market share of specific foods or food categories;

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2. information on the national market in food supplements, as defined by point (a) of Article 2 of Directive 2002/46/EC;
3. information on the most commonly added substances to foods based on information from commercially available market reports, national monitoring measures and other relevant and defined sources and shall include information on the levels of addition of other substances to specific foods or food categories;
4. information on national measures including legislative and non-legislative measures that aim to restrict or prohibit the use of other substances in the manufacture of foods, including food supplements.

## ANNEX II

### Format for the presentation of the information provided by the Member States

#### *Evolution of the market in foods to which vitamins and minerals have been added*

Type of information to be provided	Source of data
National market share of different food products to which vitamins and minerals have been added by food category, as defined by the 20 main food categories of the food classification system FoodEx <sup>a</sup> , excluding foods for particular nutritional uses and food supplements.	
Trends in the market size for foods to which vitamins and minerals have been added, and in particular information on the market prior to and after the date of application of Regulation (EC) No 1925/2006.	

<sup>a</sup> European Food Safety Authority; The food classification and description system FoodEx 2 (draft- revision 1). Supporting Publications 2011:215. [438 pp.]. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

#### *Consumption patterns of foods to which vitamins and minerals have been added*

Type of information to be provided	Source of data
<p>Average consumption levels by the population of foods to which vitamins and minerals have been added.</p> <p>Average consumption levels of foods to which vitamins and minerals have been added according to the following population groups:</p> <ul style="list-style-type: none"> <li>— adults (18 years and above);</li> <li>— children (under 18 years); and if appropriate, by specific age groups; and</li> <li>— by food category as defined by the 20 main food categories of the food classification system</li> </ul>	

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FoodEx, excluding foods for particular nutritional uses and food supplements.	
Amounts of vitamins and minerals added to the foods, according to the 20 main food categories of the food classification system FoodEx. This shall be provided as amounts or ranges of amounts added.	
Observed changes in consumption patterns of foods to which vitamins and minerals have been added including data on base-line data used to compare consumption prior to and after the date of application of Regulation (EC) No 1925/2006.	

#### *Intake levels of vitamins and minerals*

<b>Type of information to be provided</b>	<b>Source of data</b>
Average intake levels for vitamins and minerals for the population. Average intake levels for vitamins and minerals according to the following population groups: — adults (18 years and above); — children (under 18 years); and if appropriate, by specific age groups.	
Dietary survey methodology (mainly methods for dietary assessment, age groups, population subgroups).	
Observed changes in intake levels for vitamins and minerals including data on base-line data used to compare intake levels prior to and after the date of application of Regulation (EC) No 1925/2006.	

#### *Addition of substances other than vitamins or minerals*

<b>Type of information to be provided</b>	<b>Source of data</b>
National market share of food products, including food supplements, to which other substances have been added, according to the following categories of substances used: 1. Amino-acids 2. Enzymes 3. Prebiotics and probiotics 4. Essential fatty acids and other special fatty acids 5. Botanicals and botanical extracts 6. Other substances.	

ANNEX II

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Trends in the market size and in particular information on the market prior to and after the date of application of Regulation (EC) No 1925/2006.	
National measures that concern the restriction or prohibition of the use of other substances in the manufacture of foods, including food supplements.	

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- (1) [OJ L 404, 30.12.2006, p. 26.](#)
- (2) [OJ L 183, 12.7.2002, p. 51.](#)



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**Changes and effects yet to be applied to :**

- [Regulation revoked by S.I. 2019/651 reg. 47](#)