REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 307/2012

of 11 April 2012

establishing implementing rules for the application of Article 8 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

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 [1], and in particular Article 8(6) thereof,

Whereas:

(1) Requests by Member States or on the initiative of the Commission, to initiate the procedure under Article 8(2) of Regulation (EC) No 1925/2006 to prohibit, restrict or place under Union scrutiny a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals that is added to foods or used in the manufacture of foods should meet certain conditions and uniform rules should be established for checking that these conditions are met. One of the conditions laid down in Article 8(1) of Regulation (EC) No 1925/2006 is that the intake of the substance should greatly exceed normal intake of a balanced and varied diet and it should present a potential risk to consumers as demonstrated by relevant scientific data. Further, Article 8(1) of Regulation (EC) No 1925/2006 provides that the procedure should also be applied where the substance presents a potential risk to health for reasons other than a great excess of its normal intake. In addition, Article 8(1) of Regulation (EC) No 1925/2006 provides that the substance should be added to foods or used in the manufacture of foods.

(2) For the purpose of the application of the condition mentioned above, dietary intakes of the concerned substance that greatly exceed those expected under normal conditions of consumption of a balanced and varied diet should reflect actual intake of the substance and not a theoretical assumption of intake, and should be assessed on a case-by-case basis in comparison with the average level of intake of the substance by the general adult population or other population groups for which potential risks to consumers have been identified.

(3) The Member State putting forward a request should provide the necessary information to demonstrate that the conditions required by Regulation (EC) No 1925/2006 are met. This should include information on the placing on the market of food products containing the substance and the available and relevant generally accepted scientific evidence that associates the substance with a potential risk to consumers. Only those requests ascertained as complete should be sent to the European Food Safety Authority (hereafter 'the Authority') for a safety assessment based on the available information. The Authority should adopt an opinion on the safety of the substance within a specified time limit as laid down in Article 29(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council [2]. Interested parties should be allowed to submit comments to the Commission following the publication of the opinion by the Authority.

(4) Article 8(4) of Regulation (EC) No 1925/2006 states that food business operators, or any other interested parties, may at any time submit for evaluation to the Authority a file containing the scientific data demonstrating the safety of a substance listed in Annex III, Part C to that Regulation, under the conditions of its use in a food or in a category of foods and explaining the purpose of that use. Any such file submitted by a food business operator or interested party should be based on guidance documents adopted or endorsed by the Authority, such as the guidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of food, or any further revised version of such guidance.

(5) In order for the Commission to take a decision concerning a substance included in Annex III, Part C to Regulation (EC) No 1925/2006 within the required deadline, it is necessary to take into consideration only those files submitted within 18 months from the date a substance has been included in that Annex. Furthermore, in order for the Commission to take a decision within the stipulated deadline, the Authority should give its opinion on the safety of the substance within a time

[1] OJ L 404, 30.12.2006, p. 26.

[2] OJ L 31, 1.2.2002, p. 1.

limit of nine months from receiving a file that is considered to be valid and complete in accordance with the guidance documents adopted or endorsed by the Authority.

(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 8 of Regulation (EC) No 1925/2006 and in particular:

(a) the conditions for the use of the procedure referred to in paragraphs 1 and 2 of Article 8 of Regulation (EC) No 1925/2006; and

(b) the procedure referred to in paragraphs 4 and 5 of Article 8 of Regulation (EC) No 1925/2006 concerning substances listed in Annex III, Part C thereto.

Article 2

Definitions

For the purpose of this Regulation the following definitions shall apply:

(a) 'request' means the submission to the Commission by a Member State of information, including scientific data, for the purpose of initiating the procedure under paragraph 2 of Article 8 of Regulation (EC) No 1925/2006;

(b) 'file' means a file as referred to in paragraphs 4 and 5 of Article 8 of Regulation (EC) No 1925/2006 that is submitted by a food business operator or interested party to the Authority;

(c) 'placing on the market' as defined by Article 3(8) of Regulation (EC) No 178/2002.

Article 3

Conditions to be met for the request

1. In the assessment of the conditions under which the concerned substance is added to foods or used in the manufacture of foods, as laid down in paragraph 1 of Article 8 of Regulation (EC) No 1925/2006, the placing on the market in one or more Member States of the food product to which the substance has been added shall be taken into account.

2. Member States may submit a request to the Commission when the assessment referred to in paragraph 1 shows at least one of the following:

(a) a potential risk to consumers is associated with the ingestion of amounts of the substance that greatly exceed those reasonably expected under normal conditions of consumption of a balanced and varied diet, due to the conditions under which the substance is added to food or used in the manufacture of food;

(b) a potential risk to consumers is associated with the consumption of this substance by the general adult population or other specified population group for which a potential risk has been identified.

3. For the purposes of this Regulation those conditions that would result in the ingestion of amounts of a substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet shall occur under actual circumstances and shall be assessed on a case-by-case basis in comparison with the average intake of the concerned substance by the general adult population or other specified population group for which health concerns have been raised.

4. The conditions and requirements laid down in paragraphs 1, 2 and 3 of this Article and the requirements laid down in Article 4 of this Regulation, shall apply *mutatis mutandis* where the procedure under Article 8 of Regulation (EC) No 1925/2006 is initiated by the Commission.

Article 4

Content of the request

1. The request shall contain the available and relevant generally accepted scientific evidence demonstrating that the conditions specified in Article 8(1) of Regulation (EC) No 1925/2006 are met and shall include:

(a) Evidence demonstrating the addition of the substance to food or use of the substance in the manufacture of food.

Such evidence shall include information on the current placing on the market of food products containing the substance as referred to in paragraph 1 of Article 3 of this Regulation.

(b) In cases referred to in Article 3(2)(a), evidence demonstrating that intake of the substance greatly exceeds normal conditions of consumption of a balanced and varied diet, as assessed in accordance with Article 3(3).

Such evidence shall include scientific data that represents actual dietary intake of the substance obtained from the most recently available dietary intake surveys or food consumption surveys. The inclusion of foods to which the substance has been added and/or food supplements containing the substance may be taken into account. Member States shall provide justification for the basis of their assessment of 'normal conditions of consumption of a balanced and varied diet' when making the request.

(c) Evidence demonstrating a potential risk to consumers from consumption of the substance.

This evidence shall consist of relevant scientific data including unpublished validated reports, scientific opinions by a public risk assessment body or independent and peer-reviewed articles. A summary of the scientific data and the list of references of the scientific data shall be provided.

2. The Commission may ask the Member State to provide clarifications or additional information if the request is incomplete.

3. The Commission shall publish any complete request made by a Member State on its official website.

4. The Commission shall send the request to the Authority accompanied by all the available information, following consultation of the Member States. The Authority shall adopt a scientific opinion within a specified time limit as laid down by Article 29(3) of Regulation (EC) No 178/2002.

5. Interested parties may submit comments to the Commission within 30 days from the publication by the Authority of its opinion.

Article 5

Substance included in Annex III, Part C

1. To be considered valid, a file submitted by a food business operator or any other interested party to the Authority in view of a safety assessment of the substance placed in Part C of Annex III to Regulation (EC) No 1925/2006, pursuant to the procedure provided under Article 8(4) of Regulation (EC) No 1925/2006, shall be based on relevant guidance documents adopted or endorsed by the Authority.

In the case where it considers a file as not valid for the purpose of the first subparagraph, the Authority shall inform the food business operator or interested party that has submitted the file and the Commission, indicating the reasons why the file is not considered valid.

2. Only files submitted within 18 months from the entry into force of a decision that includes a substance to Part C of Annex III to Regulation (EC) No 1925/2006 pursuant to Article 8(2) of Regulation (EC) No 1925/2006 shall be taken into account by the Authority as being a valid file for the purposes of a decision as laid down in paragraph 5 of Article 8 of Regulation (EC) No 1925/2006.

Article 6

Opinion of the Authority

1. The Authority shall give its opinion on files referred to in Article 5(1) of this Regulation within nine months from the date of receipt of a valid file. The Authority shall assess the validity of the file within 30 days from receipt of the file.

2. The Authority may request the food business operator or interested party to supplement the data or information submitted in a file within a specified time limit. When the Authority seeks supplementary information from the food business operator or any other interested party, the time limit referred to in paragraph 1 shall be extended only once by up to three months and shall include the time needed by the food business operator or any interested party to provide this supplementary information. The food business operator or interested party shall submit the requested information within 15 days from the date of receipt of the Authority's request.

Article 7

This Regulation shall enter into force on the twentieth 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.

Done at Brussels, 11 April 2012.

For the Commission

The President

José Manuel BARROSO