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

COMMISSION IMPLEMENTING REGULATION (EU) No 307/2012

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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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 307/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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 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.

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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.