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

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 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:

(**1**) OJ L 404, 30.12.2006, p. 26.

(**2**) OJ L 31, 1.2.2002, p. 1.

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.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 2(a) words omitted by S.I. 2019/651 reg. 43(2)(a)
- Art. 2(b) words substituted by S.I. 2019/651 reg. 43(2)(b)
- Art. 2(d) inserted by S.I. 2019/651 reg. 43(2)(c)
- Art. 4(1)(b) words omitted by S.I. 2019/651 reg. 43(4)(b)(ii)