



ADMINISTRATIVE GUIDANCE ON SUBMISSIONS FOR SAFETY EVALUATION OF SUBSTANCES ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN THE MANUFACTURE OF FOODS

1. INTRODUCTION

Under European Union legislation, substances may be added for nutritional purposes, for example, to foods for particular nutritional uses or used as ingredients in food supplements. Such substances may include vitamins, minerals and certain other categories of nutrients such as amino acids and other nitrogen-containing substances in foods for particular nutritional uses. At the moment, regarding food supplements, specific rules have been laid down only for vitamins and minerals.

For the purposes of the addition of nutritional substances to foods, it is considered that food products will generally fall within one of three broad groups of foods:

- foods for particular nutritional uses, that might also be referred to as “dietetic foods” or “dietary foods” that are covered by Directive 2009/39/EC of the European Parliament and the Council on foodstuffs intended for particular nutritional uses¹;
- food supplements, foodstuffs covered by Directive 2002/46/EC of the European Parliament and of the Council on food supplements²; or
- foods covered 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 (fortified foods)³.

At the moment, the nutritional substances that can be added are controlled through positive lists included in three directives and two regulations:

- Commission Directive 2006/141/EC on infant formulae and follow-on formulae⁴;
- Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children⁵;

¹ OJ L 124, 20.05.2009, p. 21.

(see <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0039&rid=1>)

² OJ L 183, 12.7.2002, p. 51.

(see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0046:20081211:EN:PDF>)

³ OJ L 404, 30.12.2006, p. 26.

(see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1925:20080304:EN:PDF>)

⁴ OJ L 401, 30.12.2006, p. 1

(see <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0141&rid=2>)

⁵ OJ L 339, 06.12.2006, p. 16

(see <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0125&rid=3>)

- Commission Regulation (EC) No 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses⁶;
- Directive 2002/46/EC of the European Parliament and of the Council on food supplements; and
- 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 Directives on infant formulae and follow-on formulae (2006/141/EC), and processed cereal-based foods and baby foods (2006/125/EC), include lists of nutritional substances that may be added to the foods intended for infants and young children up to 3 years of age covered by these two specific Directives.

Regulation (EC) No 953/2009 applies to all other dietary food groups that are covered by Directive 2009/39/EC on foodstuffs intended for particular nutritional uses.

The use of the substances in Regulation (EC) No 953/2009 is permitted for either all foods for particular nutritional uses covered by the directive or only dietary foods for special medical purposes. The lists include the following categories of nutrients: vitamins, mineral substances, amino acids and other nitrogen compounds, choline and inositol.

Directive 2002/46/EC on food supplements and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to foods include lists of vitamins and minerals and their sources.

The above-mentioned lists may be revised through the regulatory committee procedure of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee).

In particular vitamin and mineral substances may be added on the request of an interested party, and provided that the substance has been positively evaluated by the European Food Safety Authority (EFSA).

⁶ OJ L 269, 14.10.2009, p. 9 (see: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:269:0009:0019:EN:PDF>)

2. PROCEDURE TO FOLLOW

2.1 General Procedure

Requests for the inclusion of a new nutritional substance in the Annexes of the Directives on foods for particular nutritional uses, of the Directive on food supplements and of the Regulation on fortified foods should be submitted to the European Commission, Health and Food Safety Directorate-General, Unit E1, Food information and composition, food waste.

The requests must not concern nutritional substances falling under the field of application of Regulation (EU) 2015/2283 on novel foods and novel foods ingredients⁷. Petitioners are invited to consider the exchange of views concerning the “Status of Food Supplements under Regulation (EC) N° 258/97 concerning novel foods and novel food ingredients” which took place during the meeting of 14 February 2005 of the Standing Committee on the Food Chain and Animal Health Section on Toxicological Safety & Section on General Food Law⁸. Moreover, it should be taken into account that the novel food working group noted that if a substance was used exclusively as an additive prior to 15 May 1997, it would be considered that other uses would require authorisation under Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients⁹.

N.B. If it is determined that a particular nutritional substance requires a safety assessment by EFSA under Regulation (EU) 2015/2283 in addition to an assessment for use in one of the categories of foods described above, it is common practice for the Commission to send one request to EFSA to provide a general assessment of the substance.

Requests for inclusion in the Annexes to the Directive on food supplements and to the Regulation on the addition of vitamins and minerals and certain other substances to foods shall be made only for vitamins and minerals and their sources. On the other hand, requests concerning the other Directives/Regulation noted above can also include additional categories of nutrients, such as: amino acids, nucleotides, taurine, carnitine, choline and inositol.

Application for the authorisation of a nutritional substance for inclusion in the appropriate EU legislation

An application for the authorisation of a nutritional substance should consist of the following separate elements:

- a letter clearly specifying the request with regard to nutrient(s) categories and, if appropriate, the specific nutrient(s) that the nutritional substance is intended to be used as a source of. In addition, the specific Union legislation that the petitioner would like the substance to be included in should be specified, namely:
 - Commission Directive 2006/141/EC on infant formula and follow-on formula;
 - Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children;
 - Commission Regulation (EC) No 953/2009 (either foods for particular nutritional uses in general or dietary foods for special medical purposes only);

⁷ OJ L 327, 11.12.2015, p. 1–22

⁸ http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/docs/summary14_en.pdf

⁹ http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/docs/summary16_en.pdf (item 8)

- Directive 2002/46/EC of the European Parliament and of the Council on food supplements;
- 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.

- a **technical dossier** compiled following the [scientific opinion](#) adopted by EFSA: *“Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources”*¹⁰

When preparing the dossier petitioners may wish to consult the EFSA secretariat for guidance on the presentation of the dossier.

Note - the dossier should contain a summary document that can be separated.

The letter, a copy of the summary document and a copy of the full technical dossier in electronic format on standard physical media should be sent by registered post to the following address:

Head of Unit,
Unit E1 – Food information and composition, food waste
DG SANTE (Health and Food Safety Directorate-General)
European Commission
Rue Breydel 4, B-1049 Brussels

Email : sante-consult-e1@ec.europa.eu

3. FOLLOW UP OF A PETITION

After the receipt of a petition, the petitioner will be sent an acknowledgement of the receipt of the request. The reference number given in the letter and the name of the nutritional substance(s) that is the subject of the petition should be quoted in any future correspondence. The Commission services will review the submission and inform the petitioner if it is administratively accepted.

Once the Commission services have confirmed the administrative acceptance of the dossier, the petitioner will be asked to send the full technical dossier (including the full text of the references, published or unpublished) in electronic format, the table of contents, list of Annexes and the signed cover letter in paper format to the European Food Safety Authority (EFSA) at the address given below by registered post:

APRDESK Unit
European Food Safety Authority
Via Carlo Magno 1A
43126 Parma, Italy

Email : APDESK.applications@efsa.europa.eu

¹⁰ doi: 10.2903/j.efsa.2018.5294

The information in electronic format should be certified as being identical to the one in paper form. Common electronic formats should be used, such as MS Office type documents (preferred at least for the technical dossier, the summary and the list of references) or Adobe Acrobat Reader (accepted for copies of original study reports and articles). The files should preferably be searchable using the search facilities of standard software packages.

The applicant should keep additional paper and electronic copies readily available in case the EFSA requires them. The EFSA Secretariat may ask the petitioner to send additional copies or sections of the dossier to additional addresses.

The Commission services and the EFSA reserve the right to request additional information as necessary for complete assessment of the substance. If additional information is submitted directly to the EFSA then the petitioner should send a copy of the covering letter and the additional information in an electronic format to the Commission services at the address indicated in section 2.1.

Confidentiality

The application in itself cannot be confidential. A confidential submission cannot be accepted. The relevant pieces of EU legislation applicable to the specific categories of foods concerned do not lay down any provisions for the application of a request for confidentiality. In the case of such a request, the general provisions concerning confidentiality laid down by Article 39 of Regulation (EC) No 178/2002 will be applied by EFSA. Therefore, it is recommended that sections considered as confidential by the applicant should be clearly marked as such and kept to a minimum. Applicants are encouraged to make publicly available a maximum of the information submitted, for example by posting on the Internet the contents of the application.

4. EFSA EVALUATION

The scientific opinions adopted by the Scientific Panels of the European Food Safety Authority will be made publicly available on the European Food Safety Authority's website (<http://www.efsa.europa.eu>).

Prepared by Unit E1 "Food information and composition, food waste"
Directorate-General Health and Food Safety
European Commission

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