EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Safety of the food chain
E4 - Food law, nutrition and labelling

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

1. INTRODUCTION

In the European Community legislation substances may be added for nutritional purposes in, for example, foods for particular nutritional uses or 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 only on vitamins and minerals have been laid down.

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 the framework Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses[1];
- food supplements, foodstuffs covered by Directive 2002/46/EC of the European Parliament and of the Council on food supplements[2]; or
- normal foods.

At the moment, the nutritional substances that can be added are controlled through positive lists included in four directives and one regulation:

[1] OJ L 186, 30.6.1989, p. 27. (for non-official consolidated text see: http://europa.eu.int/eur-lex/en/consleg/pdf/1989/en_1989L0398_do_001.pdf)
[2] OJ L 183, 12.7.2002, p. 51.
(see http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_183/l_18320020712en00510057.pdf)

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- Commission Directive 91/321/EEC on infant formula and follow-on formula[3];
- Commission Directive 96/5/EC on processed cereal-based foods and other baby foods for infants and young children[4];
- Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses[5];
- Directive 2002/46/EC of the European Parliament and of the Council on food supplements; and
- Regulation 1925/2006[6] 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 (91/321/EEC), and processed cereal-based foods and baby foods (96/5/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.

Directive 200l/15/EC apply to all other dietary food groups that are covered by Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses.

The use of the substances in Directive 2001/15/EC 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.

The food supplements Directive (2002/46/EC) and Regulation 1925/2006 on the addition of vitamins and minerals and certain other substances to foods include lists of vitamins and minerals and of their sources. Specific provisions allow Member States to provide derogations for vitamins and minerals and their forms not included in these acts.

The above mentioned lists may be revised through the regulatory committee procedure of the Standing Committee on the Food Chain and Animal Health

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

[3] OJ L 175, 4.7.1991, p. 35. (for non-official consolidated text see: http://europa.eu.int/eur-lex/en/consleg/pdf/1991/en_1991L0321_do_001.pdf)
[4] OJ L 49, 28.2.1996, p. 17. (for non-official consolidated text see http://europa.eu.int/eurlex/en/consleg/pdf/1996/en_1996L0005_do_001.pdf)
[5] OJ L 52, 22.2.2001, p. 52. (for non-official consolidated text see http://europa.eu.int/eurlex/en/consleg/pdf/2001/en_2001L0015_do_001.pdf)
[6] OJ L 404, 30.12.2006, p. 26 (see http://eurlex.europa.eu/LexUriServ/site/en/oj/2006/l_404/l_40420061230en00260038.pdf)

2. PROCEDURE TO FOLLOW

2.1 General Procedure

Requests for the inclusion of a new nutritional substance in the directives on foods for particular nutritional substances or food supplements should be submitted to the European Commission, Health and Consumer Protection Directorate-General, Unit E4, Food Law, Nutrition and Labelling.

The requests must not concern nutritional substances falling under the field of application of Regulation 258/97/EEC on novel foods and novel foods ingredients[7]. 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 Law[8]. 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 ingredients[9].

Requests for inclusion in the Directive on food supplements and in 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 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 Community legislation that the petitioner would like the substance to be included in should be specified, namely:
  - Commission Directive 91/321/EEC on infant formula and follow-on formula;
  - Commission Directive 96/5/EC on processed cereal-based foods and other baby foods intended for infants and young children;
  - Commission Directive 2001/15/EC (either foods for particular nutritional purposes in general or dietary foods for special medical uses only);
  - Directive 2002/46/EC of the European Parliament and of the Council on food supplements;

[7] O J L 043 , 14/02/1997 P. 1 (for non-official consolidated text see http://europa.eu.int/eur lex/en/consleg/pdf/1997/en_1997R0258_do_001.pdf)

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

[9] http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/summary16_en.pdf

- a **technical dossier** compiled following the guidelines entitled G*uidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods*[10].

  Petitioners should note that at the second Plenary meeting of the European Food Safety Authority's Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food, held on 9 July 2003, it was confirmed that petitioners should continue to use the above mentioned guidelines as prepared by the Scientific Committee on Food (SCF). The Panel also clarified that, to avoid initiation of unnecessary animal testing with respect to the requirements on toxicological data, the technical dossier should comprise a comprehensive compilation of the existing data. In cases when these data are found insufficient further data will be requested. Petitioners are directed to the summary of agenda item 7 of the 9 July 2003 meeting which provides more information on this issue[11].

  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 (CD-ROM or equivalent) should be sent by registered post to the following address:

European Commission
Health and Consumer Protection Directorate-General
Directorate E – Safety of the Food Chain
Unit E4 – Food Law, Nutrition and Labelling
(B232, 8/43)
B-1049 Brussels

2.2 Procedure for the addition of vitamins and minerals to foods (Article 17 of Regulation 1925/2006)

Petitioners who wish to submit a dossier for a nutritional substance for addition to foods that is the subject of a derogation by a Member State should note that the provisions of Regulation 1925/2006 Article 17(1)(b) indicate that such a dossier should be submitted to the Commission by the Member State not later than **19 January 2010**. The petitioners should follow the section relating to the **technical dossier (see Section 2.1)** when preparing such a dossier.

Petitioners should contact the competent authorities in the individual Member States if they wish to obtain such derogations.

[10] SCF/CS/ADD/NUT/21 Final, (opinion expressed on 11 July 2001) (http://ec.europa.eu/food/fs/sc/scf/out100_en.pdf).
[11] http://www.efsa.eu.int/science/afc/afc_meetings/248/minutes_afc_02_adopted_en1.pdf

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 application, i.e. a copy of the letter specifying the request, 3 copies of the summary document, 3 copies of the full dossier, and a copy of the full information in electronic format, on standard physical media (CD-ROM or equivalent), to the Secretariat of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food of the European Food Safety Authority at the address given below by registered post:

European Food Safety Authority
Scientific Panel on Food Additives, Flavourings, Processing Aids
and Materials in Contact with Food
Largo N. Palli 5/A
I-43100 Parma
Italy

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 can not be confidential. A confidential submission can not be accepted. 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.eu.int).

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