



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committee; scientific co-operation and networks

Scientific Committee on Food

SCF/CS/ADD/NUT/21 Final
12 July 2001

**GUIDANCE ON SUBMISSIONS FOR SAFETY EVALUATION OF
SOURCES OF NUTRIENTS OR OF OTHER INGREDIENTS
PROPOSED FOR USE IN THE MANUFACTURE OF FOODS**

(opinion expressed on 11 July 2001)

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium -
Telephone: direct line (+32-2) 295.81.10 / 296.48.70, exchange 299.11.11. Fax: (+32-2) 299.48.91
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

http://www.europa.eu.int/comm/dg24/health/sc/scf/index_en.html

INTRODUCTION

Nutrients and other ingredients may be used in the manufacture of foods for a variety of reasons. They may be added to foods for particular nutritional uses (FPNUs), or added to ordinary foods for the purpose of restoration or enrichment, or be ingredients of food supplements. This document offers guidance to manufacturers on the nature and extent of the information that should be submitted in support of the safety of proposed sources of nutrients or of other ingredients. In this context, “source” means the actual substance that it is intended to be added to the foods. Nutrients or other ingredients referred to here are limited to those authorised by the existing EU-legislation or to those evaluated by the SCF.

BACKGROUND

Council Directive 89/398/EEC is related to FPNUs. Annex 1 of this Directive lists the groups of FPNUs for which specific provisions are to be laid down by specific Directives. At present such Directives have been adopted on infant formulae and follow-on formulae (Commission Directive 91/321/EEC and 96/4/EC amending it), on processed cereal-based foods and baby foods for infants and young children (Commission Directive 96/5/EC and 98/36/EC amending it), on foods intended for use in energy-restricted diets for weight reduction (Commission Directive 96/8/EC) and on dietary foods for special medical purposes (Commission Directive 1999/21/EC).

The directives on infant formulae and follow-on formulae and on processed cereal-based foods and baby foods for infants and young children include, in addition to the positive list of the nutrients or other ingredients, a positive list of the sources of these nutrients or ingredients. For other categories of FPNUs, similar lists are included in Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in FPNUs. For example, for vitamin B₁, thiamin hydrochloride and thiamin mononitrate are allowed as the only sources, for magnesium, a number of magnesium salts are permitted, while for choline the chloride, citrate and bitartrate salt can be used as sources.

The potential enlargement of the positive list of these and future directives with new sources of nutrients or of other ingredients is the reason for the present guidance.

Concerning future directives, the European Commission issued a proposal for a directive on food supplements in May 2000 (COM(2000)222), followed by another proposal on addition of nutrients to foods. Both proposals contain requirements for a positive list of vitamin and mineral sources, taken from the list in Commission Directive 2001/15/EC. Furthermore, the European Parliament has requested the addition of boron, nickel, silicon, vanadium and tin to the list of minerals that may be present in food supplements.

In this guidance, only the safety of sources of nutrients or of other ingredients authorised by EU-legislation or evaluated by the SCF is considered. It should be noted that the nutritional, physiological function or safety aspects of the nutrients or other ingredients themselves will not be evaluated under this guidance. The SCF has already evaluated the nutritional and safety aspects of the nutrients themselves (SCF, 1999). The Committee has also evaluated population requirements for nutrient intakes (SCF, 1993) and is currently evaluating Tolerable Upper Intake Levels for vitamins and minerals, for some of which

opinions are already published (SCF, 2000, 2001a). The evaluation of novel foods and novel food ingredients should be considered under their specific guidelines (SCF, 1997).

The European Commission services issue separate administrative guidance containing information about where and how to submit dossiers, the number of copies required, format of the submissions and other related details.

CONTENT OF SUBMISSIONS

The following information should be provided on sources of nutrients and of other ingredients, where applicable. Where requested information is not applicable or is not submitted on any of the points set out below, reasons should be given.

1. Administrative data

- 1.1 Purpose of the request, including statement on the category/categories of food in which the source is intended to be used. (E.g. Commission Directive 2001/15/EC; specific FPNU Directives; Food supplements - Annex I, Food supplements - Annex II; addition of nutrients to foods; for multiple uses).
- 1.2 Name of the petitioner, address, telephone, telefax, e-mail.
- 1.3 Name of the manufacturer(s) of the source (if different from above), address, telephone, telefax, e-mail.
- 1.4 Name of the person responsible for the dossier, telephone, telefax, e-mail.
- 1.5 Date of submission of the dossier.
- 1.6 Table of contents of the dossier.

2. Technical data

2.1 Identity of source

- 2.1.1 Chemical name (if any) according to IUPAC nomenclature rules.
- 2.1.2 CAS number (if any).
- 2.1.3 Synonyms, trade names, abbreviations.
- 2.1.4 If a mixture: constituents of the mixture and proportion of each component.
- 2.1.5 Molecular and structural formulae.
- 2.1.6 Molecular weight.
- 2.1.7 Spectroscopic data which allow the identification of the source, e.g. IR, UV, NMR, MS, etc.
- 2.1.8 Purity in percentage; method of determination; data printout (chromatograms, spectra, etc).
- 2.1.9 Impurities: nature, percentage and methods of determination.
- 2.1.10 Description of physical state.

2.1.11 Solubility.

2.1.12 Other data that the petitioner considers may be useful to identify the source.

2.2 Specifications

2.2.1 The proposed chemical and microbiological specifications of the source should be submitted in a format modelled on recent EU or other internationally accepted specifications.

2.2.2 If no detailed specifications are available, a statement that the source proposed for use conforms to existing purity criteria laid down EU legislation, or, in their absence, conforms to generally acceptable purity criteria given by other national or international bodies.

2.3 Manufacturing process

2.3.1 Origin and method of manufacture of the source, production controls and quality assurance.

2.3.2 For chemically synthesised sources, factors such as reaction sequence, side reactions, purification and preparation of the product to be commercialised which may assist in determining likely impurities and their influence on the toxicological evaluation.

2.3.3 For sources extracted from naturally occurring substances, information on extraction procedure(s).

2.4 Methods of analysis in food

2.4.1 Analytical methods for the determination of the source and (where relevant) its degradation products in foods.

2.4.2 Analytical methods should be given in full, except where the analytical methods used are well established, in which case they may be given by reference only.

2.5 Reaction and fate in food(s) to which the source is added

2.5.1 The stability and any degradation products or reaction products appearing as a result of processing, storage and preparation of foods containing the source.

2.5.2 Any possible effect of instability on biological properties including nutrient value.

2.6 Case of need and proposed uses

- 2.6.1 Justification for this particular source (not just a general justification for the nutrient or other ingredient).
- 2.6.2 Types of products in which it is intended to use the source. Mode of incorporation.
- 2.6.3 Quantities to be added to these products.

2.7 Exposure

- 2.7.1 Known or anticipated human exposure to the source from food and other routes of exposure, including amount (e.g. maximum and average intake or exposure), frequency and other factors influencing exposure. Information should also be given on any other sources of human exposure to the same substance (e.g. from drinking water, consumer products, etc.)
- 2.7.2 The above exposure calculations should be explained, including any assumptions made. Where possible, information on consumption of the foods where the source is used or intended to be used, including variations affecting particular sections of the population (e.g. by age, sex, disease, etc).

2.8 Information on existing authorisations and evaluations

- 2.8.1 Information on any existing national authorisations and evaluations and/or evaluations by other bodies on the source should be provided.

3. Biological and toxicological data

- 3.1 Bioavailability of the nutrient or other ingredient from its source following oral consumption
 - from human data
 - from *in vitro* or animal studies
 - from information on analogous substances.
- 3.2 Subsequent metabolic fate of the source and biological distribution.
- 3.3 Any known interactions of the source with other components in the diet.
- 3.4 Impact of the source on the intestinal milieu and on the absorption of other nutrients.
- 3.5 Toxicological data on the source.
 - 3.5.1. The available data should be submitted in the first instance. The extent of the data needed will depend on safety considerations in relation to the fate of the source in the body. Any deviations from

requirements already established for food additives (SCF, 2001b) should be justified.

4. Sources that consist of, contain, or are derived from genetically modified organisms

4.1 In the case of sources of nutrients or of other ingredients that contain or are derived from genetically modified organisms, information should also be provided on the genetically modified organism(s) in accordance with the guidance given by the Scientific Committee on Food.¹

5. Annexes

5.1 Complete bibliographical list of references.

5.2 Copies of all references listed.

¹ SCF (1997). Recommendations concerning the scientific aspects of information necessary to support applications for placing on the market of novel foods and novel food ingredients. Part I. Opinion expressed on 7 June 1996. Scientific Committee for Food (Thirty-ninth Series). Part II. Opinion expressed on 13 December 1996. Scientific Committee for Food (Fortieth Series). Part III. Opinion expressed on 13 December 1996. Scientific Committee for Food (Fortieth Series). Commission of the European Communities, Directorate-General Industry, Luxembourg. Note that new guidance on novel foods and novel food ingredients is being prepared by EC Scientific Committees during 2001 and petitioners should ensure they consult the latest guidance.

REFERENCES

SCF (1993). Nutrient and Energy Intakes for the European Community. Reports of the Scientific Committee for Food (Thirty-first Series). Commission of the European Communities, Directorate-General Industry, Luxembourg.

SCF (1997). Recommendations concerning the scientific aspects of information necessary to support applications for placing on the market of novel foods and novel food ingredients. Part I. Opinion expressed on 7 June 1996. Scientific Committee for Food (Thirty-ninth Series). Part II. Opinion expressed on 13 December 1996. Scientific Committee for Food (Fortieth Series). Part III. Opinion expressed on 13 December 1996. Scientific Committee for Food (Fortieth Series). Commission of the European Communities, Directorate-General Industry, Luxembourg.

SCF (1999). Opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes ('PARNUTS'). Opinion expressed on 12 May 1999.

Available on http://www.europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

SCF (2000 and 2001a). Opinions of Tolerable Upper Intake Levels for Vitamins and Minerals (various).

Available on http://www.europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

SCF (2001b). Guidance on Submissions for Food Additive Evaluations by the Scientific Committee on Food. Opinion expressed on 11 July 2001.

Available on on http://www.europa.eu.int/comm/food/fs/sc/scf/outcome_en.html