

## SCIENTIFIC OPINION

### Data requirements for the evaluation of food additive applications<sup>1</sup>

#### Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food

(Question No EFSA-Q-2007-188)

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#### PANEL MEMBERS

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#### Key words:

Food additive, evaluation, requirements

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## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

On 16 December 2008 a legislative package of four Regulations was adopted by the European Parliament and Council. The package is consisting of Regulation (EC) No 1333/2008 on food additives, Regulation (EC) No 1332/2008 on food enzymes, Regulation (EC) No 1334/2008 on flavourings and a separate Regulation (EC) No 1331/2008 on a common procedure for evaluation and authorisation of these substances.

Regulation (EC) No 1333/2008 on food additives will replace previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market and a high level of protection of human health and the interests of consumers via comprehensive and streamlined procedures.

Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological necessity for their use, their use must not mislead the consumer and their use must bring a benefit to the consumer.

The evaluation and approval of food additives within Europe is longstanding and the safety assessments have been undertaken by EFSA since its formation and before that by the Scientific Committee on Food, the latter having established guidance on submissions for food additive evaluations most recently in 2001. This guidance has been endorsed by EFSA at the 2<sup>nd</sup> meeting of the AFC Panel on 9 July 2003.

The Regulation on food additives will apply to food additives used for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of food (excluding those used as processing aids). Food additives shall be subject to safety evaluation by the European Food Safety Authority (EFSA) and approval via a community list. The inclusion of a food additive in the Community list will be considered by the Commission on the basis of the opinion and its safety from EFSA. The Commission will additionally take into account other general criteria such as technological need and consumer aspects when considering whether to include the food additive in the Community list. For every food additive included in the positive list specifications, including the criteria on purity, and the origin of the food additive shall be laid down.

In order to increase consistency in common areas the procedural aspects of the food additives' approval, as well as for the other two sectoral proposals, such as the handling of applications within well defined deadlines, their evaluation by EFSA and decision making by the Commission, are provided in Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. This Regulation also provides that an implementing measure shall be adopted by the Commission, within 24 months from the adoption of the Regulation on food additives, i.e. by 16 December 2010, which shall concern in particular the content, drafting and presentation of the application for the evaluation and authorisation of a food additive. With a view to the adoption of this implementing measure the Commission shall consult the Authority, which, within six months of the date of entry into force of the Regulation on food additives, i.e. by 20 July 2009, shall present a proposal concerning the data required for risk assessment of the food additives.

The current data requirements for food additives applications are defined in relation to the current state of the art of risk assessment, science and technology. The Panel will monitor the evolution of these fields and will identify the need for revision of both the guidance and the data requirements.

### **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

In accordance with Article 31 of Regulation (EC) No 178/2002, and with the requirement in Regulation (EC) No 1331/2008 of the European Parliament and Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings, the European Commission asks the European Food Safety Authority (EFSA) to provide the Commission with a proposal concerning the data required for the risk assessment of food additives with a view to this data being included in the implementing measure of the Commission which will lay down amongst other aspects, the content, drafting and presentation of the application for the evaluation and authorisation of food additives.

### **ACKNOWLEDGEMENTS**

The Scientific Panel on Food Additives and Nutrient Sources added to Food of the European Food Safety Authority wishes to thank D. Gott for his contribution to the preparation of this opinion.

## INTRODUCTION

The present statement defines the general data requirements, while specific scientific approaches are suggested in the guidance for food additives applicable at the time of the application. During its second plenary meeting in September 2008, the Panel endorsed provisionally the guidance document for food additive evaluations adopted by the Scientific Committee on Food (SCF) in 2001. In order to reflect current thinking in risk assessment, the Panel will commence a detailed reappraisal of the guidance in September 2009. It is anticipated that, following a period of public consultation, this new guidance will be finalised in July 2011. Applicants should also take into consideration the opinions adopted in 2009 by the Scientific Committee of EFSA on Nanoscience and Nanotechnologies, on the use of the benchmark dose approach in risk assessment and on the replacement and reduction of animal testing, as well as the guidance on transparency in the scientific aspects of risk assessments adopted in 2009 and the guidance on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements adopted in 2008.

## Data requirements

A dossier submitted in support of an application for the evaluation of a food additive should enable an assessment to be made of the additive based on the current state of knowledge and permit verification that the additive does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed, as laid down in Article 6 of Regulation (EC) No 1333/2008 (EC, 2008).

The application dossier should include all the available data relevant for the purpose of the risk assessment (i.e. full published papers of all references cited, full copies of the original report of unpublished studies and corresponding individual raw data). When these papers and reports are not originally in English, the original language version and a complete English translation should be provided.

The documentation on the gathering of the data used in the dossier should also be provided. This documentation should specify the data gathering conducted and especially the literature search strategies (assumptions made, key words used, databases used, limitation criteria, etc.). The comprehensive outcome of the literature search should also be provided.

The individual raw data of the unpublished studies should be available on request from EFSA, preferably in a computer-readable format. The individual results of examinations and raw data, including microscopic slides, should also be available on request from EFSA.

The safety evaluation strategy and the corresponding testing strategy should be described and justified with rationales for inclusion and exclusion of specific studies.

Information should be provided on:

- the applicant and the application dossier (administrative data)
- the identity and characterisation of the additive (including the proposed specifications and analytical method)
- the manufacturing process
- the stability, reaction and fate in foods to which the additive is added
- the case of need and proposed uses

- the existing authorisations and evaluations
- the exposure assessment
- the biological and toxicological data.

Regarding the biological and toxicological data, the following core areas should normally be covered:

- Toxicokinetics
- Subchronic toxicity
- Genotoxicity
- Chronic toxicity/carcinogenicity
- Reproductive and developmental toxicity

Applicants are reminded that for each study performed it should be stated whether the test material conforms to the proposed or existing specification. Where the test material differs from this specification, the applicant should demonstrate the relevance of these data to the food additive under consideration.

Overall conclusions should be proposed by the applicant on the safety of the proposed uses of the additive. The overall evaluation of potential human risk should be made in the context of known or likely human exposure, including that from other sources.

A summary of the information given in the dossier should also be provided.

The dossier should be presented in a standard way. For this purpose, EFSA will establish standard templates for the different sections of the application dossiers and for the reporting of the toxicological studies. Once established, these templates should be used.

Details of any applications made to other evaluation bodies or regulatory agencies together with their status and outcome should be disclosed.

During the evaluation process, EFSA may request any additional data that is considered necessary for the safety assessment.

### **Administrative requirements**

In order to enable EFSA to process adequately the application dossier and contact the applicant as necessary for the purpose of the evaluation of the application, the following information should be provided:

1. **Applicant's contact details:** name of the applicant or company, address (street, number, postcode, city, country), telephone, fax, e-mail (if available).
2. **Manufacturer's contact details:** name of the manufacturer(s) of the substance (if different from above), address (street, number, postcode, city, country), telephone, fax, e-mail (if available).
3. **Contact person's details** (for all correspondence with EFSA): name of the contact person, position, address (street, number, postcode, city, country), telephone, fax, e-mail (if available).
4. **Type of application** (i.e. new food additive, new use of a permitted food additive)

5. **Proposed (or existing) common name** of the additive
6. **Chemical name of the additive according to the IUPAC nomenclature**
7. **CAS number of the additive (if defined)**
8. **E number** of the additive as defined in the European legislation on food additives (if applicable)
9. **ELINCS and/or EINECS number** of the additive (if attributed)
10. **Date** of submission of the dossier
11. **Table of contents** of the dossier
12. **List of documents and other particulars.** The applicant must identify the number and titles of volumes of documentation submitted in support of the application. A detailed index with reference to volumes and pages shall be added
13. **List of parts of the dossiers requested to be treated as confidential**, where necessary. The list shall make reference to the relevant volumes and pages of the dossier.

## REFERENCES

- EC, 2008. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L354/16. 31.12.2008.
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## GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Food
EC	European Commission
EFSA	European Food Safety Authority
SCF	Scientific Committee on Food