

**Opinion of the Panel on
food contact materials, enzymes, flavourings and processing aids (CEF)**

**Guidelines on submission of a dossier for safety evaluation by the EFSA of
active or intelligent substances present in active and intelligent materials and
articles intended to come into contact with food**

Question number EFSA-Q-2005-041

Adopted on 21/07/2009

AFTER PUBLIC CONSULTATION

TABLE OF CONTENTS

1 INTRODUCTION	4
2. GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF ACTIVE AND INTELLIGENT MATERIALS AND ARTICLES.....	5
3. SUBMISSION OF AN APPLICATION	6
4. INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR THE AUTHORISATION OF ACTIVE AND INTELLIGENT SUBSTANCE(S)	6
4.1. SUMMARY DOCUMENT	7
4.2. ADMINISTRATIVE PART	7
4.3. TECHNICAL DOSSIER	8
REFERENCES	11

DEFINITIONS

For the purpose of the current guidelines, the definitions laid down in Regulation (EC) No 1935/2004 and in Regulation (EC) No 450 /2009 shall apply:

“*active materials and articles*” means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food (Regulation (EC) No 1935/2004 Article 2.2.a and Regulation (EC) No 450/2009 Article 3.a).

For the purpose of this document, this definition of active materials and articles is interpreted as including all materials and articles that are designed to deliberately interact with food and/or the food surrounding environment, and bring about change in their composition or characteristics.

“*intelligent materials and articles*” means materials and articles which monitor the condition of packaged food or the environment surrounding the food. (Regulation (EC) No 1935/2004 Article 2.2.b and Regulation (EC) No 450/2009 Article 3.b);

“*component*” means an individual substance or a combination of individual substances which cause the active and/or intelligent function of a material or article, including the products of *in situ* reaction of these substances. It does not include the passive part, such as the material they are added to or incorporated into. (Regulation (EC) No 450/2009 Article 3.c);

“*functional barrier*” means a barrier consisting of one or more layers of food contact materials which ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with Regulation (EC) No 450/2009;

“*releasing active materials and articles*” are those active materials and articles designed to deliberately incorporate components that would release substances into or onto the packaged food or the environment surrounding the food. (Regulation (EC) No 450/2009 Article 3.e);

“*released active substances*” are those substances intended to be released from releasing active materials and articles into or onto the packaged food or the environment surrounding the food and fulfilling a purpose in the food.(Regulation (EC) No 450/2009 Article 3.f);

For the purpose of this document, the following additional definition shall also apply:

“*active and/or intelligent substance*” means a substance which contributes to the active and/or intelligent function;

“*passive parts*” means all material(s) and article(s) into which the component is added or incorporated (such as the container and the primary packaging into which that component is placed or the primary packaging material into which it is incorporated).

1 INTRODUCTION

Framework Regulation (EC) no 1935/2004 and the specific Regulation (EC) No 450/2009 regulate the use of active and intelligent materials and articles intended to be used in contact with foodstuffs.

The general principles applicable to food contact materials are set out in Regulation (EC) No 1935/2004 stating that materials and articles in contact with food shall only be authorised if it is demonstrated that they do not present risks to human health (article 8). This regulation establishes that active and intelligent materials and articles are included in its field of application, and sets out general rules applicable only to active and intelligent materials and articles. Regulation (EC) No 450/2009 is a specific measure that lays down specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use. The substance(s) responsible for the active and/or intelligent function of the material should be evaluated under the regulation (EC) No 450/2009.

A community list of authorised substances, that can be used to manufacture an active or intelligent component of active and/or intelligent materials and articles, shall therefore be established after the European Food Safety Authority (EFSA) has performed a risk assessment and has issued an opinion on each substance. In some cases, restrictions may be proposed by the EFSA on a group of substances especially when the active or intelligent function implies interactions between different substances.

Substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food, do not need to be listed in the Community list. They shall be used in full compliance with the relevant Community and national provisions applicable to food, and shall comply with the provisions of Regulation (EC) No 1935/2004 and its implementing measures. The same shall apply to substances which are incorporated in active materials and articles by techniques such as grafting and immobilisation, in order to have a technological effect in the food.

However, for these substances already approved in food legislation, their stability under the intended packaging manufacturing and processing conditions must be verified by the packaging manufacturer and a dossier for safety evaluation has to be submitted if chemical reaction, degradation or decomposition of these substances is likely to occur.

Passive parts should be covered by the specific community or national legislation applicable to those materials.

These guidelines do not apply to substances used behind a functional barrier as defined by article 3 of Regulation (EC) No 450/2009. Substances behind such a barrier will not, by definition, migrate in amounts which could endanger human health or bring about unacceptable changes in the composition of the food or of its organoleptic properties.

Consequently, these active and intelligent substances do not need a safety evaluation and are also outside the scope of Regulation (EC) No 450/2009.

However, this functional barrier concept does not apply to substances in nanoparticulate form which should be assessed on a case by case basis (article 5(2)(c)ii of regulation No 450/2009).

The purpose of this document is to give guidance to applicants and other interested parties for the preparation and the submission of a dossier for the evaluation of the safety of active and/or intelligent substances responsible for active and/or intelligent functions of active and/or intelligent materials and articles intended to be used in contact with food. It gives guidance on the administrative and technical data required, and on the format of a submission (hereinafter referred to as “dossier”) for the evaluation by the EFSA.

2. GENERAL PRINCIPLES OF SAFETY ASSESSMENT OF ACTIVE AND INTELLIGENT MATERIALS AND ARTICLES

The safety assessment will focus on the risks related to the dietary exposure to chemicals due to:

- the migration of the active and/or intelligent substance(s)
- the migration of their degradation and/or reaction products
- their toxicological properties

The dossier submitted by the applicant shall include all relevant information enabling the EFSA to perform a safety assessment. In order to guarantee that the foods in contact with active and intelligent materials and articles are safe, the EFSA will, where appropriate, issue opinion, recommendations, specifications or restrictions on the substance(s) or group of substances incorporated in active or intelligent food contact materials and articles and when necessary, special conditions of manufacture and use for these substances and/or the materials and articles in which they are incorporated.

It should be noted that efficacy of active and/or intelligent material and article and most importantly any technical parameters and restrictions needed to ensure efficacy will be considered only when relevant for safety evaluation. The EFSA evaluation can not be considered as proof of the technical efficacy of active and/or intelligent material and article.

It should be noted that these guidelines do not include any consideration of environmental aspects such as persistence in the environment, ecological impact of food contact materials constituents and their fate after the food contact material has been submitted to waste disposal treatment.

3. SUBMISSION OF AN APPLICATION

Applications shall be submitted in accordance with Regulation (EC) No 450/2009, Art. 8. The applicant should provide all available data relevant to the evaluation by the EFSA.

The applicant shall submit a dossier with the full information, both on paper and in electronic format on standard physical media (CD-ROM). It has to be declared by letter that the electronic and the paper version are identical. The CD ROM should contain two files or sets of files. One should be protected from modification for example as a locked Acrobat or Word document(s). The second should be identical to the first except that it should not be protected, so that all the information can be copied, summarised and/or annotated as necessary, to facilitate the evaluation process. In addition to the complete version with the full information, applicants should provide a second version of the CD-ROM without the confidential information. This version will be made available to anyone who might submit a request to EFSA according to regulation (EC) No 1935/2004 Art. 19. The applicant should keep additional paper and electronic copies readily available in case the EFSA requires them.

Any specific literature reference (scientific papers) mentioned and used to support the application must be supplied in the dossier as full length paper. When reference is made to a book or to extensive publications, only the relevant parts need be supplied.

Applicants may deviate from the guidelines, provided valid and documented scientific reasons are given in the dossier. In all cases, the EFSA may request additional data.

Applicants shall note that competent authorities in member States will get full access to any dossier submitted to the EFSA (Art.9 of the Regulation (EC) No 1935/2004). It should also be noted that applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public (Art. 19 of regulation (EC) N° 1935/2004). Confidential information in the dossier has to be clearly marked.

Verifiable justification must be provided by the applicant for information considered confidential. Information relating to the following shall not be considered confidential:

- (a) the name and address of the applicant and the chemical name of the substance;
- (b) information of direct relevance to the assessment of the safety of the substance;
- (c) the analytical methods.

(Art. 20 of the Regulation (EC) No 1935/2004).

4. INFORMATION TO BE SUPPLIED WITH AN APPLICATION FOR THE AUTHORISATION OF ACTIVE AND INTELLIGENT SUBSTANCE(S)

The dossier shall be composed of three sections:

1. the summary document,
2. the administrative part,
3. the technical part (technical dossier).

To allow a complete safety assessment, sufficient information must be provided in all the sections 1 to 3.

4.1. SUMMARY DOCUMENT

The summary document should contain a summary of all information provided in the technical dossier (TD) and the safety evaluation, including:

- the principle and target function of the active or intelligent material or article,
- the identity and relevant physical and chemical characteristics of the active and/or intelligent substance(s),
- the manufacturing process of the active or intelligent substance(s), the type(s) of materials in which the substance(s) can be added or incorporated into and manufacturing conditions of the active and/or intelligent materials and articles,
- the intended use of the active and/or intelligent materials or articles with respect to the types of foods and the conditions of time and temperature of use,
- the existing authorization in EU Member States and other countries,
- the migration data,
- the toxicological data.

This document should be a stand alone document. If a reference is made to other documents, a summary of the relevant information in these documents shall also be provided. The applicant should highlight the crucial parameters related to safety assessment.

4.2. ADMINISTRATIVE PART

The data supplied shall identify the legal entities and the business involved, as well as the person in charge of the application:

1. Name of the applicant (company, organisation submitting the application), address and other means of communication e.g. telephone, e-mail.
2. Name of the business operator on whose behalf the application is submitted (if different from above), address and others means of communication e.g. telephone, e-mail.
3. Name of the person responsible for the dossier, address and other means of communication e.g. telephone, e-mail.
4. Date of submission of the dossier.
5. Table of contents of the dossier.

4.3. TECHNICAL DOSSIER

1. Overview of the application

Provide an overview of the composition, structure and working principle of the active or intelligent material or article. The target function, the active and intelligent substance(s) and passive parts of the material or article, their functions and other information necessary for understanding their mode of action such as intended migration or reaction, as well as the importance of usage conditions should be presented in a synthetic and comprehensive way. This description could be illustrated with a scheme showing the place and the role of the different elements including the primary packaging and the separate article if any, as well as the food itself if necessary.

In the case of interactions among substances responsible for the active or intelligent function, all the relevant information, as described in the sections below, for all these substances should be submitted in the dossier.

If nanoparticles are used, information and recommendations on the data to be submitted can be found in the opinion of EFSA Scientific Committee (EFSA, 2009).

2. Identity of the active or intelligent substance(s)

Provide all relevant information on the identity of the active or intelligent substance(s) and its(their) impurities.

Substances, either single or in a mixture, must be clearly identified giving respective chemical name (IUPAC), CAS registry number, synonyms and trade names, abbreviation, molecular weight, molecular and structural formula, spectroscopic data which allow the identification of the substance, purity, impurities. If a mixture, also the proportion of each constituent in the mixture must be given.

3. Physical/chemical characteristics of the active and/or intelligent substance(s)

All relevant information on the physical and chemical properties of the active and intelligent substance(s), such as physical state, melting point, boiling point, solubility, octanol/water partition, stability, decomposition temperature, reactivity and hydrolysis shall be provided.

Information on any intended or potential unintended reaction or breakdown products originating for instance during the manufacturing process, the storage or the use of active and intelligent substance(s) including, if any, reactions with passive parts of packaging materials, substances of the food

surrounding atmosphere or natural compounds of the food shall also be provided.

4. Manufacturing process of the active or intelligent substance(s) and materials and articles

In this section a detailed description should be given of:

- the manufacturing process of the active or intelligent substance(s),
- the nature of the passive parts and,
- the process of incorporation of the active and/or intelligent substances in the finished material or article,
- the types of the food contact material(s),
- the maximum percentage of the active or intelligent substance(s) in the food contact material.

The applicant shall identify any possible reaction and/or degradation products under the conditions of the manufacturing processes.

5. Intended use of the active and intelligent materials and articles

Information shall be provided on the range of food categories that active and intelligent materials and articles are intended/recommended to be used with.

Intended and worst case conditions of use (time, temperature, surface/volume ratio or anything of relevance for the safety evaluation) of active or intelligent materials and articles with those foods should be given.

In this section the applicant shall also provide data relevant to the efficacy of the active and/or intelligent materials and articles for the intended use.

6. Existing authorisations

All relevant information on the legal status of the active and intelligent substances in respect to the EU and/or national legislation as well as information concerning authorisation in other countries (e.g. USA, Japan) shall be provided. It should be indicated whether the material and article has been authorized as such (the same active or intelligent substance(s) for the same passive parts and same usage conditions) or a similar material or article (material or article having similar principle and function i.e. similar active or intelligent substance(s), passive parts and usage conditions). If available, the internet address for the authorization should be supplied; a copy of the authorization letter can be annexed. Any other useful information on the existing authorization can be supplied.

7. Migration data

Migration data of active and/or intelligent substances and, if any, impurities, reaction products and degradation products, should be provided using where appropriate conventional migration tests, as described in the Directive 82/711/EEC (EC, 1982) or dedicated migration/evaluation tests in foods or simulants with demonstrated adequacy for the intended/recommended conditions of use. Alternatively, calculations based on worst case transfer scenarios or recognised mathematical migration models (EC, 2002) may be used including any assumptions made.

Validated analytical methods for the determination of the substances and if relevant their degradation and reaction products in food or food simulants and/or in the final material should be given in detail except where the analytical methods used are well established and may be given by reference only.

If known, estimates of exposure to the migrating substances from other sources should be provided.

8. Toxicological data

Toxicological data on each substance and if relevant on its (their) degradation products and any identified reaction by-products, should be provided.

As a general principle, the extent of toxicological studies needed will be dependent on the level of exposure through migration. The greater the exposure, the more toxicological information will be required.

The same tiered approach as described in the guidelines of the Scientific Committee on Food (European Commission, 2001) for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation has to be followed.

In cases where a substance is already authorised in food or food contact materials Community legislation or evaluated by the SCF or EFSA, a reference to that legislation or evaluation of the substance should in first instance be provided instead of the above toxicological data. The EFSA still may request more data if this is considered appropriate.

For items 2-8 of this section relevant information can also be found in the “Guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA” (EFSA, 2006).

All other data that may be relevant for the evaluation should also be provided.

REFERENCES

EC (European Commission), 2009. Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food.

EC (European Commission), 2004. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and article intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, *Official Journal L 338 13.11.2004*.

EC (European Commission), 2002. Directive No 2002/72/EC of the Commission relating to plastic materials and articles intended to come into contact with foodstuffs, *Official Journal L 220, 15/08/20052 P. 0018*.

EC (European Commission), 2001. Guidelines of the Scientific Committee on food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorization. SCF/CS/PLEN/GEN/100 Final, 19 December 2001, http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf.

EC (European Commission), 1982. Directive 82/711/EEC of the Council of 18 October 1982 laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs, *Official Journal L 297, 23/10/1982 P. 0026 – 0030*.

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Scientific Committee on a request from the European Commission on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. *The EFSA Journal* (2009) 958, 1-39, http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm.

EFSA (European Food Safety Authority), 2008. Guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA by the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC), http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902600222.htm