

Administrative guidance for the request of authorisation of a food additive

1. INTRODUCTION

Until the establishment of the Community lists of food additives, as provided for in Article 30 of Regulation (EC) No 1333/2008, is completed, the Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC can be amended by the procedure laid down in Article 5a of Decision 1999/468/EC (regulatory procedure with scrutiny).

This administrative should be used until the implementing measures of Regulation (EC) No 1331/2008 guidance will be adopted.

2. PROCEDURE TO FOLLOW

Requests for

- an authorisation of a new food additive within the meaning of Council Directive 89/107/EEC. This Directive be replaced by Regulation (EC) No 1333/2008 on 20 January 2010;
- a modification in conditions of use of an authorised additive as laid down in the annexes Directives 94/35/EC on sweeteners, 94/36/EC on food colours or 95/2/EC on miscellaneous additives or;
- a modification in the purity criteria for food additives laid down in relevant Directives 95/31/EC for sweeteners, 95/45/EC for colours and 96/77/EC for miscellaneous additives

should be addressed to the European Commission, Health and Consumers Directorate-General, Unit E3, Chemicals, contaminants, pesticides.

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2.1. Application for the authorisation of a new food additive

An application for the authorisation of a new food additive should consist of the following separate elements:

- a **letter** clearly specifying the request and the specific Community legislation concerned
- a **technical dossier** compiled following the guidelines entitled *guidance on submissions for additive evaluations by the Scientific Committee on Food prior to its authorisation*.

Please note that the dossier should contain a summary document that can be also separated.

The letter and two copies of the summary document should be sent to the following address:

European Commission
Health and Consumer Directorate-General
Directorate E – Safety of the food chain
Unit E3 – Chemicals, contaminants, pesticides
Office B232, 4/49
B-1049 Brussels

At the same time, the full application (a copy of the letter specifying the request, 30 copies of the summary document, 3 copies of the full dossier) should be sent to the Secretariat of the Panel on food additives, flavourings, processing aids and materials in contact with food of the European Food Safety Authority at the following address:

European Food Safety Authority
Panel on food additives and nutrient sources added to food
Largo N. Palli 5/A
I - 43100 Parma
Italy

In addition, the full information should be submitted in electronic format on standard physical media (CD-ROM or equivalent) to the Secretariat of the Panel Food additives and nutrient sources added to food. The information should be certified as being identical to the one on paper. Common electronic formats should be used, such as MS Office or Adobe Acrobat Reader. The files should be searchable using the search facilities of standard software packages.

The applicant should keep additional paper and electronic copies readily available for the cases where the secretariat of the Panel requires them. The secretariat may ask the petitioner to send additional copies or sections of the dossier to additional addresses.

The petitions should be sent by registered post.

Confidentiality issues:

The application in itself can not be confidential. A confidential submission can not be accepted. Sections considered as confidential by the applicant should be 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.

2.2. Applications for a modification of the conditions of use or purity criteria of an authorised additive

A letter clearly specifying the request and the specific Community legislation concerned should be addressed to the European Commission, Health and Consumer Protection Directorate-General, Unit E3, Chemicals, contaminants, pesticides. The supporting

technical information should be compiled according to the relevant parts of the guidelines of the Scientific Committee on Food.

3. ADDITIONAL INFORMATION

Applicants are encouraged to contact the Commission service mentioned above for further details before submitting formally an application to the Commission in case of doubt, in order to clarify the pertinence and details of the submission.

This document exists in English language at present only.