

**New version of Commission Practical Guidance
on the submission of applications on additives, enzymes and flavourings**

DG SANCO (EU Commission) updated its Practical Guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings. Version 9 of the document has been adopted on 16 October 2014. Some modifications regarding flavourings are identified.

Objectives of the Practical Guidance

This guidance document provides applicants with practical information which aims at facilitating the preparation and submission of applications for authorisations of food flavourings¹, additives and enzymes according to the respective sectoral Regulations and to the procedure described in Regulation (EC) No 1331/2008².

The Practical Guidance clarifies the type of requested information and data that need to be included in application dossiers.

Changes in version 9 for food flavourings

A new version of the document, version 9 adopted on 16 October 2014, has recently been issued on DG SANCO website: http://ec.europa.eu/food/food/FAEF/authorisation_application_en.htm

EFFA Secretariat compared its content with the previous known version (version 5, June 2013). The following modifications have been identified regarding flavourings. Changes specific to additives and enzymes are not described here.

- **Number of copies and form of dossiers** are modified (2.1.8). For flavourings, DG SANCO asks now for three electronic copies (1 for EFSA and 2 for the Commission) and one simplified paper copy of the dossier (Commission's copy) namely, accompanying letter, summary of the dossier and confidential information has to be provided. Moreover, if the applicant requests that some parts of the dossier are to be treated as confidential, only 2 CDs/DVD without confidential parts in electronic format are requested. No more need of a complete paper dossier without confidential parts (2.1).
- **In the risk assessment data** (2.1.2.2) chapter, the document no more refers to Scientific Report of EFSA on Evaluation of trial descriptions of strains of *Bacillus licheniformis* and *Aspergillus niger* genetically modified with alpha-amylase gene(s).
- **A new reference** (3.2) is introduced: "Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer" which was adopted end of May 2014.

Finally, the new version takes into account the recent renaming of "Standing Committee on the Food Chain and Animal Health" into "Standing Committee on Plants, Animals Food and Feed".

If you have further questions, please do not hesitate to contact EFFA at info@effa.eu or your respective national association.

EFFA Secretariat – 27 October 2014

Enclosure: DG SANCO Practical guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings, version 9, 16th October 2014 (FL/11/69-Vs9)

¹ Except for smoke flavourings. Procedure for their authorisation is covered by Regulation (EC) No 2065/2003.

² Further elaborated in Regulation (EU) No 234/2011