# Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (Text with EEA relevance)

## COMMISSION REGULATION (EU) No 234/2011

## of 10 March 2011

## implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings

## (Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(1)], and in particular Article 9(1) thereof,

After consulting the European Food Safety Authority pursuant to Article 9(2) of Regulation (EC) No 1331/2008,

Whereas:

(1) Regulation (EC) No 1331/2008 lays down procedural arrangements for updating the lists of substances the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(2)], Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes[(3)] and Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[(4)] (hereinafter referred to as 'the sectoral food laws').

(2) Pursuant to Article 9 of Regulation (EC) No 1331/2008 it is for the Commission to adopt the implementing measure as regards the content, drafting and presentation of applications to update the Union lists under each sectoral food law, arrangements for checking the validity of applications and the type of information that should be included in the opinion of the European Food Safety Authority (hereinafter referred to as 'the Authority').

(3) In order to update the lists it is necessary to verify that the use of the substance complies with the general and specific conditions of use as provided for in the respective sectoral food laws.

(4) The Authority adopted a scientific opinion on 9 July 2009 on data requirements for the evaluation of food additive applications[(5)]. This data should be provided when an

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application for the use of a new food additive is submitted. In case of an application for a modification of the conditions of use of an already authorised food additive or for a modification of the specifications of an already authorised food additive, the data required for risk assessment may not be required, as long as this is justified by the applicant.

(5) The Authority adopted a scientific opinion on 23 July 2009 on data requirements for the evaluation of food enzyme applications[(6)]. This data should be provided when an application for the use of a new food enzyme is submitted. In case of an application for a modification of the conditions of use of an already authorised food enzyme or for a modification of the specifications of an already authorised food enzyme, the data required for risk assessment may not be required, as long as this is justified by the applicant.

(6) The Authority adopted a scientific opinion on 19 May 2010 on data requirements for the risk assessment of flavourings to be used in or on foods[(7)]. This data should be provided when an application for the use of a new flavouring is submitted. In case of an application for a modification of the conditions of use of an already authorised flavouring or for a modification of the specifications of an already authorised flavouring, the data required for risk assessment may not be required, as long as this is justified by the applicant.

(7) It is important that toxicological tests are performed to a certain standard. Therefore Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[(8)] should be followed. Where such tests are carried out outside the territory of the Union, they should follow 'the OECD Principles of Good Laboratory Practice' (GLP) (OECD, 1998)[(9)].

(8) The use of food additives and food enzymes should always be technologically justified. Applicants should also explain in case of a food additive why the technological effect cannot be achieved by any other economically and technologically practicable means.

(9) The use of a substance should be authorised if it does not mislead the consumer. Applicants should explain that the requested uses do not mislead the consumer. The advantages and benefits for the consumer should also be explained in case of a food additive.

(10) Without prejudice to Article 9 of Regulation (EC) No 1332/2008, Article 19 of Regulation (EC) No 1333/2008 and Article 13 of Regulation (EC) No 1334/2008, the Commission should verify the validity of the application and whether it falls within the scope of the respective sectoral food law. An advice from the Authority should be taken into account, where appropriate, on the suitability of the submitted data for risk assessment. Such verification should not delay the assessment of an application.

(11) The information provided in the opinion of the Authority should be sufficient to ascertain whether the authorisation of the proposed use of the substance is safe for consumers. This includes conclusions on the toxicity of the substance, where

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appropriate, and possible establishment of an acceptable daily intake (ADI) expressed in a numerical form with details of a dietary exposure assessment for all food categories, including exposure of vulnerable consumer groups.

(12) The applicant should also take into account detailed guidance concerning the data required for risk assessment established by the Authority (The EFSA Journal[(10)]).

(13) This Regulation takes into account current scientific and technical knowledge. The Commission may revise this Regulation in the light of any developments in this field and the publication of any revised or additional scientific guidance by the Authority.

(14) Practical arrangements related to an application for the authorisation of food additives, food enzymes and flavourings, such as addresses, persons to contact, transmission of documents, etc., should be made available in a separate communication of the Commission and/or the Authority.

(15) It is necessary to provide for a time period in order to allow the applicants to comply with the provisions of this Regulation.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

## CHAPTER I

## GENERAL PROVISIONS

### *Article 1*

### Scope

This Regulation shall apply to applications as referred to in Article 3(1) of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

### *[F1 Article 1a*

### Definitions

For the purposes of this Regulation the following definitions shall apply:

(a) ‘Status of Qualified Presumption of Safety’ means the safety status assigned by the Authority to selected groups of micro-organisms on the basis of an assessment showing no safety concerns.

(b) ‘SCF guidelines of 1992’ means the guidelines for the presentation of data on food enzymes set out in the opinion expressed by the Scientific Committee for Food on 11 April 1991[(11)].**]**

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**Textual Amendments**

**F1** Inserted by Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes (Text with EEA relevance).

## CHAPTER II

## CONTENT, DRAFTING AND PRESENTATION OF AN APPLICATION

### *Article 2*

### Content of an application

1 The application referred to in Article 1 shall consist of the following:

a a letter;

b a technical dossier;

c a summary of the dossier.

2 The letter referred to in paragraph 1(a) shall be drafted in accordance with the model provided in the Annex.

3 The technical dossier referred to in paragraph 1(b) shall contain:

a the administrative data as provided for in Article 4;

b the data required for risk assessment as provided for in Articles 5, 6, 8 and 10; and

c the data required for risk management as provided for in Articles 7, 9 and 11.

4 In case of an application for a modification of the conditions of use of an already authorised food additive, food enzyme or flavouring all the data mentioned in Articles 5 to 11 may not be required. The applicant shall submit a verifiable justification why the proposed changes do not affect the results of the existing risk assessment.

5 In case of an application for a modification of the specifications of an already authorised food additive, food enzyme or flavouring:

a the data may be limited to the justification of the request and the changes in the specification;

b the applicant shall submit a verifiable justification why the proposed changes do not affect the results of the existing risk assessment.

6 The summary of the dossier referred to in paragraph 1(c) shall include a reasoned statement that the use of the product complies with the conditions laid down in:

a Article 6 of Regulation (EC) No 1332/2008; or

b Articles 6, 7 and 8 of Regulation (EC) No 1333/2008; or

c Article 4 of Regulation (EC) No 1334/2008.

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*Article 3*

**Drafting and presentation**

1 Applications shall be sent to the Commission. The applicant shall take into account the practical guidance on the submission of applications made available by the Commission (Directorate General for Health and Consumers'[(12)] website).

2 For the establishment of the Union list of food enzymes as referred to in Article 17 of Regulation (EC) No 1332/2008, the deadline for submitting applications shall be 24 months after the date of application of the implementing measures established by this Regulation.

*Article 4*

**Administrative data**

The administrative data as referred to in Article 2(3)(a) shall include:

(a) name of the applicant (company, organisation, etc.), address and contact details;

(b) name of the manufacturer(s) of the substance, if different than the applicant's, address and contact details;

(c) name of the person responsible for the dossier, address and contact details;

(d) date of submission of the dossier;

(e) type of the application, i.e. concerning a food additive, a food enzyme, or a flavouring;

(f) where applicable, chemical name according to IUPAC nomenclature;

(g) where applicable, E-number of the additive as defined in the Union legislation on food additives;

(h) where applicable, a reference to similar authorised food enzymes;

(i) where applicable, the FL-number of a flavouring substance as defined in the Union legislation on flavourings;

(j) where applicable, the information on authorisations falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(13)];

(k) table of content of the dossier;

(l) list of documents and other particulars; the applicant shall identify the number and titles of volumes of documentation submitted in support of the application; a detailed index with a reference to volumes and pages shall be included;

(m) list of the parts of the dossier to be treated as confidential; applicants shall indicate what they wish to be treated as confidential and give verifiable justification in accordance with Article 12 of Regulation (EC) No 1331/2008.