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)

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.

Article 3

Drafting and presentation

1 Applications shall be sent to the **[**F1appropriate authority**]**. **[**F2The applicant must take into account any practical guidance on the submission of applications made available by the Authority.**]**

F3 2 . . . . . .

Textual Amendments

F1 Words in Art. 3(1) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **140(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Art. 3(1) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **140(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Art. 3(2) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **140(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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 **[**F4retained EU law**]** 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 **[**F5retained EU law**]** 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(1);

(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.

Textual Amendments

F4 Words in Art. 4(g) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **141(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 4(i) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **141(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 5

General provisions on data required for risk assessment

1 The dossier submitted in support of an application for the safety evaluation of a substance shall enable a comprehensive risk assessment of the substance and shall permit verification that the substance does not pose a safety concern to consumers within the meaning of Article 6(a) of Regulation (EC) No 1332/2008, Article 6(1)(a) of Regulation (EC) No 1333/2008 and Article 4(a) of Regulation (EC) No 1334/2008.

2 The application dossier shall include all the available data relevant for the purpose of the risk assessment (i.e. full published papers of all references cited or full copies of the original unpublished studies).

3 The applicant shall take into account the latest guidance documents adopted or endorsed by the Authority available at the time of the submission of the application [F6]....

4 The documentation on the procedure followed when gathering the data shall be provided, including the literature search strategies (assumptions made, key words used, databases used, time period covered, limitation criteria, etc.) and a comprehensive outcome of such search.

5 The safety evaluation strategy and the corresponding testing strategy shall be described and justified with rationales for inclusion and exclusion of specific studies and/or information.

6 The individual raw data of the unpublished studies and, where possible, of the published studies as well as the individual results of examinations shall be made available on request from the Authority.

7 For each biological or toxicological study, it shall be clarified whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the substance under consideration.

Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC of the European Parliament and of the Council or,

if they are carried out outside the territory of the **[**F7United Kingdom**]**, they shall follow 'the OECD Principles of Good Laboratory Practice' (GLP). The applicant shall provide evidence to demonstrate that those requirements are complied with. For studies not conducted according to standard protocols, data interpretation, as well as a justification on their appropriateness for the risk assessment, shall be provided.

8 The applicant shall propose an overall conclusion on the safety of the proposed uses of the substance. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Textual Amendments

F6 Words in Art. 5(3) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **142(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in Art. 5(7) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **142(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Specific data required for risk assessment of food additives

1 In addition to data to be provided pursuant to Article 5, information shall be provided on:

a the identity and characterisation of the additive, including the proposed specifications and analytical data;

b where applicable, the particle size, particle size distribution and other physicochemical characteristics;

c the manufacturing process;

d presence of impurities;

e the stability, reaction and fate in foods to which the additive is added;

f where applicable, the existing authorisations and risk assessments;

g proposed normal and maximum use levels in the food categories mentioned in the **[**F8domestic**]** list, or in a newly proposed food category, or in a more specific foodstuff belonging to one of these categories;

h a dietary exposure assessment;

i the biological and toxicological data.

2 As regards to the biological and toxicological data, referred to in point (i) of paragraph 1, the following core areas shall be covered:

a toxicokinetics;

b subchronic toxicity;

c genotoxicity;

d chronic toxicity/carcinogenicity;

e reproductive and developmental toxicity.

Textual Amendments

F8 Word in Art. 6(1)(g) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **143**; 2020 c. 1, Sch. 5 para. 1(1)

Article 7

Data required for risk management of food additives

1 The dossier submitted in support of an application shall include the information necessary to verify whether there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means and whether the proposed use does not mislead the consumer within the meaning of points (b) and (c) of Article 6(1) of Regulation (EC) No 1333/2008.

2 In order to ensure the verification referred to in paragraph 1, appropriate and sufficient information shall be provided on:

a the identity of the food additive, including reference to the existing specifications;

b the function and technological need for the level proposed in each of the food categories or products for which authorisation is requested and an explanation that this can not be reasonably achieved by other economically and technologically practical means;

c the investigations on the efficacy of the food additive for the intended effect at the use level proposed;

d advantages and benefit for the consumer. The applicant shall take into account the requirements laid down in Article 6(2) of Regulation (EC) No 1333/2008;

e why the use would not mislead the consumer;

f proposed normal and maximum use levels in the food categories mentioned in the **[**[F9]domestic**]** list, or in a newly proposed food category, or in a more specific foodstuff belonging to one of these categories;

g the exposure assessment, based on normal and maximum intended use for each of the categories or products concerned;

h the amount of the food additive present in the final food as consumed by the consumer;

i analytical methods allowing the identification and quantification of the additive or its residues in food;

j where applicable, the compliance with the specific conditions for sweeteners and for colours as laid down in Articles 7 and 8 of Regulation (EC) No 1333/2008.

Textual Amendments

F9 Word in Art. 7(2)(f) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **144**; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Specific data required for risk assessment of food enzymes

1 In addition to data to be provided pursuant to Article 5, information shall be provided on:

a name(s), synonyms, abbreviations and classification(s);
b Enzyme Commission Number;
c the proposed specifications, including the origin;
d the properties;
e the reference to any similar food enzyme;
f the source material;
g the manufacturing process;
h the stability, reaction and fate in foods in which the food enzyme is used;
i where applicable the existing authorisations and evaluations;
j the proposed uses in food and, where applicable, the proposed normal and maximum use levels;
k the dietary exposure assessment;
l the biological and toxicological data.

2 As regards to the biological and toxicological data, referred to in point (l) of paragraph 1, the following core areas shall be covered:

a subchronic toxicity;
b genotoxicity.

[F10 3 By way of derogation from point (l) of paragraph 1 the dossier submitted in support of an application for the safety evaluation of a food enzyme does not need to include toxicological data if the food enzyme in question is obtained from:

a edible parts of plants or animals intended to be or reasonably expected to be ingested by humans; or
b micro-organisms having the status of Qualified Presumption of Safety.

4 Paragraph 3 shall not apply where the plants or animals concerned are genetically modified organisms as defined in point 5 of Article 2 of Regulation (EC) No 1829/2003 or where the micro-organism concerned is a genetically modified micro-organism as defined in Article 2 (b) of Directive 2009/41/EC[(2)]. However, paragraph 3, point (b) shall apply to micro-organisms where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A, point 4 of Directive 2009/41/EC.

5 Food enzymes may be grouped under one application provided that they have the same catalytic activity, are processed from the same source material (e.g. at species level) and with a substantially same production process, and have been obtained from:

a edible parts of plants or animals intended to be or reasonably expected to be ingested by humans; or
b micro-organisms having the status of Qualified Presumption of Safety; or
c micro-organisms which have been used in the production of food enzymes that have been evaluated and authorised by the competent authorities in either France or Denmark in accordance with the SCF guidelines of 1992.

6 Paragraph 5 shall not apply where the plants or animals concerned are genetically modified organisms as defined in point 5 of Article 2 of Regulation (EC) No 1829/2003 or where the micro-organism concerned is a genetically modified micro-organism as defined in Article 2 (b) of Directive 2009/41/EC.**]**

Textual Amendments

F10 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).

Article 9

Data required for risk management of food enzymes

1 The dossier submitted in support of an application shall include the information necessary to verify whether there is a reasonable technological need and whether the proposed use does not mislead the consumer within the meaning of points (b) and (c) of Article 6 of Regulation (EC) No 1332/2008.

2 In order to ensure the verification referred to in paragraph 1, appropriate and sufficient information shall be provided on:

a the identity of the food enzyme, including reference to the specifications;

b the function and technological need, including a description of the typical process(es) in which the food enzyme may be applied;

c the effect of the food enzyme on the final food;

d why the use would not mislead the consumer;

e the proposed normal and maximum use levels where applicable;

f the dietary exposure assessment [F11]... .

Textual Amendments

F11 Words in Art. 9(2)(f) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **145**; 2020 c. 1, Sch. 5 para. 1(1)

Article 10

Specific data required for risk assessment of flavourings

1 In addition to data to be provided pursuant to Article 5, information shall be provided on:

a the manufacturing process;

b specifications;

c where applicable, information on particle size, particle size distribution and other physicochemical characteristics;

d where applicable the existing authorisations and evaluations;

e the proposed uses in food and proposed normal and maximum use levels in the categories according to the **[**F12domestic**]** list or in a more specified type of product within the categories;

f the data on dietary sources;

g the dietary exposure assessment;

h the biological and toxicological data.

2 As regards to the biological and toxicological data, referred to in point (h) of paragraph 1, the following core areas shall be covered:

a examination for structural/metabolic similarity to flavouring substances in an existing flavouring group evaluation (FGE);

b genotoxicity;

c subchronic toxicity, where applicable;

d developmental toxicity, where applicable;

e chronic toxicity and carcinogenicity data, where applicable.

Textual Amendments

F12 Word in Art. 10(1)(e) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **146**; 2020 c. 1, Sch. 5 para. 1(1)

Article 11

Data required for risk management of flavourings

The dossier submitted in support of an application shall include the following information:

(a) the identity of the flavouring, including reference to the existing specifications;

(b) organoleptic properties of the substance;

(c) the proposed normal and maximum use levels in the food categories or in a more specific food belonging to one of these categories;

(d) the exposure assessment, based on normal and maximum intended use for each of the categories or products concerned.

(**1**) OJ L 268, 18.10.2003, p. 1.

(**2**) **[**[F10]OJ L 125, 21.5.2009, p. 75.**]**

Textual Amendments

F10 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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 234/2011, CHAPTER II.