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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)

(OJ L 64, 11.3.2011, p. 15)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012	L 168	21	28.6.2012
►**M2**	Commission Implementing Regulation (EU) 2020/1823 of 2 December 2020	L 406	43	3.12.2020

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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 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.

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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 ([1]).

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CHAPTER II

CONTENT, DRAFTING AND PRESENTATION OF AN APPLICATION

Article 2

Content of an application

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

(a) a letter;

(b) a technical dossier;

(c) a detailed summary and a public summary of the dossier.

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

([1]) http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_27.pdf.

▼M2

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 information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002; and

(c) the data required for risk management as provided for in Articles 7, 9 and 11 and information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002.

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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.

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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.

The public summary of the dossier shall not contain any information subject to a request for confidential treatment pursuant to Article 12 of Regulation (EC) No 1331/2008 and 39a of Regulation (EC) No 178/2002.

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Article 3

Drafting and presentation

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1. Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading,

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printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats. The applicant shall take into account the practical guidance on the submission of applications made available by the Commission (Directorate-General for Health and Food Safety ([1]) website).

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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 ([2]);

(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;

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(m) where the applicant submits, in accordance with Article 12 of Regulation (EC) No 1331/2008, a request to treat as confidential

([1]) https://ec.europa.eu/food/safety_en
([2]) OJ L 268, 18.10.2003, p. 1.

▼M2

certain parts of the information of the dossier, including supplementary information, a list of the parts to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree;

(n) a list of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002.

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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 (The EFSA Journal).

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 Union, 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.

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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.

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 Union 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.

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;

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(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 Union 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.

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.

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

(a) subchronic toxicity;

(b) genotoxicity.

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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 ([1]). 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.

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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.

([1]) OJ L 125, 21.5.2009, p. 75.

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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, as described in the Authority's guidance document on food enzymes ([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 Union 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.

([1]) Guidance of EFSA prepared by the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids on the Submission of a Dossier on Food Enzymes. *The EFSA Journal* (2009) 1305, p. 1.

▼B

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.

CHAPTER III

ARRANGEMENTS FOR CHECKING THE VALIDITY OF AN APPLICATION

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Article 12

Procedures

1. On receipt of an application the Commission shall, without delay, verify whether the food additive, food enzyme or flavouring falls within the scope of the appropriate sectoral food law, whether the application contains all the elements required under Chapter II and whether it fulfils the requirements set out in Article 32b of Regulation (EC) No 178/2002.

2. The Commission may consult the Authority on the suitability of the data for risk assessment in accordance with the scientific opinions on data requirements for the evaluation of substance applications and on whether the application fulfils the requirements set out in Article 32b of Regulation (EC) No 178/2002. The Authority shall provide the Commission with its views within 30 working days.

3. If the application is considered valid by the Commission, the evaluation period referred to in Article 5(1) of Regulation (EC) No 1331/2008 shall begin on the date of receipt of the Authority's reply referred to in paragraph 2 of this Article.

However, in accordance with point (a) of the second subparagraph of Article 17(4) of Regulation (EC) No 1332/2008, in the case of establishment of the Union list of food enzymes, Article 5(1) of Regulation (EC) No 1331/2008 shall not apply.

4. In case of an application to update the Union list of food additives, food enzymes or flavourings, the Commission may request additional information from the applicant on matters regarding the validity of the application and inform the applicant of the period within which that information has to be provided. In the case of applications submitted in compliance with Article 17(2) of Regulation (EC) No 1332/2008, the Commission shall determine that period together with the applicant.

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5. The application shall be considered not valid if:

(a) it does not fall within the appropriate sectoral food law,

(b) it does not contain all the elements required under Chapter II,

(c) it does not comply with Article 32b of Regulation (EC) No 178/2002 or,

(d) the Authority considers that the data for risk assessment are not suitable.

In such a case, the Commission shall inform the applicant, the Member States and the Authority indicating the reasons why the application is considered not valid.

6. By way of derogation from paragraph 5 and without prejudice to Article 32b(4) and (5) of Regulation (EC) No 178/2002, an application may be considered as valid even if it does not contain all the elements required under Chapter II, provided that the applicant has submitted appropriate justification for each missing element.

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CHAPTER IV

OPINION OF THE AUTHORITY

Article 13

Information to be included in the opinion of the Authority

1. The opinion of the Authority shall include the following information:

(a) the identity and characterisation of the food additive, food enzyme or flavouring;

(b) the assessment of the biological and toxicological data;

(c) a dietary exposure assessment for the European population taking into account other possible sources of dietary exposure;

(d) an overall risk assessment establishing if possible and relevant a health-based guidance value, and highlighting uncertainties and limitations where relevant;

(e) when the dietary exposure exceeds the health-based guidance value identified in the overall risk assessment, the dietary exposure assessment of the substance shall be detailed, providing where possible the contribution to the total exposure of each food category or foodstuff for which the use is authorised or has been requested;

(f) conclusions;

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(g) the results of consultations performed during the risk assessment process in accordance with Article 32c(2) of Regulation (EC) No 178/2002.

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2. The Commission may ask for more specific additional information in its request for an opinion of the Authority.

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CHAPTER V

FINAL PROVISIONS

Article 14

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 11 September 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼M2

ANNEX

MODEL LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF FOOD ADDITIVES

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: .....

Subject: **Application for the authorisation of a food additive in accordance with Regulation (EC) No 1331/2008**

☐ Application for the authorisation of a new food additive

☐ Application for the modification of the conditions of use of an already authorised food additive

☐ Application for the modification of the specifications of an already authorised food additive

(Please indicate clearly by ticking one of the boxes).

The Applicant(s) and/or his/their Representative(s) in the European Union.

(name, address, …)

.....

.....

.....

submit(s) the present application for the authorisation of (a) food additive(s).

Food additive name:

.....

ELINCS or Einecs number (if attributed):

CAS No (if applicable):

Functional class(es) of food additives [1]:

(list)

.....

Food categories and required levels:

Food category	Normal use level	Maximum proposed use level

Yours sincerely,

Signature: .....

[1] The functional classes of food additives in foods and of food additives in food additives and food enzymes are listed in Annex I to Regulation (EC) No 1333/2008. If the additive does not belong to one of the mentioned classes, a new functional class name and definition can be proposed.

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Enclosures:

☐ Complete dossier

☐ Public summary of the dossier (non-confidential)

☐ Detailed summary of the dossier

☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree

☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002

☐ Copy of administrative data of applicant(s)

MODEL LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF FOOD ENZYMES

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: .....

Subject: **Application for the authorisation of a food enzyme in accordance with Regulation (EC) No 1331/2008**

☐ Application for the authorisation of a new food enzyme

☐ Application for the modification of the conditions of use of an already authorised food enzyme

☐ Application for the modification of the specifications of an already authorised food enzyme

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the European Union

(name, address, …)

.....

.....

submit(s) the present application for the authorisation of (a) food enzyme(s).

Food enzyme name:

.....

Enzyme Classification Number of Enzyme Commission of the IUBMB:

Source material:

.....

.....

Name	Specifi-cations	Foods	Conditi-ons of use	Restrictions on the sale of the food enzyme to the final consumer	Specific requirement in respect of labelling of food

Yours sincerely,

Signature: .....

▼M2

Enclosures:

☐ Complete dossier

☐ Public summary of the dossier (non-confidential)

☐ Detailed summary of the dossier

☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree

☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002

☐ Copy of administrative data of applicant(s)

MODEL LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF FOOD FLAVOURINGS

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: .....

Subject: **Application for the authorisation of a food flavouring in accordance with Regulation (EC) No 1331/2008**

☐ Application for the authorisation of a new flavouring substance

☐ Application for the authorisation of a new flavouring preparation

☐ Application for the authorisation of a new flavour precursor

☐ Application for the authorisation of a new thermal process flavouring

☐ Application for the authorisation of a new other flavouring

☐ Application for the authorisation of a new source material

☐ Application for the modification of the conditions of use of an already authorised food flavouring

☐ Application for the modification of the specifications of an already authorised food flavouring

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the European Union

(name, address, …)

.....

.....

submit(s) the present application for the authorisation of (a) food flavouring(s).

Name of the flavouring or source material:

.....

FL-, CAS-, JECFA-, CoE-number (if attributed):

Organoleptic properties of the flavouring:

.....

Food categories and required levels:

▼**M2**

Food category	Normal use level	Maximum proposed use level

Yours sincerely,

Signature: .....

Enclosures:

☐ Complete dossier

☐ Public summary of the dossier (non-confidential)

☐ Detailed summary of the dossier

☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree

☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002

☐ Copy of administrative data of applicant(s)