Procedure for submitting an application on flavourings

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Health and Consumers

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   what is, updating

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Union list of flavourings and source materials

Regulation ***872/2012*** *– lays down the Union list*

Union list = Annex I of Regulation 1334/2008

- **Part A Flavouring substances**
  Around 2500 substances listed
- **Part B to F - Other categories of flavourings and non-food source materials**
  No substances listed yet

Part A Flavouring substances (1)

- Around 2100 authorised flavouring substances
- Around **350 flavouring substances under evaluation** which may continue to be placed on the market (substances under evaluation)
  - Regulation (EC) No 2232/96 - a Union procedure for flavouring substances – still applies to substances under evaluation
  - Commission Regulation (EC) No 1565/2000 – an evaluation programme – still applies to substances under evaluation

Part A Flavouring substances (2)

Substances under evaluation by EFSA (evaluation programme)

Data is submitted to COM

COM sends a mandate to EFSA

EFSA evaluates the submitted data within 9 months from the receipt of such data

Update of the Union list in accordance with the **common authorisation procedure (Regulation 1331/2008)**

Part A Flavouring substances (3)

New substances or re-evaluations of authorised substances or new conditions of use

- Applicants must follow the **common authorisation procedure**
- Time lines set in the CAP legislation for EFSA evaluation and COM authorisation apply for those flavouring substances submitted
- Update of the Union list in accordance with common authorisation procedure

Part B to F - Other categories of flavourings and non-food source materials

Reg No 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation 1334/2008

- For substances currently on the market applications should be submitted by 22 October 2015
- Applicants must follow the **common authorisation procedure.** All time lines apply
- Update of the Union list in accordance with the common authorisation procedure

Common authorisation procedure Reg. 1331/2008

Reg **1331/2008** establishing a common authorisation procedure for food additives, food enzymes and food flavourings

- **Procedures, deadlines for evaluation and authorisation, confidentiality**

Reg 234/2011 implementing Reg 1331/2008

(as amended by Reg 562/2012)

- The content, drafting and presentation of the application
- The arrangements for checking the validity of applications
- The type of information that must be included in the opinion of EFSA

COM Practical guidance for applicants

EFSA scientific guidance

Common authorisation procedure

Applies to:

- Flavourings for which placing on the market in the EU is authorised by the Union list

  (and also other substances: food enzymes, food additives)

  - Does not apply to smoke flavourings

Updating the Union list means:

- Adding the substance on the list
- Removing the substance from the list
- Addition, removing or changing of the conditions, specifications or restrictions which are associated with the presence of the substance on the list

Procedure (1)

May be **started** either on the initiative of the Commission or following an application.

Applications may be made by a Member State or by an interested party.

Applications shall be sent to the Commission.

Reference documents for applicants

- **Regulation 1334/2008 (for concepts, scope, definitions, preocedures,…)**

- **Regulation 1331/2008**
- **Implementing Regulation 234/2011**

- **Practical Guidance from the Commission (2014)**
- **Guidance on flavour enhancers and substances with modifying properties (2014)**

- **EFSA guidance (2010)**
- **EFSA proposed template (2012)**

All these documents in our Santé's website (formerly SANCO) or EFSA's

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(3) In order to protect human health, the safety of additives, enzymes and flavourings for use in foodstuffs for human consumption must be assessed before they are placed on the Community market.

(4) Regulation (EC) No 1333/2008 of the ment and of the Council of 16 Decer additives [3], Regulation (EC) No 133 pean Parliament and of the Council on food enzymes [4] and Regulatio of the European Parliament ar 16 December 2008 on flavourin dients with flavouring properties (hereinafter referred to as the s harmonised criteria and re assessment and authorisatior

(5) It is envisaged, in parti enzymes and food flavo of food flavourings m Regulation (EC) No 1? food ingredients wit on foods], must nc foodstuffs for hum conditions laid d are included on

(6) Ensuring tra food is abs confidenc

(7) In this three asse tin m

[1] OJ C 168, 20.7.2007, p. 34.

[2] Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 134), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 1), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

[3] See

[4] Se

[5]

▶B

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:

▶M1 Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012

	Official Journal		
	No	page	date
	L 168	21	28.6.2012

Version 9
Updated on 5 November 2014

Practical guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings

Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer

27.5.2014

Contents

IMPORTANT DISCLAIMER

guidance notes have been produced by the European Commission's DG Health and ers with the aim of providing informal guidance for the applicants and they do not ly represent the official views of the Commission. This document has no formal legal l should be read in conjunction with the appropriate legislation. In the event of a imate responsibility for the interpretation of the law lies with the Court of Justice.

e notes have been subject to consultation with the EU Member States' experts on d the relevant stakeholders.

European Commission

European Food Safety Authority

EFSA Journal 2010; 8(6):1623

SCIENTIFIC OPINION

Guidance on the data required for the risk assessment of flavourings to be used in or on foods[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This Opinion follows a request from the European Commission for the data required for the risk assessment of flavourings.

The Panel considered that the elaboration of a proposal concerning the data required for the risk assessment of new flavouring substances should build upon the experience gained in the course of the evaluation of flavouring substances included in the Union list.

A general principle of this Opinion is that new flavouring substances that can be assigned to one of the existing Flavouring Group Evaluations (FGEs) on the basis of structural and metabolic similarities should be evaluated according to the scientific principles and to the group-based approach underlying the former evaluation programme.

In addition, the proposal provides a Procedure for the evaluation of flavouring substances which cannot be assigned to one of the existing FGEs. This should allow an individual evaluation of the new flavouring substance.

The proposal also covers flavourings other than flavouring substances for which an evaluation and an approval is required according to Article 9 (b) – (f) of the Regulation (EC) No 1334/2008.

1 On request from the European Commission, Question No EFSA-Q-2009-00004, adopted on 20 May 2010.

2 Panel members: Arturo Anadon, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertle, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettil Svensson, Fidel Toldra, Rosemary Waring, Detlef [illegible] on Flavourings for the preparation of this

European Food Safety Authority

EFSA Journal 2012;10(1):218

TECHNICAL REPORT OF EFSA

Proposed template to be used in drafting scientific opinion on flavouring substances (explanatory notes for guidance included)[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The proposed template is expected to facilitate the drafting and the harmonization of scientific opinions on flavouring substances.

t the 13th CEF Plenary held on 10 May 2010, the Panel adopted an Opinion on data needed for the aluation of flavourings in accordance with Regulation (EC) No 1334/2008. This Opinion has been ed by the Commission for the preparation of the implementing measures (Regulation (EC) No 1/2011), which lay down amongst other aspects, the content, drafting and presentation of the lications for the evaluation and authorisation of flavourings.

ler to assist the application process, the CEF Unit was invited by EFSA to prepare, together with EF Flavouring Working Group, the current note for guidance giving explanatory examples of fic data needed for the risk assessment established in the EFSA Guidance. The explanatory ave been incorporated into the proposed template to be used in drafting opinions on flavourings ices.

der is recommended to go through the EFSA Scientific Opinion (EFSA Journal 2010;8(6): ı "Guidance on data required for the risk assessment of flavourings to be used in or on food" detailed insight into data to be incorporated in this technical report.

DS

substances, guidance, template, note for guidance

Health and Food Safety

Commission Practical Guidance

- Accompanying letter
- Technical dossier
  - Administrative data
  - Risk assessment data
  - Risk mangement data
- Summary of the dossier
- Public summary of the dossier
- Checklist
- CD/DVD
- List of the parts of the dossier requested to be treated as confidential

European Commission

Wonderful Flavourings Applicant

Michael Flüh, Head of Unit
European Commission
Health and Consumer Directorate-General
Directorate E – Safety of the food chain
Unit E3 – Chemicals, contaminants, pesticides
B-1049 Brussels

Date

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

☒ Application for an authorisation of a new flavouring substance
☐ Application for an authorisation of a new flavouring preparation
☐ Application for an authorisation of a new flavour precursor
☐ Application for an authorisation of a new thermal process flavouring
☐ Application for an authorisation of a new other flavouring
☐ Application for an authorisation of a new source material
☐ Application for a modification of the conditions of use of an already authorised food flavouring

escription of appli

enclosures

Procedure (Commission)

Submission of the application

- **Acknowledgment within 14 working days**
- **Verification that the application falls within the appropriate legislation**
- **Validity check of the data by COM (completeness of the application)**

  If not complete, COM sends a letter to the applicant with request for missing data and gives a certain time to provide this.

  If not provided within the set time limit, COM sends a letter to the applicant to confirm that the application was not considered valid.

Procedure (Com, EFSA)

If the requested use is liable to have an effect on human health, the Commission will ask EFSA for an opinion.

- **Mandate from COM to EFSA**
- **EFSA has 30 working days to check the suitability of the data**

  Letter to COM whether data is suitable or not.

  If not suitable, COM sends a letter to the applicant with request for missing data and gives a certain time to provide this.

  If not provided within the set time limit, COM will send a letter to the applicant to confirm that the application was not considered valid

  If not valid, for COM to inform the applicant, the Member States and EFSA why not.

- **Application will be made available to the Member States**

Procedure (EFSA)

EFSA must give an opinion within 9 months of receipt of a valid application.

- **Time shall begin from the date when the Authority's letter is received by COM**
- **Time may be extended if additional information is needed**
  - EFSA to decide the time but after consulting with the applicant
  - EFSA has to inform COM
    - COM has 8 working days to object, if not, time extended
    - COM informs the Member States of the extension
    - If data not sent within the agreed time limit, EFSA will finalise its opinion on the basis of the data available.
    - If applicant sends new information on their own initiative, this is to be sent to EFSA and COM but no change to time limits (except in exceptional circumstances)
  - New information made available to the Member States

Procedure (After EFSA)

Ends with the adoption by COM of a regulation implementing the update

- **Within 9 months from the EFSA opinion**
- **COM submits a draft regulation to the Standing Committee (PAFF)**

Regulatory procedure with scrutiny

Removal of a substance: scrutiny period of 3 months

Addition of a substance or changes to conditions of use: scrutiny period of 2 months

Immediately applicable implementing act

Urgency for removal of a substance or for changing conditions of use

Some statistics on applications on flavourings under CAP, since 2012

Year	No of applications	Additional information	Not suitable	Suitable	Handled by Comm	Pending
(2010-11)	22	Not reported here	Not reported here			
2012	2			2		
2013	9		3	2	4	
2014	11	5	2	0	1	3
2015	-		-	-		

Conclusions (1)

- **The number of applications of new flavourings under the CAP is likely to increase**
- **It is the only way to add new flavourings to the Union list**
- **Flavourings not on the list can not be used**

- **There seems to be some difficulties with the submission of valid and suitable applications by some applicants as the existing guidances by the Commission and EFSA are not followed properly**

- **Some applicants may have not paid sufficient attention to the changes from the old system to the new**

Conclusions (2)

There is still also a big workload of the old evaluation program, but the situation is improving → effort by applicants, EFSA, the Commission

Regarding new flavourings: Learning for everybody (applicants, the Commission, EFSA, …)!!!








Thank you!

Questions?

More info on flavourings:

http://ec.europa.eu/food/food/fAEF/flavouring/index_en.htm