Commission Implementing Regulation (EU) 2020/1823 of 2 December 2020 amending Regulation (EU) No 234/2011 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 IMPLEMENTING REGULATION (EU) 2020/1823

of 2 December 2020

amending Regulation (EU) No 234/2011 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,

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[(2)], Regulation (EC) No 1332/2008 of the European Parliament and of the Council[(3)] and Regulation (EC) No 1334/2008 of the European Parliament and of the Council[(4)] ('the sectoral food laws').

(2) Commission Regulation (EU) No 234/2011[(5)] lays down provisions regarding the content, drafting and presentation of applications to update the Union lists under each sectoral food law. That Regulation provides for detailed arrangements for checking the validity of applications for food additives, food enzymes and food flavourings and the type of information that should be included in the opinion of the European Food Safety Authority ('the Authority').

(3) Regulation (EU) 2019/1381 of the European Parliament and the Council[(6)] amended Regulation (EC) No 178/2002[(7)] and Regulation (EC) No 1331/2008. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where the Authority delivers a scientific risk assessment, including in the area of food additives, food enzymes and food flavourings.

(4) As regards the placing on the market of food additives, food enzymes and food flavourings and ingredients with flavouring properties for use in and on foods, the

amendments to Regulation (EC) No 178/2002 introduced new provisions concerning, amongst other issues: general pre-submission advice by the staff of the Authority at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application and the consequences of non-compliance with that obligation. It also introduced provisions on the public disclosure, by the Authority, of all scientific data, studies and other information supporting applications with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by the Authority in relation to the information submitted by an applicant, where the Commission requests the opinion of the Authority.

(5) Regulation (EU) 2019/1381 also amended Regulation (EC) No 1331/2008 to include provisions ensuring consistency with the adaptations of Regulation (EC) No 178/2002 and taking into account sectoral specificities with respect to confidential information.

(6) Given the scope and application of all those amendments, Regulation (EU) No 234/2011 should be adjusted to accommodate the changes as regards the content, drafting and presentation of applications to update the Union lists under each sectoral food law, the arrangements for checking the validity of applications and the information to be included in the opinions of the Authority. In particular, Regulation (EU) No 234/2011 should make reference to the standard data formats and require that applications provide information demonstrating compliance with the notification requirement laid down in Article 32b of Regulation (EC) No 178/2002, It should also clarify that the assessment of compliance with the notification requirement forms part of the verification of the validity of an application.

(7) Furthermore, taking into account the fact that the Authority is responsible for managing the database of studies in accordance with Article 32b of Regulation (EC) No 178/2002, it should also be made possible for the Commission to consult the Authority as part of the verification of the validity of applications to ascertain that the application fulfils the relevant requirements that are laid down in that Article.

(8) Where public consultations are performed during the risk assessment in accordance with Article 32c(2) of Regulation (EC) No 178/2002, the opinion of the Authority should also include the results of those consultations, in line with the transparency requirements to which the Authority is subject.

(9) This Regulation should apply from 27 March 2021 and to applications submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 234/2011

Regulation (EU) No 234/2011 is amended as follows:

(1) Article 2 is amended as follows:

(a) paragraph 1 is replaced by the following:

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.;

(b) paragraph 3 is replaced by the following:

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.;

(c) paragraph 6 is replaced by the following:

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.;

(2) Article 3, paragraph 1 is replaced by the following

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, 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[8] website).;

(3) Article 4 is amended as follows:

(a) point (m) is replaced by the following:

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

(b) point (n) is added:

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

(4) Article 12 is replaced by the following:

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.

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.;

(5) in Article 13(1), the following point (g) is added:

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

(6) the Annex is replaced by the Annex to this Regulation.

Article 2

Entry into force and application

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

It shall apply from 27 March 2021 and to applications submitted to the Commission from that date.

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

Done at Brussels, 2 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

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[(9)]:

(list)

….

Food categories and required levels:

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)

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	**Specifications**	**Foods**	**Conditions 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: ……

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:

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)

(**1**) OJ L 354, 31.12.2008, p. 1.

(**2**) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

(**3**) Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

(**4**) 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 and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

(**5**) 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 (OJ L 64, 11.3.2011, p. 15).

(**6**) Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

(**7**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**8**) https://ec.europa.eu/food/safety_en';

(**9**) 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.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1823.