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)

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[(1)] 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.

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