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)

CHAPTER II

COMMON PROCEDURE

Article 3

Main stages of the common procedure

1 The common procedure for updating the Community list 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, who may represent several interested parties, in accordance with the conditions provided for by the implementing measures referred to in Article 9(1)(a) (hereinafter referred to as the applicant). Applications shall be sent to the Commission.

2 The Commission shall seek the opinion of the European Food Safety Authority (hereinafter referred to as the Authority), to be given in accordance with Article 5.

However, for the updates referred to in Article 2(2)(b) and (c), the Commission shall not be required to seek the opinion of the Authority if the updates in question are not liable to have an effect on human health.

3 The common procedure shall end with the adoption by the Commission of a regulation implementing the update, in accordance with Article 7.

4 By way of derogation from paragraph 3, the Commission may end the common procedure and decide not to proceed with a planned update, at any stage of the procedure, if it judges that such an update is not justified. Where applicable, it shall take account of the opinion of the Authority, the views of Member States, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

In such cases, where applicable, the Commission shall inform the applicant and the Member States directly, indicating in its letter the reasons for not considering the update justified.

Article 4

Initiating the procedure

1 On receipt of an application to update the Community list, the Commission:

a shall acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;

b where applicable, shall as soon as possible notify the Authority of the application and request its opinion in accordance with Article 3(2).

The application shall be made available to the Member States by the Commission.

2 Where it starts the procedure on its own initiative, the Commission shall inform the Member States and, where applicable, request the opinion of the Authority.

Article 5

Opinion of the Authority

1 The Authority shall give its opinion within nine months of receipt of a valid application.

2 The Authority shall forward its opinion to the Commission, the Member States and, where applicable, the applicant.

Article 6

Additional information concerning risk assessment

1 In duly justified cases where the Authority requests additional information from applicants, the period referred to in Article 5(1) may be extended. After consulting the applicant, the Authority shall lay down a period within which this information can be provided and shall inform the Commission of the additional period needed. If the Commission does not object within eight working days of being informed by the Authority, the period referred to in Article 5(1) shall be automatically extended by the additional period. The Commission shall inform the Member States of the extension.

2 If the additional information is not sent to the Authority within the additional period referred to in paragraph 1, the Authority shall finalise its opinion on the basis of the information already provided.

3 Where applicants submit additional information on their own initiative, they shall send it to the Authority and to the Commission. In such cases, the Authority shall give its opinion within the original period without prejudice to Article 10.

4 The additional information shall be made available to the Member States and the Commission by the Authority.

Article 7

Updating the Community list

1 Within nine months of the Authority giving its opinion, the Commission shall submit to the Committee referred to in Article 14(1) a draft regulation updating the Community list, taking account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

In those cases where an opinion of the Authority has not been requested, the nine-month period shall start from the date the Commission receives a valid application.

2 In the Regulation updating the Community list, the considerations on which it is based shall be explained.

3 Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the reasons for its decision.

4 The measures, designed to amend non-essential elements of each sectoral food law, relating to the removal of a substance from the Community list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

5 On grounds of efficiency, the measures designed to amend non-essential elements of each sectoral food law, *inter alia*, by supplementing it, relating to the addition of a substance to the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Community list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(4).

6 On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14(5) for the removal of a substance from the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

Article 8

Additional information concerning risk management

1 Where the Commission requests additional information from applicants on matters concerning risk management, it shall determine, together with the applicant, a period within which that information can be provided. In such cases, the period referred to in Article 7 may be extended accordingly. The Commission shall inform the Member States of the extension and shall make the additional information available to the Member States once it has been provided.

2 If the additional information is not sent within the additional period referred to in paragraph 1, the Commission shall act on the basis of the information already provided.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1331/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.