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 III

MISCELLANEOUS PROVISIONS

Article 9

Implementing measures

1 In accordance with the regulatory procedure referred to in Article 14(2), within a period of no longer than 24 months from the adoption of each sectoral food law, the implementing measures for this Regulation shall be adopted by the Commission, and shall concern in particular:

a the content, drafting and presentation of the application referred to in Article 4(1);

b the arrangements for checking the validity of applications;

c the type of information that must be included in the opinion of the Authority referred to in Article 5.

2 With a view to the adoption of the implementing measures referred to in paragraph 1(a), the Commission shall consult the Authority, which, within six months of the date of entry into force of each sectoral food law, shall present it with a proposal concerning the data required for risk assessment of the substances concerned.

Article 10

Extension of time periods

In exceptional circumstances, the periods referred to in Article 5(1) and Article 7 may be extended by the Commission on its own initiative or, where applicable, at the Authority's request, if the nature of the matter in question so justifies, without prejudice to Article 6(1) and Article 8(1). In such cases the Commission shall, where appropriate, inform the applicant and the Member States of the extension and the reasons for it.

Article 11

Transparency

The Authority shall ensure the transparency of its activities in accordance with Article 38 of Regulation (EC) No 178/2002. In particular, it shall make its opinions public without delay. It shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1).

Article 12

Confidentiality

1 Among the information provided by applicants, confidential treatment may be given to information the disclosure of which might significantly harm their competitive position.

Information relating to the following shall not, in any circumstances, be regarded as confidential:

a the name and address of the applicant;

b the name and a clear description of the substance;

c the justification for the use of the substance in or on specific foodstuffs or food categories;

d information that is relevant to the assessment of the safety of the substance;

e where applicable, the analysis method(s).

2 For the purposes of implementing paragraph 1, applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

3 The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants and the Member States accordingly.

4 After being made aware of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.

5 The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

6 If an applicant withdraws, or has withdrawn, its application, the Commission, the Authority and the Member States shall not disclose confidential information, including information the confidentiality of which is the subject of disagreement between the Commission and the applicant.

7 The implementation of paragraphs 1 to 6 shall not affect the circulation of information between the Commission, the Authority and the Member States.

Article 13

Emergencies

In the event of an emergency concerning a substance on the Community list, particularly in the light of an opinion of the Authority, measures shall be adopted in accordance with the procedures referred to in Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 14

Committee

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be two months, two months and four months respectively.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 15

Competent authorities of the Member States

Not later than six months after the entry into force of each sectoral food law, Member States shall forward to the Commission and to the Authority, in relation to each sectoral food law, the name and address of the national competent authority for the purposes of the common procedure, as well as a contact point therein.

Status:
Point in time view as at 16/12/2008.

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.