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)

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 European Parliament and of the Council of 16 December 2008 on food additives[(3)], Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes[(4)] and 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[(5)] (hereinafter referred to as the sectoral food laws) lay down harmonised criteria and requirements concerning the assessment and authorisation of these substances.

(5) It is envisaged, in particular, that food additives, food enzymes and food flavourings, to the extent that the safety of food flavourings must be assessed in accordance with Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods], must not be placed on the market or

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used in foodstuffs for human consumption, in accordance with the conditions laid down in each sectoral food law, unless they are included on a Community list of authorised substances.

(6) Ensuring transparency in the production and handling of food is absolutely crucial in order to maintain consumer confidence.

(7) In this context, it appears appropriate to establish for these three categories of substances a common Community assessment and authorisation procedure that is effective, time-limited and transparent, so as to facilitate their free movement within the Community market.

(8) This common procedure must be founded on the principles of good administration and legal certainty and must be implemented in compliance with those principles.

(9) This Regulation will thus complete the regulatory framework concerning the authorisation of the substances by laying down the various stages of the procedure, the deadlines for those stages, the role of the parties involved and the principles that apply. Nevertheless, for some aspects of the procedure, it is necessary to take the specific characteristics of each sectoral food law into consideration.

(10) The deadlines laid down in the procedure take into account the time needed to consider the different criteria set in each sectoral food law, as well as allowing adequate time for consultation when preparing the draft measures. In particular, the nine-months deadline for the Commission to present a draft regulation updating the Community list should not preclude the possibility of this being done within a shorter period.

(11) Upon receipt of an application the Commission should initiate the procedure and where necessary seek the opinion of the European Food Safety Authority (hereinafter referred to as the Authority) established by 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[(6)] as soon as possible after the validity and applicability of the application have been assessed.

(12) In accordance with the framework for risk assessment in matters of food safety established by Regulation (EC) No 178/2002, the authorisation to place substances on the market must be preceded by an independent scientific assessment, of the highest possible standard, of the risks that they pose to human health. This assessment, which must be carried out under the responsibility of the Authority, must be followed by a risk management decision taken by the Commission under a regulatory procedure that ensures close cooperation between the Commission and the Member States.

(13) The authorisation to place substances on the market should be granted pursuant to this Regulation provided that the criteria for authorisation laid down under the sectoral food laws are satisfied.

(14) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into

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account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

(15) In order to ensure that both business operators in the sectors concerned and the public are kept informed of the authorisations in force, the authorised substances should be included on a Community list created, maintained and published by the Commission.

(16) Where appropriate and under certain circumstances, the specific sectoral food law may provide for protection of scientific data and other information submitted by the applicant for a certain period of time. In this case, the sectoral food law should lay down the conditions under which these data may not be used for the benefit of another applicant.

(17) Networking between the Authority and the Member States' organisations operating in the fields within the Authority's mission is one of the basic principles of the Authority's operation. In consequence, in preparing its opinion, the Authority may use the network made available to it by Article 36 of Regulation (EC) No 178/2002 and by Commission Regulation (EC) No 2230/2004[(7)].

(18) The common authorisation procedure for the substances must fulfil transparency and public information requirements while guaranteeing the right of applicants to preserve the confidentiality of certain information.

(19) Protecting the confidentiality of certain aspects of an application should be maintained as a consideration in order to protect the competitive position of an applicant. However, information relating to the safety of a substance, including, but not limited to, toxicological studies, other safety studies and raw data as such, should under no circumstances be confidential.

(20) Pursuant to Regulation (EC) No 178/2002, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[(8)] applies to documents held by the Authority.

(21) Regulation (EC) No 178/2002 establishes procedures for taking emergency measures in relation to foodstuffs of Community origin or imported from third countries. It authorises the Commission to adopt such measures in situations where foodstuffs are likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.

(22) In the interests of efficiency and legislative simplification, there should be a medium-term examination of the question whether to extend the scope of the common procedure to other legislation in the area of food.

(23) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States on account of differences between national laws and provisions and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

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(24) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(9)].

(25) In particular the Commission should be empowered to update the Community lists. Since those measures are of general scope and are designed to amend non-essential elements of each sectoral food law, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(26) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the addition of substances to the Community lists and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community lists.

(27) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the removal of a substance from the Community lists and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community lists,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PRINCIPLES

Article 1

Subject matter and scope

1 This Regulation lays down a common procedure for the assessment and authorisation (hereinafter referred to as the common procedure) of food additives, food enzymes, food flavourings and source materials of food flavourings and of food ingredients with flavouring properties used or intended for use in or on foodstuffs (hereinafter referred to as the substances), which contributes to the free movement of food within the Community and to a high level of protection of human health and to a high level of consumer protection, including the protection of consumer interests. This Regulation shall not apply to smoke flavourings falling within the scope of Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods[(10)].

2 The common procedure shall lay down the procedural arrangements for updating the lists of substances the marketing of which is authorised in the Community pursuant to Regulation (EC) No 1333/2008 [on food additives], Regulation (EC) No 1332/2008 [on food enzymes] and Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods] (hereinafter referred to as the sectoral food laws).

3 The criteria according to which substances can be included on the Community list provided for in Article 2, the content of the regulation referred to in Article 7 and, where

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applicable, the transitional provisions concerning ongoing procedures are laid down in each sectoral food law.

Article 2

Community list of substances

1 Under each sectoral food law, substances that have been authorised to be placed on the Community market shall be included on a list the content of which is determined by the said law (hereinafter referred to as the Community list). The Community list shall be updated by the Commission. It shall be published in the *Official Journal of the European Union*.

2 'Updating the Community list' means:

a adding a substance to the Community list;

b removing a substance from the Community list;

c adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

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.