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 (Text with EEA relevance)

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

(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) Food enzymes other than those used as food additives are not currently regulated or are regulated as processing aids under the legislation of the Member States. Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of food enzymes may hinder their free movement, creating conditions for unequal and unfair competition. It is therefore necessary to adopt Community rules harmonising national provisions relating to the use of enzymes in foods.

(4) This Regulation should only cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids (hereinafter referred to as food enzymes). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function but are intended for human consumption, such as enzymes for nutritional or digestive

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purposes. Microbial cultures traditionally used in the production of food such as cheese and wine, and which may incidentally produce enzymes but are not specifically used to produce them, should not be considered food enzymes.

(5) Food enzymes used exclusively in the production of food additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(3)] should be excluded from the scope of this Regulation, since the safety of these foods is already assessed and regulated. However, when these food enzymes are used as such in food, they are covered by this Regulation.

(6) Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes must be safe when used, there must be a technological need for their use and their use must not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. The approval of food enzymes should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors, the precautionary principle and the feasibility of controls.

(7) Some food enzymes are permitted for specific uses, such as in fruit juices and certain similar products and certain lactoproteins intended for human consumption, and for certain authorised oenological practices and processes. The use of such food enzymes should comply with this Regulation and with the specific provisions laid down in the relevant Community legislation. Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption[(4)], Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption[(5)] and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine[(6)] should therefore be amended accordingly. Since all food enzymes should be covered by this Regulation, Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[(7)] should be amended accordingly.

(8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes and specify any conditions governing their use, including where necessary information on their function in the final food. This list should be supplemented by specifications, in particular on their origin, including where relevant information about allergenic properties, and purity criteria.

(9) In order to ensure harmonisation, the risk assessment of food enzymes and their inclusion in the Community list should be carried out in accordance with the procedure laid down in 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[(8)].

(10) Under 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

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of food safety[9], the European Food Safety Authority (hereinafter referred to as the Authority) is to be consulted on matters likely to affect public health.

(11) A food enzyme which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[10] should be authorised in accordance with that Regulation as well as under this Regulation.

(12) A food enzyme already included in the Community list under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the authorisation and the specifications under this Regulation, should be submitted for evaluation by the Authority. 'Significantly different' could mean *inter alia* a change of the production method from extraction from a plant to production by fermentation using a micro-organism or a genetic modification of the original micro-organism, a change in starting materials, or a change in particle size.

(13) Since many food enzymes are already on the Community market, provision should be made to ensure that the switchover to a Community list of food enzymes takes place smoothly and does not disturb the existing food enzyme market. Sufficient time should be allowed for applicants to make available the information necessary for the risk assessment of these products. An initial two-year period should therefore be allowed following the date of application of the implementing measures to be laid down in accordance with Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], in order to give applicants sufficient time to submit the information on existing enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period.

(14) In order to ensure fair and equal conditions for all applicants, the Community list should be drawn up in a single step. That list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period. However, the risk assessments of the Authority for individual enzymes should be published as soon as they are completed.

(15) A significant number of applications is expected to be submitted during the initial two-year period. A lengthy period may therefore be needed before the risk assessment of these has been completed and the Community list is drawn up. In order to ensure equal access to the market for new food enzymes after the initial two-year period, a transitional period should be provided for during which food enzymes and food using food enzymes may be placed on the market and used, in accordance with the existing national rules in the Member States, until the Community list has been drawn up.

(16) The food enzymes E 1103 Invertase and E 1105 Lysozyme, that have been authorised as food additives under Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners[11], and the conditions governing their use should be carried over from Directive 95/2/EC to the

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Community list when it is drawn up by this Regulation. In addition, Council Regulation (EC) No 1493/1999 authorises the use of urease, beta-glucanase and lysozyme in wine subject to the conditions laid down in Commission Regulation (EC) No 423/2008 of 8 May 2008 on laying down certain detailed rules for implementing Council Regulation (EC) No 1493/1999 and establishing a Community code of oenological practices and processes[(12)]. Those substances are food enzymes and they should fall within the scope of this Regulation. They should therefore also be added to the Community list when it is drawn up for their use in wine in accordance with Regulation (EC) No 1493/1999 and Regulation (EC) No 423/2008.

(17) Food enzymes remain subject to the general labelling obligations provided for in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[(13)] and, as the case may be, in Regulation (EC) No 1829/2003 and in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms[(14)]. In addition, specific provisions on the labelling of food enzymes sold as such to the manufacturer or to the consumer should be contained in this Regulation.

(18) Food enzymes are covered by the definition of food in Regulation (EC) No 178/2002 and are therefore, when used in food, required to be indicated as ingredients in the labelling of the food in compliance with Directive 2000/13/EC. Food enzymes should be designated by their technological function in food, followed by the specific name of the food enzyme. However, provision should be made for a derogation from the provisions on labelling in cases where the enzyme performs no technological function in the final product but is present in the foodstuff only as a result of carry-over from one or more of the ingredients of the foodstuff or where it is used as a processing aid. Directive 2000/13/EC should be amended accordingly.

(19) Food enzymes should be kept under continuous observation and should be re-evaluated whenever necessary in the light of changing conditions governing their use and new scientific information.

(20) 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[(15)].

(21) In particular the Commission should be empowered to adopt appropriate transitional measures. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *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.

(22) In order to develop and update Community law on food enzymes in a proportionate and effective way, it is necessary to collect data, share information and coordinate work between Member States. For that purpose, it may be useful to undertake studies to address specific issues with a view to facilitating the decision-making process. It is

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appropriate that the Community finance such studies as part of its budgetary procedure. The financing of such measures is covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[16].

(23) Member States are to carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.

(24) Since the objective of this Regulation, namely to lay down Community rules on food enzymes, cannot be sufficiently achieved by the Member States and can therefore, in the interests of market unity and a high level of consumer protection, 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 that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules on food enzymes used in foods, including such enzymes used as processing aids, with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

For those purposes, this Regulation provides for:

(a) a Community list of approved food enzymes;

(b) conditions of use of food enzymes in foods;

(c) rules on the labelling of food enzymes sold as such.

Article 2

Scope

1 This Regulation shall apply to food enzymes as defined in Article 3.

2 This Regulation shall not apply to food enzymes when and insofar as they are used in the production of: