Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance)

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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) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods 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, via comprehensive and streamlined procedures.

(4) This Regulation harmonises the use of food additives in foods in the Community. This includes the use of food additives in foods covered by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[(3)] and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs. It also harmonises the use of food additives in food additives and food enzymes thus ensuring their safety and quality and facilitating their storage and use. This has not previously been regulated at Community level.

(5) Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose described in this Regulation, such as the preservation of food. All food additives should be covered by this Regulation, and therefore in the light of scientific progress and technological

development the list of functional classes should be updated. However, substances should not be considered as food additives when they are used for the purpose of imparting flavour and/or taste or for nutritional purposes, such as salt replacers, vitamins and minerals. Moreover, substances considered as foods which may be used for a technological function, such as sodium chloride or saffron for colouring and food enzymes should also not fall within the scope of this Regulation. However, preparations obtained from foods and other natural source material that are intended to have a technological effect in the final food and which are obtained by selective extraction of constituents (e.g. pigments) relative to the nutritive or aromatic constituents, should be considered additives within the meaning of this Regulation. Finally, food enzymes are covered by Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes[(4)], which excludes the application of this Regulation.

(6) Substances not consumed as food itself but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

(7) Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological need for their use, and their use must not mislead the consumer and must be of benefit to 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, including its fruit and vegetable content. The approval of food additives 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. The use and maximum levels of a food additive should take into account the intake of the food additive from other sources and the exposure to the food additive by special groups of consumers (e.g. allergic consumers).

(8) Food additives must comply with the approved specifications, which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity. The specifications previously developed for food additives included in Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs[(5)], Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs[(6)] and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners[(7)] should be maintained until the corresponding additives are entered in the Annexes to this Regulation. At that time, the specifications related to such additives should be set out in a Regulation. Those specifications should relate directly to the additives included in the Community lists in the Annexes to this Regulation. However, considering the complex character and substance of such specifications, for the sake of clarity they should not be integrated as such in the Community lists but should be set out in one or more separate Regulations.

(9) Some food additives are permitted for specific uses for certain authorised oenological practices and processes. The use of such food additives should comply with this Regulation and with the specific provisions laid down in the relevant Community legislation.

(10) In order to ensure harmonisation, the risk assessment and approval of food additives 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)]

(11) 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 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.

(12) A food additive 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.

(13) A food additive already approved 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 specifications laid down, 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, including the use of nanotechnology.

(14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Where necessary, the Commission together with the Member States should consider appropriate action.

(15) Member States which maintained on 1 January 1992 prohibitions on the use of certain additives in certain specific foods which are considered traditional and are produced on their territory should be permitted to continue to apply those prohibitions. Moreover, as regard products such as 'Feta' or 'Salame cacciatore', this Regulation should be without prejudice to more restrictive rules linked to the use of certain denominations under Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs[(11)] and Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed[(12)].

(16) Unless subject to further restrictions, an additive may be present in food, other than by direct addition, as a result of carry-over from an ingredient in which the additive was permitted, provided that the level of the additive in the final food is no greater than

would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice.

(17) Food additives remain subject to the general labelling obligations as 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 additives sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

(18) Sweeteners authorised under this Regulation may be used in table-top sweeteners sold directly to consumers. Manufacturers of such products should make information available to the consumer by appropriate means to allow them to use the product in a safe manner. Such information could be made available in a number of ways including on product labels, Internet websites, consumer information lines or at the point of sale. In order to adopt a uniform approach to the implementation of this requirement, guidance drawn up at Community level may be necessary.

(19) 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)].

(20) In particular the Commission should be empowered to amend the Annexes of this Regulation and 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.

(21) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of certain amendments to Annexes II and III relating to substances already authorised under other Community law as well as any appropriate transitional measures related to these substances.

(22) In order to develop and update Community law on food additives 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 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 additives, 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.

(25) Following the adoption of this Regulation the Commission, assisted by the Standing Committee on the Food Chain and Animal Health, should review all the existing authorisations for criteria, other than safety, such as intake, technological need and the potential to mislead the consumer. All food additives that are to continue to be authorised in the Community should be transferred to the Community lists in Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and food enzymes as well as carriers for nutrients and their conditions of use in accordance with Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings]. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives and food additives in flavourings, should not apply until 1 January 2011.

(26) Until the future Community lists of food additives are established, it is necessary to provide for a simplified procedure allowing the current lists of food additives contained in the existing Directives to be updated.

(27) Without prejudice to the outcome of the review referred to in recital 25, within one year following the adoption of this Regulation the Commission should set up an evaluation programme for the Authority to re-evaluate the safety of the food additives that were already approved in the Community. That programme should define the needs and the order of priorities according to which the approved food additives are to be examined.

(28) This Regulation repeals and replaces the following acts: Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption[(17)], Council Directive 65/66/EEC of 26 January 1965 laying down specific criteria of purity for preservatives authorised for use in foodstuffs intended for human consumption[(18)], Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs[(19)], Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption[(20)], First Commission Directive 81/712/EEC of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity[(21)], Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[(22)], Directive 94/35/EC of the European

Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs[(23)], Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs[(24)], Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners[(25)], Decision No 292/97/EC of the European Parliament and of the Council of 19 December 1996 on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs[(26)] and Commission Decision 2002/247/EC of 27 March 2002 suspending the placing on the market and import of jelly confectionary containing the food additive E 425 konjac[(27)]. However, it is appropriate that certain provisions of those acts remain in force during a transitional period to allow time for the preparation of the Community lists in the Annexes to this Regulation,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 168, 20.7.2007, p. 34.

(**2**) Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 142), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 10), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

(**3**) OJ L 186, 30.6.1989, p. 27.

(**4**) See page 7 of this Official Journal.

(**5**) OJ L 178, 28.7.1995, p. 1.

(**6**) OJ L 226, 22.9.1995, p. 1.

(**7**) OJ L 339, 30.12.1996, p. 1.

(**8**) See page 1 of this Official Journal.

(**9**) OJ L 31, 1.2.2002, p. 1.

(**10**) OJ L 268, 18.10.2003, p. 1.

(**11**) OJ L 93, 31.3.2006, p. 12.

(**12**) OJ L 93, 31.3.2006, p. 1.

(**13**) OJ L 109, 6.5.2000, p. 29.

(**14**) OJ L 268, 18.10.2003, p. 24.

(**15**) OJ L 184, 17.7.1999, p. 23.

(**16**) OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.

(**17**) OJ 115, 11.11.1962, p. 2645/62.

(**18**) OJ 22, 9.2.1965, p. 373.

(**19**) OJ L 223, 14.8.1978, p. 7.

(**20**) OJ L 223, 14.8.1978, p. 30.

(**21**) OJ L 257, 10.9.1981, p. 1.

(**22**) OJ L 40, 11.2.1989, p. 27.

(**23**) OJ L 237, 10.9.1994, p. 3.

(**24**) OJ L 237, 10.9.1994, p. 13.

(**25**) OJ L 61, 18.3.1995, p. 1.

(**26**) OJ L 48, 19.2.1997, p. 13.

(**27**) OJ L 84, 28.3.2002, p. 69.

Status:
Point in time view as at 06/02/2013.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1333/2008 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.