

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 and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (Text with EEA relevance)

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 and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

(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) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production⁽³⁾ needs to be updated in the light of technical and scientific developments. In the interests of clarity and efficiency Directive 88/388/EEC should be replaced by this Regulation.
- (2) Council Decision 88/389/EEC of 22 June 1988 on the establishment, by the Commission, of an inventory of the source materials and substances used in the preparation of flavourings⁽⁴⁾ provides for the establishment of that inventory within 24 months of its adoption. That Decision is now obsolete and should be repealed.
- (3) Commission Directive 91/71/EEC of 16 January 1991 completing Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production⁽⁵⁾ lays down rules on the labelling of flavourings. Those rules are replaced by this Regulation and the Directive should now be repealed.
- (4) 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.

- (5) In order to protect human health, this Regulation should cover flavourings, source materials for flavourings and foods containing flavourings. It should also cover certain food ingredients with flavouring properties which are added to food for the main purpose of adding flavour and which contribute significantly to the presence in food of certain naturally occurring undesirable substances (hereinafter referred to as food ingredients with flavouring properties), their source material and foods containing them.
- (6) Raw foodstuffs which have not undergone any processing treatment and non-compound foodstuffs such as spices, herbs, teas and infusions (e.g. fruit or herbal tea) as well as mixtures of spices and/or herbs, mixtures of tea and mixtures for infusion, as long as they are consumed as such and/or not added to the food, do not fall within the scope of this Regulation.
- (7) Flavourings are used to improve or modify the odour and/or taste of foods for the benefit of the consumer. Flavourings and food ingredients with flavouring properties should only be used if they fulfil the criteria laid down in this Regulation. They must be safe when used, and certain flavourings should, therefore, undergo a risk assessment before they can be permitted in food. Where possible, attention should be focused on whether or not the use of certain flavourings could have any negative consequences on vulnerable groups. The use of flavourings must not mislead the consumer and their presence in food should, therefore, always be indicated by appropriate labelling. Flavourings should, in particular, not be used in a way as to mislead the consumer about issues related to, amongst other things, 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 flavourings 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.
- (8) Since 1999, the Scientific Committee on Food and subsequently 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⁾ have expressed opinions on a number of substances occurring naturally in source materials for flavourings and food ingredients with flavouring properties which, according to the Committee of Experts on Flavouring Substances of the Council of Europe, raise toxicological concern. Substances for which the toxicological concern was confirmed by the Scientific Committee on Food should be regarded as undesirable substances which should not be added as such to food.
- (9) Due to their natural occurrence in plants, undesirable substances might be present in flavouring preparations and food ingredients with flavouring properties. The plants are used traditionally as food or food ingredients. Appropriate maximum levels should be established for the presence of these undesirable substances in foods which contribute most to the human intake of these substances, taking into account both the need to protect human health and their unavoidable presence in traditional foods.

- (10) Maximum levels for certain naturally occurring undesirable substances should focus on the food or food categories which contribute most to dietary intake. Should additional naturally occurring undesirable substances pose a risk to the health of the consumer, maximum levels should be set following the opinion of the Authority. Member States should organise controls on a risk basis in line with 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⁽⁷⁾. Food producers are obliged to take into account the presence of these substances when using food ingredients with flavouring properties and/or flavourings for preparation of all food to ensure that food which is not safe is not placed on the market.
- (11) Provisions should be established at Community level in order to prohibit, or restrict the use of, certain plant, animal, microbiological or mineral materials which raise concern for human health in the production of flavourings and food ingredients with flavouring properties and their applications in food production.
- (12) Risk assessments should be carried out by the Authority.
- (13) In order to ensure harmonisation, the risk assessment and approval of flavourings and source materials that need to undergo an evaluation 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⁾.
- (14) Flavouring substances are defined chemical substances, which include flavouring substances obtained by chemical synthesis or isolated using chemical processes, and natural flavouring substances. An evaluation programme of flavouring substances is ongoing in accordance with Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs⁽⁹⁾. Under that Regulation a list of flavouring substances is to be adopted within five years of adoption of that programme. A new deadline should be set for the adoption of that list. That list will be proposed for inclusion in the list referred to in Article 2(1) of Regulation (EC) No 1331/2008.
- (15) Flavouring preparations are flavourings other than defined chemical substances obtained from materials of vegetable, animal or microbiological origin, by appropriate physical, enzymatic or microbiological processes, either in the raw state of the material or after processing for human consumption. Flavouring preparations produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the safety of flavouring preparations produced from non-food material should be evaluated and approved.
- (16) Regulation (EC) No 178/2002 defines food as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. Materials of vegetable, animal or microbiological origin, for which it can be sufficiently demonstrated that they have hitherto been used for the

production of flavourings, are considered to be food materials for this purpose, even though some of these source materials, such as rose wood and strawberry leaves, may not have been used for food as such. They do not need to be evaluated.

- (17) Likewise, thermal process flavourings produced from food under specified conditions need not undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the safety of thermal process flavourings produced from non-food material or not complying with certain conditions of production should be evaluated and approved.
- (18) 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⁾ lays down a procedure for the safety assessment and approval of smoke flavourings and aims to establish a list of primary smoke condensates and primary tar fractions the use of which is authorised to the exclusion of all others.
- (19) Flavour precursors such as carbohydrates, oligo-peptides and amino acids impart flavour to food by chemical reactions which occur during food processing. Flavour precursors produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the safety of flavour precursors produced from non-food material should be evaluated and approved.
- (20) Other flavourings which do not fall under the definitions of the previously mentioned flavourings may be used in and on foods after they have undergone an evaluation and approval procedure. An example could be flavourings which are obtained by heating oil or fat to an extremely high temperature for a very short period of time, resulting in a grill-like flavour.
- (21) Material of vegetable, animal, microbiological or mineral origin other than food may only be authorised for the production of flavourings after its safety has been evaluated scientifically. It might be necessary to authorise the use of only certain parts of the material or to set conditions of use.
- (22) Flavourings can contain food additives as permitted by Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁽¹¹⁾ and/or other food ingredients for technological purposes such as for their storage, standardisation, dilution or dissolution and stabilisation.
- (23) A flavouring or a source material 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⁽¹²⁾ should be authorised in accordance with that Regulation as well as under this Regulation.
- (24) Flavourings 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 Regulations (EC) No 1829/2003 and Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically

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modified organisms and the traceability of food and feed products produced from genetically modified organisms⁽¹⁴⁾. In addition, specific provisions on the labelling of flavourings sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

- (25) Flavouring substances or flavouring preparations should only be labelled as ‘natural’ if they comply with certain criteria which ensure that consumers are not misled.
- (26) Specific information requirements should ensure that consumers are not misled concerning the source material used for the production of natural flavourings. In particular, if the term natural is used to describe a flavour, the flavouring components used should be entirely of natural origin. In addition, the source of the flavourings should be labelled, except when the source materials referred to would not be recognised in the flavour or taste of the food. If a source is mentioned, at least 95 % of the flavouring component should be obtained from the material referred to. As the use of flavourings should not mislead the consumer, the other maximum 5 % can only be used for standardisation or to give a, for example, more fresh, pungent, ripe or green note to the flavouring. When less than 95 % of the flavouring component derived from the source referred to has been used and the flavour of the source can still be recognised, the source should be revealed together with a statement that other natural flavourings have been added, for example cacao extract in which other natural flavourings have been added to impart a banana note.
- (27) Consumers should be informed if the smoky taste of a particular food is due to the addition of smoke flavourings. In accordance with Directive 2000/13/EC, the labelling should not confuse the consumer as to whether the product is smoked conventionally with fresh smoke or treated with smoke flavourings. Directive 2000/13/EC needs to be adapted to the definitions of flavourings, smoke flavourings and the term ‘natural’ for the description of flavourings laid down in this Regulation.
- (28) For the evaluation of the safety of flavouring substances for human health, information on the consumption and use of flavouring substances is crucial. The amounts of flavouring substances added to food should therefore be checked on a regular basis.
- (29) 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⁾.
- (30) In particular the Commission should be empowered to amend the Annexes to this Regulation and to adopt appropriate transitional measures regarding the establishment of the Community list. 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.
- (31) 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

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the adoption of measures described in Article 8(2) and amendments to Annexes II to V to this Regulation.

- (32) Annexes II to V to this Regulation should be adapted as necessary to scientific and technical progress, taking into account the information provided by producers and users of flavourings and/or resulting from the monitoring and controls by the Member States.
- (33) In order to develop and update Community law on flavourings 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.
- (34) Pending the establishment of the Community list, provision should be made for the evaluation and approval of flavouring substances which are not covered by the evaluation programme provided for in Regulation (EC) No 2232/96. A transitional regime should therefore be laid down. Under that regime such flavouring substances should be evaluated and approved in accordance with the procedure laid down in Regulation (EC) No 1331/2008. However, the time periods provided for in that Regulation for the adoption by the Authority of its opinion and for the submission by the Commission to the Standing Committee on the Food Chain and Animal Health of a draft regulation updating the Community list should not apply, because priority should be given to the ongoing evaluation programme.
- (35) Since the objective of this Regulation, namely to lay down Community rules on the use of flavourings and certain food ingredients with flavouring properties in and on foods, 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.
- (36) Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails⁽¹⁶⁾ and Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks⁽¹⁷⁾ need to be adapted to certain new definitions laid down in this Regulation.
- (37) Regulations (EEC) No 1601/91, (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

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Modifications etc. (not altering text)

- C1** Regulation applied (with modifications) (N.I.) (1.10.2023) by [The Windsor Framework \(Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions\) Regulations 2023 \(S.I. 2023/959\)](#), regs. 1(2), 4(a), **Sch. 1** (with regs. 7, 8)

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- (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. 176](#)), Council Common Position of 10 March 2008 ([OJ C 111 E, 6.5.2008, p. 46](#)). Position of the European Parliament of 8 July 2008 (not yet published) and Council Decision of 18 November 2008.
- (3) [OJ L 184, 15.7.1988, p. 61.](#)
- (4) [OJ L 184, 15.7.1988, p. 67.](#)
- (5) [OJ L 42, 15.2.1991, p. 25.](#)
- (6) [OJ L 31, 1.2.2002, p. 1.](#)
- (7) [OJ L 165, 30.4.2004, p. 1.](#) Corrected version in [OJ L 191, 28.5.2004, p. 1.](#)
- (8) See page 1 of this Official Journal.
- (9) [OJ L 299, 23.11.1996, p. 1.](#)
- (10) [OJ L 309, 26.11.2003, p. 1.](#)
- (11) See page 16 of this Official Journal.
- (12) [OJ L 268, 18.10.2003, 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 149, 14.6.1991, p. 1.](#)
- (17) [OJ L 39, 13.2.2008, p. 16.](#)

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