

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 That Decision is now obsolete and should be repealed.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 Those rules are replaced by this Regulation and the Directive should now be repealed.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.

⁽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.

- (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 ⁽¹⁾ 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 ⁽²⁾. 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 ⁽³⁾.
- (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 ⁽⁴⁾. 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.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1.

⁽³⁾ See page 1 of this Official Journal.

⁽⁴⁾ OJ L 299, 23.11.1996, p. 1.

- (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 ⁽¹⁾ 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 ⁽²⁾ 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 ⁽³⁾ 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 ⁽⁴⁾ 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 modified organisms and the traceability of food and feed products produced from genetically modified organisms ⁽⁵⁾. 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.

⁽¹⁾ OJ L 309, 26.11.2003, p. 1.

⁽²⁾ See page 16 of this Official Journal.

⁽³⁾ OJ L 268, 18.10.2003, p. 1.

⁽⁴⁾ OJ L 109, 6.5.2000, p. 29.

⁽⁵⁾ OJ L 268, 18.10.2003, p. 24.

- (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 ⁽¹⁾.
- (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 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 ⁽²⁾ 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 ⁽³⁾ 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:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules on flavourings and food ingredients with flavouring properties for use in and on 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 and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 149, 14.6.1991, p. 1.

⁽³⁾ OJ L 39, 13.2.2008, p. 16.

For those purposes, this Regulation provides for:

- (a) a Community list of flavourings and source materials approved for use in and on foods, set out in Annex I (hereinafter referred to as the 'Community list');
 - (b) conditions of use of flavourings and food ingredients with flavouring properties in and on foods;
 - (c) rules on the labelling of flavourings.
- (ii) made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof;
 - (b) 'flavouring substance' shall mean a defined chemical substance with flavouring properties;
 - (c) 'natural flavouring substance' shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;

Article 2

Scope

1. This Regulation shall apply to:
 - (a) flavourings which are used or intended to be used in or on foods, without prejudice to more specific provisions laid down in Regulation (EC) No 2065/2003;
 - (b) food ingredients with flavouring properties;
 - (c) food containing flavourings and/or food ingredients with flavouring properties;
 - (d) source materials for flavourings and/or source materials for food ingredients with flavouring properties.
 2. This Regulation shall not apply to:
 - (a) substances which have exclusively a sweet, sour or salty taste;
 - (b) raw foods;
 - (c) non-compound foods and mixtures such as, but not exclusively, fresh, dried or frozen spices and/or herbs, mixtures of tea and mixtures for infusion as such as long as they have not been used as food ingredients.
- (d) 'flavouring preparation' shall mean a product, other than a flavouring substance, obtained from:
 - (i) food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II;

and/or

 - (ii) material of vegetable, animal or microbiological origin, other than food, by appropriate physical, enzymatic or microbiological processes, the material being taken as such or prepared by one or more of the traditional food preparation processes listed in Annex II;
- (e) 'thermal process flavouring' shall mean a product obtained after heat treatment from a mixture of ingredients not necessarily having flavouring properties themselves, of which at least one contains nitrogen (amino) and another is a reducing sugar; the ingredients for the production of thermal process flavourings may be:
 - (i) food;

and/or

 - (ii) source material other than food;
- (f) 'smoke flavouring' shall mean a product obtained by fractionation and purification of a condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived smoke flavourings as defined in points (1), (2) and (4) of Article 3 of Regulation (EC) No 2065/2003;

Article 3

Definitions

1. For the purposes of this Regulation, the definitions laid down in Regulations (EC) No 178/2002 and (EC) No 1829/2003 shall apply.
2. For the purposes of this Regulation, the following definitions shall also apply:
 - (a) 'flavourings' shall mean products:
 - (i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste;

(g) 'flavour precursor' shall mean a product, not necessarily having flavouring properties itself, intentionally added to food for the sole purpose of producing flavour by breaking down or reacting with other components during food processing; it may be obtained from:

(i) food;

and/or

(ii) source material other than food;

(h) 'other flavouring' shall mean a flavouring added or intended to be added to food in order to impart odour and/or taste and which does not fall under definitions (b) to (g);

(i) 'food ingredient with flavouring properties' shall mean a food ingredient other than flavourings which may be added to food for the main purpose of adding flavour to it or modifying its flavour and which contributes significantly to the presence in food of certain naturally occurring undesirable substances;

(j) 'source material' shall mean material of vegetable, animal, microbiological or mineral origin from which flavourings or food ingredients with flavouring properties are produced; it may be:

(i) food;

or

(ii) source material other than food;

(k) 'appropriate physical process' shall mean a physical process which does not intentionally modify the chemical nature of the components of the flavouring, without prejudice to the listing of traditional food preparation processes in Annex II, and does not involve, *inter alia*, the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.

3. For the purpose of the definitions listed in paragraph 2(d), (e), (g) and (j), source materials for which hitherto there is significant evidence of use for the production of flavourings shall be considered as food for the purpose of this Regulation.

4. Flavourings may contain food additives as permitted by Regulation (EC) No 1333/2008 and/or other food ingredients incorporated for technological purposes.

CHAPTER II

CONDITIONS FOR USE OF FLAVOURINGS, FOOD INGREDIENTS WITH FLAVOURING PROPERTIES AND SOURCE MATERIALS

Article 4

General conditions for use of flavourings or food ingredients with flavouring properties

Only flavourings or food ingredients with flavouring properties which meet the following conditions may be used in or on foods:

(a) they do not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer; and

(b) their use does not mislead the consumer.

Article 5

Prohibition of non-compliant flavourings and/or non-compliant food

No person shall place on the market a flavouring or any food in which such a flavouring and/or food ingredients with flavouring properties are present if their use does not comply with this Regulation.

Article 6

Presence of certain substances

1. Substances listed in Part A of Annex III shall not be added as such to food.

2. Without prejudice to Regulation (EC) No 110/2008, maximum levels of certain substances, naturally present in flavourings and/or food ingredients with flavouring properties, in the compound foods listed in Part B of Annex III shall not be exceeded as a result of the use of flavourings and/or food ingredients with flavouring properties in and on those foods. The maximum levels of the substances set out in Annex III shall apply to foods as marketed, unless otherwise stated. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted, the maximum levels shall apply to the food as reconstituted according to the instructions on the label, taking into account the minimum dilution factor.

3. Detailed rules for the implementation of paragraph 2 may be adopted in accordance with the regulatory procedure referred to in Article 21(2), following the opinion of the European Food Safety Authority (hereinafter referred to as the 'Authority'), where necessary.

Article 7

Use of certain source materials

1. Source materials listed in Part A of Annex IV shall not be used for the production of flavourings and/or food ingredients with flavouring properties.
2. Flavourings and/or food ingredients with flavouring properties produced from source materials listed in Part B of Annex IV may be used only under the conditions indicated in that Annex.

Article 8

Flavourings and food ingredients with flavouring properties for which evaluation and approval are not required

1. The following flavourings and food ingredients with flavouring properties may be used in or on foods without an evaluation and approval under this Regulation, provided that they comply with Article 4:
 - (a) flavouring preparations referred to in Article 3(2)(d)(i);
 - (b) thermal process flavourings referred to in Article 3(2)(e)(i) which comply with the conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings set out in Annex V;
 - (c) flavour precursors referred to in Article 3(2)(g)(i);
 - (d) food ingredients with flavouring properties.

2. Notwithstanding paragraph 1, if the Commission, a Member State or the Authority expresses doubts concerning the safety of a flavouring or food ingredient with flavouring properties referred to in paragraph 1, a risk assessment of such flavouring or food ingredient with flavouring properties shall be carried out by the Authority. Articles 4, 5 and 6 of Regulation (EC) No 1331/2008 shall then apply *mutatis mutandis*. If necessary, the Commission shall adopt measures, following the opinion of the Authority, which are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, in accordance with the regulatory procedure with scrutiny referred to in Article 21(3). Such measures shall be laid down in Annexes III, IV and/or V where appropriate. On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 21(4).

CHAPTER III

COMMUNITY LIST OF FLAVOURINGS AND SOURCE MATERIALS APPROVED FOR USE IN OR ON FOODS

Article 9

Flavourings and source materials for which an evaluation and approval is required

This Chapter shall apply to:

- (a) flavouring substances;
- (b) flavouring preparations referred to in Article 3(2)(d)(ii);
- (c) thermal process flavourings obtained by heating ingredients which fall partially or totally within Article 3(2)(e)(ii) and/or for which the conditions for the production of thermal process flavourings and/or the maximum levels for certain undesirable substances set out in Annex V are not met;
- (d) flavour precursors referred to in Article 3(2)(g)(ii);
- (e) other flavourings referred to in Article 3(2)(h);
- (f) source materials other than food referred to in Article 3(2)(j)(ii).

Article 10

Community list of flavourings and source materials

Of the flavourings and source materials referred to in Article 9, only those included in the Community list may be placed on the market as such and used in or on foods under the conditions of use specified therein, where applicable.

Article 11

Inclusion of flavourings and source materials in the Community list

1. A flavouring or source material may be included in the Community list, in accordance with the procedure laid down by Regulation (EC) No 1331/2008, only if it complies with the conditions set out in Article 4 of this Regulation.
2. The entry for a flavouring or source material in the Community list shall specify:
 - (a) the identification of the flavouring or the source material approved;
 - (b) where necessary, the conditions under which the flavouring may be used.

3. The Community list shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008.

Article 12

Flavourings or source materials falling within the scope of Regulation (EC) No 1829/2003

1. A flavouring or source material falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community list in Annex I in accordance with this Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.

2. When a flavouring already included in the Community list is produced from a different source falling within the scope of Regulation (EC) No 1829/2003, it will not require a new authorisation under this Regulation, as long as the new source is covered by an authorisation in accordance with Regulation (EC) No 1829/2003 and the flavouring complies with the specifications established under this Regulation.

Article 13

Interpretation decisions

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 21(2):

- (a) whether or not a given substance or mixture of substances, material or type of food falls within the categories listed in Article 2(1);
- (b) to which specific category, defined in Article 3(2)(b) to (j), a given substance belongs;
- (c) whether or not a particular product belongs to a food category or is a food referred to in Annex I or Annex III, Part B.

CHAPTER IV

LABELLING

Article 14

Labelling of flavourings not intended for sale to the final consumer

1. Flavourings not intended for sale to the final consumer may only be marketed with the labelling provided for in Articles 15 and 16, which must be easily visible, clearly legible and indelible. The information provided for in Article 15 shall be in a language easily understandable to purchasers.

2. Within its own territory, the Member State in which the product is marketed may, in accordance with the Treaty, stipulate that the information provided for in Article 15 shall be given in one or more of the official languages of the Community, to be determined by that Member State. This shall not preclude such information from being indicated in several languages.

Article 15

General labelling requirements for flavourings not intended for sale to the final consumer

1. Where flavourings not intended for sale to the final consumer are sold singly or mixed with each other and/or with other food ingredients and/or with other substances added to them in accordance with Article 3(4), their packaging or containers shall bear the following information:

- (a) the sales description: either the word 'flavouring' or a more specific name or description of the flavouring;
- (b) the statement either 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;
- (c) if necessary, the special conditions for storage and/or use;
- (d) a mark identifying the batch or lot;
- (e) in descending order of weight, a list of:
 - (i) the categories of flavourings present and
 - (ii) the names of each of the other substances or materials in the product or, where appropriate, their E-number;
- (f) the name or business name and address of the manufacturer, packager or seller;
- (g) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law;
- (h) the net quantity;
- (i) a date of minimum durability or use-by-date;
- (j) where relevant, information on a flavouring or other substances referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC as regards the indication of the ingredients present in foodstuffs.

2. By way of derogation from paragraph 1, the information required in points (e) and (g) of that paragraph may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question.

3. By way of derogation from paragraph 1, where flavourings are supplied in tankers, all of the information may appear merely on the accompanying documents relating to the consignment which are to be supplied with the delivery.

*Article 16***Specific requirements for use of the term 'natural'**

1. If the term 'natural' is used to describe a flavouring in the sales description referred to in Article 15(1)(a) the provisions of paragraphs 2 to 6 of this Article shall apply.
2. The term 'natural' for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances.
3. The term 'natural flavouring substance(s)' may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances.
4. The term 'natural' may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95 % by w/w from the source material referred to.

The description shall read 'natural "food(s) or food category or source(s)" flavouring'.

5. The term 'natural "food(s) or food category or source(s)" flavouring with other natural flavourings' may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.
6. The term 'natural flavouring' may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

*Article 17***Labelling of flavourings intended for sale to the final consumer**

1. Without prejudice to Directive 2000/13/EC, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs ⁽¹⁾ and Regulation (EC) No 1829/2003, flavourings sold singly or mixed with each other and/or with other food ingredients and/or to which other substances are added and which are intended for sale to the final consumer may be marketed only if their packaging contains the statement either 'for food' or 'restricted use in food' or a more specific reference to their intended food use, which must be easily visible, clearly legible and indelible.
2. If the term 'natural' is used to describe a flavouring in the sales description referred to in Article 15(1)(a), Article 16 shall apply.

⁽¹⁾ OJ L 186, 30.6.1989, p. 21.

*Article 18***Other labelling requirements**

Articles 14 to 17 shall be without prejudice to more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or applying to the transport of such substances and preparations.

CHAPTER V

PROCEDURAL PROVISIONS AND IMPLEMENTATION*Article 19***Reporting by the food business operators**

1. A producer or user of a flavouring substance, or the representative of such producer or user, shall, at the request of the Commission, inform it of the amount of the substance added to foods in the Community in a period of 12 months. The information provided in this context shall be treated as confidential insofar as this information is not required for the safety assessment.

Information on the use levels for specific food categories in the Community shall be made available to Member States by the Commission.

2. Where applicable, for a flavouring already approved under this Regulation which is prepared by production methods or starting materials significantly different from those included in the risk assessment of the Authority, a producer or user shall, before marketing the flavouring, submit to the Commission the necessary data to allow an evaluation of the flavouring to be undertaken by the Authority with regard to the modified production method or characteristics.

3. A producer or user of flavourings and/or source materials shall inform the Commission immediately of any new scientific or technical information which is known and accessible to him and which might affect the assessment of the safety of the flavouring substance.

4. Detailed rules for the implementation of paragraph 1 shall be adopted in accordance with the regulatory procedure referred to in Article 21(2).

*Article 20***Monitoring and reporting by the Member States**

1. Member States shall establish systems to monitor the consumption and use of flavourings set out in the Community list and the consumption of the substances listed in Annex III on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to the Authority.

2. After the Authority has been consulted, a common methodology for the gathering by Member States of information on the consumption and use of flavourings set out in the Community list and of the substances listed in Annex III shall be adopted in accordance with the regulatory procedure referred to in Article 21(2) by 20 January 2011.

Article 21

Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

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), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 22

Amendments to Annexes II to V

Amendments to Annexes II to V to this Regulation to reflect scientific and technical progress which are designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3), following the opinion of the Authority, where necessary.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 21(4).

Article 23

Community financing of harmonised policies

The legal basis for the financing of measures resulting from this Regulation shall be Article 66(1)(c) of Regulation (EC) No 882/2004.

CHAPTER VI

TRANSITIONAL AND FINAL PROVISIONS

Article 24

Repeals

1. Directive 88/388/EEC, Decision 88/389/EEC and Directive 91/71/EEC shall be repealed from 20 January 2011.

2. Regulation (EC) No 2232/96 shall be repealed from the date of application of the list referred to in Article 2(2) of that Regulation.

3. References to the repealed acts shall be construed as references to this Regulation.

Article 25

Introduction of the list of flavouring substances into the Community list of flavourings and source materials and transitional regime

1. The Community list shall be established by introducing the list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 into Annex I to this Regulation at the time of its adoption.

2. Pending the establishment of the Community list, Regulation (EC) No 1331/2008 shall apply for the evaluation and approval of flavouring substances which are not covered by the evaluation programme provided for in Article 4 of Regulation (EC) No 2232/96.

By way of derogation from that procedure, the period of nine months referred to in Article 5(1) and Article 7 of Regulation (EC) No 1331/2008 shall not apply to such evaluation and approval.

3. Any appropriate transitional measures which are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).

Article 26

Amendments to Regulation (EEC) No 1601/91

Article 2(1) is hereby amended as follows:

1. in point (a), the first sub-indent of the third indent shall be replaced by the following:

‘— flavouring substances and/or flavouring preparations as defined in Article 3(2)(b) and (d) of 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/or

(*) OJ L 354, 31.12.2008, p. 34.’

2. in point (b), the first sub-indent of the second indent shall be replaced by the following:

‘— flavouring substances and/or flavouring preparations as defined in Article 3(2)(b) and (d) of Regulation (EC) No 1334/2008, and/or’;

3. in point (c), the first sub-indent of the second indent shall be replaced by the following:

‘— flavouring substances and/or flavouring preparations as defined in Article 3(2)(b) and (d) of Regulation (EC) No 1334/2008, and/or’.

Article 27

Amendment to Regulation (EC) No 2232/96

Article 5(1) of Regulation (EC) No 2232/96 shall be replaced by the following:

- ‘1. The list of flavouring substances referred to in Article 2(2) shall be adopted in accordance with the procedure referred to in Article 7 by 31 December 2010 at the latest.’

Article 28

Amendments to Regulation (EC) No 110/2008

Regulation (EC) No 110/2008 is hereby amended as follows:

1. in Article 5(2), point (c) shall be replaced by the following:

‘(c) contain flavouring substances as defined in Article 3(2)(b) of 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 flavouring preparations as defined in Article 3(2)(d) of that Regulation;

(*) OJ L 354, 31.12.2008, p. 34.’

2. in Article 5(3), point (c) shall be replaced by the following:

‘(c) contain one or more flavourings as defined in Article 3(2)(a) of Regulation (EC) No 1334/2008;’

3. in Annex I, point (9) shall be replaced by the following:

‘(9) *Flavouring*

Flavouring means using in the preparation of a spirit drink one or more of the flavourings defined in Article 3(2)(a) of Regulation (EC) No 1334/2008.’

4. Annex II shall be amended as follows:

- (a) paragraph 19(c) shall be replaced by the following:

‘(c) Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation, and/or aromatic plants or parts of aromatic plants may be used in addition, but the organoleptic characteristics of juniper must be discernible, even if they are sometimes attenuated.’

- (b) paragraph 20(c) shall be replaced by the following:

‘(c) Only flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in

Article 3(2)(d) of that Regulation shall be used for the production of gin so that the taste is predominantly that of juniper.’;

- (c) paragraph 21(a) (ii) shall be replaced by the following:

‘(ii) the mixture of the product of such distillation and ethyl alcohol of agricultural origin with the same composition, purity and alcoholic strength; flavouring substances and/or flavouring preparations as specified in category 20(c) may also be used to flavour distilled gin.’;

- (d) paragraph 23(c) shall be replaced by the following:

‘(c) Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation may additionally be used but there must be a predominant taste of caraway.’;

- (e) paragraph 24(c) shall be replaced by the following:

‘(c) Other natural flavouring substances as defined in Article 3(2)(c) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation may additionally be used, but the flavour of these drinks is largely attributable to distillates of caraway (*Carum carvi* L.) and/or dill (*Anethum graveolens* L.) seeds, the use of essential oils being prohibited.’;

- (f) paragraph 30(a) shall be replaced by the following:

‘(a) Bitter-tasting spirit drinks or bitter are spirit drinks with a predominantly bitter taste produced by flavouring ethyl alcohol of agricultural origin with flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation.’;

- (g) in paragraph 32(c), the first subparagraph and the introductory part of the second subparagraph shall be replaced by the following:

‘(c) Flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and flavouring preparations as defined in Article 3(2)(d) of that Regulation may be used in the preparation of liqueur. However, only natural flavouring substances as defined in Article 3(2)(c) of Regulation (EC) No 1334/2008 and flavouring preparations as defined in Article 3(2)(d) of that Regulation shall be used in the preparation of the following liqueurs.’;

(h) paragraph 41(c) shall be replaced by the following:

‘(c) Only flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and flavouring preparations as defined in Article 3(2)(d) of that Regulation may be used in the preparation of egg liqueur or advocaat or avocát or advokát.’;

(i) paragraph 44(a) shall be replaced by the following:

‘(a) Vákevá glögi or spritglögg is a spirit drink produced by flavouring ethyl alcohol of agricultural origin with flavour of cloves and/or cinnamon using one of the following processes: maceration and/or distillation, redistillation of the alcohol in the presence of parts of the plants specified above, addition of natural flavouring substances as defined in Article 3(2)(c) of Regulation (EC) No 1334/2008 of cloves or cinnamon or a combination of these methods.’;

(j) paragraph 44(c) shall be replaced by the following:

‘(c) Other flavourings, flavouring substances and/or flavouring preparations as defined in Article 3(2)(b), (d) and (h) of Regulation (EC) No 1334/2008 may also be used, but the flavour of the specified spices must be predominant.’;

(k) In point (c) of paragraphs 25, 26, 27, 28, 29, 33, 34, 35, 36, 37, 38, 39, 40, 42, 43, 45 and 46, the word ‘preparations’ shall be replaced by ‘flavouring preparations’.

Article 29

Amendment to Directive 2000/13/EC

In Directive 2000/13/EC, Annex III shall be replaced by the following:

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

‘ANNEX III

DESIGNATION OF FLAVOURINGS IN THE LIST OF INGREDIENTS

1. Without prejudice to paragraph 2, flavourings shall be designated by the terms
 - “flavourings” or a more specific name or description of the flavouring, if the flavouring component contains flavourings as defined in Article 3(2)(b), (c), (d), (e), (f), (g) and (h) of 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 (*);
 - “smoke flavouring(s)”, or “smoke flavouring(s) produced from “food(s) or food category or source(s)”” (e.g. smoke flavouring produced from beech), if the flavouring component contains flavourings as defined in Article 3(2)(f) of Regulation (EC) No 1334/2008 and imparts a smoky flavour to the food.
2. The term “natural” for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No 1334/2008.

(*) OJ L 354, 31.12.2008, p. 34.’

Article 30

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 20 January 2011.

Article 10 shall apply from 18 months after the date of application of the Community list.

Articles 26 and 28 shall apply from the date of application of the Community list.

Article 22 shall apply from 20 January 2009. Foods lawfully placed on the market or labelled prior to 20 January 2011 which do not comply with this Regulation may be marketed until their date of minimum durability or use-by-date.

ANNEX I

Community list of flavourings and source materials approved for use in and on foods

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ANNEX II

List of traditional food preparation processes

Chopping	Coating
Heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C)	Cooling
Cutting	Distillation/rectification
Drying	Emulsification
Evaporation	Extraction, incl. solvent extraction in accordance with Directive 88/344/EEC
Fermentation	Filtration
Grinding	
Infusion	Maceration
Microbiological processes	Mixing
Peeling	Percolation
Pressing	Refrigeration/Freezing
Roasting/Grilling	Squeezing
Steeping	

ANNEX III

Presence of certain substances

Part A: *Substances which shall not be added as such to food*

Agaric acid
 Aloin
 Capsaicin
 1,2-Benzopyrone, coumarin
 Hypericine
 Beta-asarone
 1-Allyl-4-methoxybenzene, estragole
 Hydrocyanic acid
 Menthofuran
 4-Allyl-1,2-dimethoxybenzene, methyleugenol
 Pulegone
 Quassin
 1-Allyl-3,4-methylene dioxy benzene, safrole
 Teucrin A
 Thujone (alpha and beta)

Part B: *Maximum levels of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have been added*

Name of the substance	Compound food in which the presence of the substance is restricted	Maximum level mg/kg
Beta-asarone	Alcoholic beverages	1,0
1-Allyl-4-methoxybenzene, Estragol (*)	Dairy products	50
	Processed fruits, vegetables (incl. mushrooms, fungi, roots, tubers, pulses and legumes), nuts and seeds	50
	Fish products	50
	Non-alcoholic beverages	10
Hydrocyanic acid	Nougat, marzipan or its substitutes or similar products	50
	Canned stone fruits	5
	Alcoholic beverages	35
Menthofuran	Mint/peppermint containing confectionery, except micro breath freshening confectionery	500
	Micro breath freshening confectionery	3 000
	Chewing gum	1 000
	Mint/peppermint containing alcoholic beverages	200
4-Allyl-1,2-dimethoxy-benzene, Methyleugenol (*)	Dairy products	20
	Meat preparations and meat products, including poultry and game	15
	Fish preparations and fish products	10
	Soups and sauces	60
	Ready-to-eat savouries	20
	Non-alcoholic beverages	1

Name of the substance	Compound food in which the presence of the substance is restricted	Maximum level mg/kg
Pulegone	Mint/peppermint containing confectionery, except micro breath freshening confectionery	250
	Micro breath freshening confectionery	2 000
	Chewing gum	350
	Mint/peppermint containing non-alcoholic beverages	20
	Mint/peppermint containing alcoholic beverages	100
Quassin	Non-alcoholic beverages	0,5
	Bakery wares	1
	Alcoholic beverages	1,5
1-Allyl-3,4-methylene dioxy benzene, safrole (*)	Meat preparations and meat products, including poultry and game	15
	Fish preparations and fish products	15
	Soups and sauces	25
	Non-alcoholic beverages	1
Teucrin A	Bitter-tasting spirit drinks or bitter (1)	5
	Liqueurs (2) with a bitter taste	5
	Other alcoholic beverages	2
Thujone (alpha and beta)	Alcoholic beverages, except those produced from Artemisia species	10
	Alcoholic beverages produced from Artemisia species	35
	Non-alcoholic beverages produced from Artemisia species	0,5
Coumarin	Traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling	50
	Breakfast cereals including muesli	20
	Fine bakery ware, with the exception of traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling	15
	Desserts	5

(*) The maximum levels shall not apply where a compound food contains no added flavourings and the only food ingredients with flavouring properties which have been added are fresh, dried or frozen herbs and spices. After consultation with the Member States and the Authority, based on data made available by the Member States and on the newest scientific information, and taking into account the use of herbs and spices and natural flavouring preparations, the Commission, if appropriate, proposes amendments to this derogation.

(1) As defined in Annex II, paragraph 30 of Regulation (EC) No 110/2008.

(2) As defined in Annex II, paragraph 32 of Regulation (EC) No 110/2008.

ANNEX IV

List of source materials to which restrictions apply for their use in the production of flavourings and food ingredients with flavouring properties

Part A: *Source materials which shall not be used for the production of flavourings and food ingredients with flavouring properties*

Source material	
Latin name	Common name
Tetraploid form of <i>Acorus calamus</i> L.	Tetraploid form of Calamus

Part B: *Conditions of use for flavourings and food ingredients with flavouring properties produced from certain source materials*

Source material		Conditions of use
Latin name	Common name	
<i>Quassia amara</i> L. and <i>Picrasma excelsa</i> (Sw)	Quassia	Flavourings and food ingredients with flavouring properties produced from the source material may only be used for the production of beverages and bakery wares
<i>Laricifomes officinales</i> (Vill.: Fr) Kotl. et Pouz or <i>Fomes officinalis</i>	White agaric mushroom	Flavourings and food ingredients with flavouring properties produced from the source material may only be used for the production of alcoholic beverages
<i>Hypericum perforatum</i> L.	St John's wort	
<i>Teucrium chamaedrys</i> L.	Wall germander	

ANNEX V

Conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavouringsPart A: *Conditions for the production*

- (a) The temperature of the products during processing shall not exceed 180 °C.
- (b) The duration of the thermal processing shall not exceed 15 minutes at 180 °C with correspondingly longer times at lower temperatures, i.e. a doubling of the heating time for each decrease of temperature by 10 °C, up to a maximum of 12 hours.
- (c) The pH during processing should not exceed the value of 8,0.

Part B: *Maximum levels for certain substances*

Substance	Maximum levels µg/kg
2-amino-3,4,8-trimethylimidazo [4,5-f] quinoxaline (4,8-DiMeIQx)	50
2-amino-1-methyl-6-phenylimidazol [4,5-b]pyridine (PhIP)	50