

**COMMON POSITION (EC) No 9/2008****adopted by the Council on 10 March 2008****with a view to adopting Regulation (EC) No .../2008 of the European Parliament and of the Council of ... on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC**

(Text with EEA relevance)

(2008/C 111 E/04)

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 <sup>(1)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(2)</sup>,

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 <sup>(3)</sup> 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 <sup>(4)</sup> 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 That Decision is now obsolete and should be repealed.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 <sup>(5)</sup> lays down rules on the labelling of flavourings. Those rules are replaced by this Regulation and the Directive should now be repealed.

<sup>(1)</sup> OJ C 168, 20.7.2007, p. 34.

<sup>(2)</sup> Opinion of the European Parliament of 10 July 2007 (not yet published in the Official Journal), Council Common Position of 10 March 2008, Position of the European Parliament of ... (not yet published in the Official Journal) and Council Decision of ...

<sup>(3)</sup> OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>(4)</sup> OJ L 184, 15.7.1988, p. 67.

<sup>(5)</sup> OJ L 42, 15.2.1991, p. 25.

(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 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. Their use must not mislead the consumer and their presence in food should, therefore, always be indicated by appropriate labelling. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. The approval of flavourings should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors 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 <sup>(1)</sup> 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. This would allow Member States to 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 <sup>(2)</sup>. Food producers are however 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 .../2008 of ... establishing a common authorisation procedure for food additives, food enzymes and food flavourings <sup>(3)</sup>.
- (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 <sup>(4)</sup>. 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 .../2008 <sup>(\*)</sup>.
- (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,

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

<sup>(2)</sup> OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1. Regulation as amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

<sup>(3)</sup> See page 1 of this Official Journal.

<sup>(4)</sup> OJ L 299, 23.11.1996, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

<sup>(\*)</sup> See page 1 of this Official Journal.

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 <sup>(1)</sup> 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 .../2008 of the European Parliament and of the Council of ... on food additives <sup>(2)</sup> 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 <sup>(3)</sup> should be subject

to the authorisation procedure under that Regulation with regard to the safety assessment of the genetic modification, while the final authorisation of the flavouring or source material should be granted 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 <sup>(4)</sup> 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 <sup>(5)</sup>. 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. 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. When a source material is claimed in the description of natural flavourings, the fraction of the flavouring component other than that derived from this particular source should not reproduce or imitate the flavour of the source referred to.

<sup>(1)</sup> OJ L 309, 26.11.2003, p. 1.

<sup>(2)</sup> See page 10 of this Official Journal.

<sup>(3)</sup> OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

<sup>(4)</sup> OJ L 109, 6.5.2000, p. 29. Directive as last amended by Commission Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).

<sup>(5)</sup> OJ L 268, 18.10.2003, p. 24.

- (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 <sup>(1)</sup>.
- (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 .../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 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks <sup>(2)</sup> and 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 <sup>(3)</sup> need to be adapted to certain new definitions laid down in this Regulation.
- (37) Regulations (EEC) No 1576/89, (EEC) No 1601/91 and (EC) No 2232/96 and Directive 2000/13/EC should be amended accordingly,

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

(2) OJ L 160, 12.6.1989, p. 1. Regulation as last amended by the 2005 Act of Accession.

(3) OJ L 149, 14.6.1991, p. 1. Regulation as last amended by the 2005 Act of Accession.

(1) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

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 to ensure the effective functioning of the internal market and a high level of protection of human health and protection of consumers' interests, including fair practices in food trade, taking into account, where appropriate, the protection of the environment.

For those purposes, this Regulation provides for:

- (a) a Community list of 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.

*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 of spices and/or herbs, mixtures of tea and mixtures for infusion as such as long as they have not been used as food ingredients.

*Article 3*

**Definitions**

1. For the purposes of this Regulation, the definitions laid down in Regulations (EC) Nos 178/2002 and 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 odour and/or taste;
  - (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;
- (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;

(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 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 .../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:

(\*) See page 10 of this Official Journal.

(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 1576/89, 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 to 6 of Regulation (EC) No .../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);

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

- (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 .../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 .../2008 (\*).

#### Article 12

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

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.

*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 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 maximum of 5 % (w/w) of the flavouring component derived from other source materials shall not reproduce the flavour of the source material referred to.

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

5. '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 <sup>(1)</sup> 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.

#### 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.

<sup>(1)</sup> OJ L 186, 30.6.1989, p. 21. Directive as last amended by Directive 92/11/EEC (OJ L 65, 11.3.1992, p. 32).

## 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 as well as the use levels for specific food categories in the Community. Such information 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 might affect the assessment of the safety of the flavouring and/or source materials.

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 ... (\*).

(\*). Two years after the entry into force of this Regulation.

## 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 ... (\*).

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.

(\*) Two years after the entry into force of 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 .../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 periods of six months and nine months referred to in Article 5(1) and Article 7 of Regulation (EC) No .../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

**Amendment to Regulation (EEC) No 1576/89**

Regulation (EEC) No 1576/89 is hereby amended as follows:

1. Article 1(4)(m) shall be amended as follows:

(a) In point (1)(a), the second subparagraph shall be replaced by the following:

‘Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No .../2008 of the European Parliament and of the Council of ... on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1575/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (\*), 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.

(\*) OJ L ...’.

(b) Point 2(a) shall be replaced by the following:

‘The drink may be called “gin” if it is produced by flavouring organoleptically suitable ethyl alcohol of agricultural origin with flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No .../2008 (\*\*\*) and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation so that the taste is predominantly that of juniper.’.

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

(\*\*\*) This Regulation.

- (c) In point 2(b), the first subparagraph shall be replaced by the following:

‘The drink may be called “distilled *gin*” if it is produced solely by redistilling organoleptically suitable ethyl alcohol of agricultural origin of an appropriate quality with an initial alcoholic strength of at least 96 % vol. in stills traditionally used for *gin*, in the presence of juniper berries and of other natural botanicals provided that the juniper taste is predominant. The term “distilled *gin*” may also apply to a 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, both of which are specified in (a), may also be used to flavour distilled *gin*. *London gin* is a type of distilled *gin*.’

2. In Article 1(4)(n)(1), the second subparagraph shall be replaced by the following:

‘Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No .../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.’

3. In Article 1(4)(p), the first subparagraph shall be replaced by the following:

‘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 .../2008 (\*) and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation.’

4. In Article 1(4)(u), the first subparagraph shall be replaced by the following:

‘A spirit drink produced by flavouring ethyl alcohol of agricultural origin with flavouring 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 flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No .../2008 (\*) of cloves or cinnamon or a combination of these methods.’

5. In Article 4(5), the first and second paragraphs, excluding the lists in points (a) and (b), shall be replaced by the following:

‘Only natural flavouring substances and flavouring preparations as defined in Article 3(2)(c) and (d) of Regulation (EC)

(\*) This Regulation.

No .../2008 (\*) may be used in the preparation of the spirit drinks defined in Article 1(4), except in the case of those defined in Article 1(4)(m), (n) and (p). However, flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No .../2008 (\*) shall be authorised in liqueurs except those mentioned below.’

#### Article 27

### Amendment 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 .../2008 of the European Parliament and of the Council of ... on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (\*\*), and/or

(\*\*) OJ L ...’.

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 .../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 .../2008 (\*), and/or’.

#### Article 28

### 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 2008 at the latest.’

*Article 29***Amendment to Directive 2000/13/EC**

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

*'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 .../2008 of the European Parliament and of the Council of ... on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (\*),
  - “smoke flavouring(s)” if the flavouring component contains flavourings as defined in Article 3(2)(f) of Regulation (EC) No .../2008 (\*) and imparts a smoky flavour to the food.

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

2. The term “natural” for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No .../2008 (\*).

(\*) O J L ...'.

*Article 30***Entry into force**

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

It shall apply from ... (\*).

Articles 10, 26 and 27 shall apply from the date of application of the Community list.

Article 22 shall apply from the date of the entry into force of this Regulation. Foods lawfully placed on the market or labelled prior to ... (\*) which do not comply with this Regulation may be marketed until their date of minimum durability or use-by-date.

(\*) Two years after the entry into force of this Regulation.

## 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.

These maximum levels shall not apply to compound foods which are prepared and consumed on the same site, contain no added flavourings and contain only herbs and spices as food ingredients with flavouring properties.

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 dioxycyclohexene, 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 <sup>(1)</sup>	5
	Liqueurs <sup>(2)</sup> with a bitter taste	5
	Other alcoholic beverages	2
Thujone (alpha and beta)	Alcoholic beverages, except those produced from <i>Artemisia</i> species	10
	Alcoholic beverages produced from <i>Artemisia</i> species	35
	Non-alcoholic beverages produced from <i>Artemisia</i> 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

<sup>(1)</sup> As defined in Article 1(4)(p) of Council Regulation (EEC) No 1576/89.

<sup>(2)</sup> As defined in Article 1(4)(r) of Council Regulation (EEC) No 1576/89.

## 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 FLAVOURINGS**

PART 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

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 28 July 2006, the Commission adopted its proposal on flavourings and certain food ingredients with flavouring properties for use in foods <sup>(1)</sup>. The proposal is based on Article 95 of the Treaty establishing the European Community.

The European Parliament adopted its Opinion in first reading on 10 July 2007 <sup>(2)</sup>.

Following the European Parliament's first reading opinion, the Commission submitted an amended proposal on 24 October 2007 <sup>(3)</sup>.

On 10 March 2008, the Council adopted its Common Position in accordance with Article 251(2) of the Treaty.

In carrying out its work, the Council also took account of the opinion of the European Economic and Social Committee adopted on 25 April 2007 <sup>(4)</sup>.

### II. OBJECTIVE OF THE PROPOSED REGULATION

The aim of the proposed Regulation, as part of four proposals designed to overhaul the Community's rules on food improvement agents, is to update the Community rules on flavourings and certain food ingredients with flavouring properties, taking into account the technological and scientific developments in this area <sup>(5)</sup> as well as the developments in food legislation in the European Community, in particular, the new legislation on food safety <sup>(6)</sup>.

The proposed Regulation provides for the establishment of a Community list of flavourings and of source materials approved for use, as well as for rules on labelling the flavourings.

The objective of the proposed Regulation is to ensure the proper functioning of the internal market, including fair practices in food trade, and a high level of protection of human health, of consumer interests and of the environment.

### III. ANALYSIS OF THE COMMON POSITION <sup>(7)</sup>

#### 1. Introductory remarks

The Common Position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced a number of modifications in the text, some of them inspired by the amendments proposed by the European Parliament. On its own initiative, the Council introduced some of the European Parliament amendments in each of the three sectoral proposals, with a view to harmonising their provisions. The modifications introduced by the Council may be summed up as follows:

<sup>(1)</sup> COM(2006) 427 final.

<sup>(2)</sup> Doc. 11639/07 CODEC 775.

<sup>(3)</sup> COM(2007) 671 final.

<sup>(4)</sup> OJ C 168, 20.7.2007, p. 29.

<sup>(5)</sup> 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 foods and to source materials for their production (OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)) will be replaced.

<sup>(6)</sup> Approved 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 (OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4)).

<sup>(7)</sup> In addition to changes already introduced by the Council, Article 26 will require update due to entry into force on 20 February 2008 of the Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008).

— *Preference for a single legal basis: Article 95 of the Treaty*

According to established case-law <sup>(1)</sup>, the legal basis for an act must be determined having regard to its own aim and content. If the examination of a Community measure reveals that it serves a two-fold purpose or that it has a two-fold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the act must be based on a single legal basis, namely that required by the main or predominant purpose or component <sup>(2)</sup>. In this case, the Council considered that the agricultural aspects of the proposal are merely incidental while the internal market objective is the main or predominant purpose or component and as such, in line with the case law of the ECJ, it decided to retain Article 95 as the sole legal basis.

— *'Misleading the consumer'* (in line with amendment 1, second part)

The Council included, in recital 7, elements integrating the notion of misleading the consumer.

— *Protection of the environment*

The Council considered that, apart from scientific evidence, the authorisation of the flavourings should also take into account other relevant factors, such as the protection of the environment. The Council also included a reference to the protection of the environment among the objectives of the proposed Regulation.

— *Clarification of the scope and definitions* (in line with amendment 8)

The Council clarified that smoke flavourings are not completely excluded from the scope of the proposed Regulation. It opted for complementary application of two Regulations, i.e. this Regulation would apply in the absence of more specific rules in the Regulation (EC) 2065/2003 on smoke flavourings <sup>(3)</sup>.

Furthermore, it was made clear that the Regulation would also not apply to mixtures of herbs and/or spices, mixtures of tea and mixtures for infusions, as long as they are not used as food ingredients (in line with amendment 45).

The clarification of Article 2(2) can be found in recital 6.

The Council paid particular attention to the accuracy of definitions and their consistency with other Community legislation. Clarifications were made in line with amendments 12 and 14. The term 'flavourings not elsewhere specified' in amendment 13 has the same meaning as the Commission formulation 'other flavouring', meaning flavouring not defined under points (b) to (g) of Article 3. The Council favours the latter, which is more clear in the context of Article 3.

— *Introduction of the regulatory comitology procedure with scrutiny* (in line with amendments 24, 33, 34, 35)

The Council adapted the proposal to the new comitology procedure rules, requiring the regulatory procedure with scrutiny to be applied for the adoption of measures supplementing the Regulation.

The Council also introduced the urgency procedure to enable the Commission to modify, on the imperative ground of urgency, restrictions for the use of flavourings and food ingredients with flavouring properties for which an approval is not required and if appropriate to amend Annexes II to V.

<sup>(1)</sup> See Case 45/86, *Commission v Council* [1987] ECR 1493, paragraph 11; Case C-300/89, *Commission v Council (Titanium Dioxide)* [1991] ECR I-2867, paragraph 10; Case C-268/94, *Portugal v Council* [1996] ECR I-6177, paragraph 22; and Case C-176/03, *Commission v Council* [2005] ECR I-0000, paragraph 45.

<sup>(2)</sup> See Case C-36/98, *Spain v Council* [2001] ECR I-779, paragraph 59; Case C-211/01, *Commission v Council* [2003] ECR I-8913, paragraph 39; and Case C-338/01, *Commission v Council* [2004] ECR I-4829, paragraph 55.

<sup>(3)</sup> OJ L 309, 26.11.2003, p. 1.

— *Interpretation decisions*

The Council regrouped all the provisions on interpretation decisions into a new single Article and, as they would not supplement the Regulation, made them subject to the regulatory comitology procedure without scrutiny.

— *Provision prohibiting the placing on the market of non compliant flavourings or food containing such flavourings*

For reasons of clarity, legal certainty and proper functioning of the market, the Council inserted an Article on the prohibition on placing non-compliant flavourings and/or food ingredients with flavouring properties on the market. This is consistent with proposals on food additives and on food enzymes.

— *Use of the term 'natural' flavouring*

To safeguard consumer interests, the Council agreed that the term 'natural' may only be used with a reference to a food, food category or a vegetable or animal flavouring source if at least 95 % by w/w has been obtained from the source material referred to (in line with amendment 29).

The Council has however added that the 5 % of the flavouring component derived from other source materials shall not reproduce the flavour of the source material referred to.

— *Authorisation of flavourings falling within the scope of Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>(1)</sup> (in line with amendments 41 and 42)*

The Council agrees that, for any substance, the two authorisation procedures (one for its use as a flavouring and the other with respect to its genetic modifications) can be carried out simultaneously, which is in line with the above amendments. The Council subjected that principle to some drafting changes in order to make the provision more compatible with Regulation (EC) No 1829/2003.

— *Labelling*

The Council streamlined labelling provisions, respecting the distinction between 'business to business' labelling and labelling requirements for products intended for the sale to the final consumer. Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are the same and are in line with amendments 5, 29 and 30.

— *Transitional measures for products already on the market (in line with amendment 39)*

The Council provided for a 2 years transition period from the date of entry into force of the proposed Regulation. Foods lawfully placed on the market or labeled during this 2 years may be marketed until their date of minimum durability or use-by-date.

The Commission has accepted the Common Position agreed by the Council.

## 2. The amendments of the European Parliament

In its Plenary vote on 10 July 2007, the European Parliament adopted 43 amendments to the proposal. In its Common Position, the Council incorporated, in full or in principle, 27 amendments.

<sup>(1)</sup> OJL 268, 18.10.2003, p. 1.

### **Amendments incorporated in the Common Position**

In addition to amendments mentioned in part 1 above, the Common Position incorporates, in full or in principle, other European Parliament's first reading amendments, aimed at improving or clarifying the text, in particular amendments 4, 6, 7, 9, 12, 14, 31, 36, 41, 42.

### **Amendments not introduced <sup>(1)</sup>**

The Council was not able to accept all amendments, sometimes because it did not consider that they would bring drafting clarity (see amendments 13 and 37) or for the specific reasons outlined below:

— *Precautionary principle* (amendments 2, 17 — recital 13 and Article 4(a))

The precautionary principle is one of the general principles underlying the general food law <sup>(2)</sup>. Consequently, it applies to the proposed Regulation with no need for a specific reference to it. Moreover, in the risk analyses framework, the precautionary principle can only be taken into account in the context risk management, never in the risk assessment phase as suggested by the European Parliament.

— *Definition of 'appropriate physical process'* (amendment 15 — Article 3(2)(k))

The traditional food preparation processes listed in Annex II should not be confused with the 'appropriate physical process' defined in Article (3)(2)(k).

— *Definition of 'flavouring substance'* (amendment 49 — Article 3(2)(b))

The Council indicated, in recital 14, through which processes the flavouring substance can be produced. The amendment would restrict the methods that can be used.

— *Decisions submitted to the regulatory comitology procedure without scrutiny* (amendments 11, 16, 23, 32 — Article 13(a), 13(b), 6(3), 20(2))

Decisions on whether or not a given substance falls within the scope of the Regulation (amendment 11); rules implementing methods on how to monitor Annex IIIB (amendment 23) and the common methodology for monitoring of the consumption and use of flavourings (amendment 32) are of an interpretative nature and would not supplement the Regulation. Therefore, they do not fall within the scope of the regulatory comitology procedure with scrutiny.

— *Labelling of genetically modified organisms (GMOs)* (amendments 27, 28, 38 — Article 15(1)(e)(ii) and (g), Article 29 (2a new))

As mentioned in recital 24, flavourings remain subject to the labelling provisions defined 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 <sup>(3)</sup> and in Regulation (EC) No 1829/2003 on genetically modified food and feed and their labelling (Articles 12 and 13 of the later). The Council insisted on retaining the consistency between 'GMOs' Regulation, Directive 2000/13/EC ('Labelling Directive') and this Regulation. Therefore, the Council did not accept amendments 27 and 38 as they are already covered by Regulation (EC) No 1829/2003. Amendment 28 is not necessary as the term 'other relevant Community legislation' in Article 15(1)(g) in the Common Position also includes the above-mentioned Regulation.

<sup>(1)</sup> Numbering of Articles in this part refers to the text of the Common Position.

<sup>(2)</sup> 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 (OJ L 31, 1.2.2002, p. 1). Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 34).

<sup>(3)</sup> OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).

A definition of general scope, such as the one proposed in amendment 52 would have to be part of Regulation (EC) No 1829/2003 and not of the proposed Regulation.

— *Conditions for use* (amendments 19 and 20 — Article 4(ba new) and Article 4(bb new))

The Council did not include a reference to the benefit of the consumer and to the technological need as general conditions for the use of flavourings because their implementation would have been not possible owing to possible subjective interpretations. These two aspects are already covered in the definition of flavourings, which states that they are added to food to impart odour and/or taste.

— *Labelling*

Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are in line with some of the amendments related to Articles 14 to 18. However, the Council was not able to accept the suggestions relating to labelling of GMOs as explained above (amendments 27, 28, 38) and amendment 26, which is not consistent with other specific Community legislation and may create barriers to trade. Amendment 43 is not in line with the spirit of the provisions of Article 16, which aims at providing adequate information to the consumers and protecting consumer interests.

— *Entry into force of Articles 10, 26, 27* (amendment 44 — Article 30(2))

Amendment 44 was not accepted as Articles 10, 26 and 27 can only apply after the Community list of authorized flavourings and source materials has become applicable. In addition, the date of application of that Community list can only be determined after it has been adopted through the comitology procedure with scrutiny pending the outcome of the evaluation by EFSA as referred to in Article 4 of Regulation (EC) 2232/96.

— *Presence of toxic substances* (amendments 21, 40, 46 — Article 6(2), Annex IIIB, Article 6(2a new))

Substances in Annex III B of the proposed Regulation pose a toxicological problem, confirmed by the Scientific Committee on Food (SCF) or EFSA. Knowing that these substances are a toxicological problem, they must be regulated based on the most recent scientific advice available. The Council attached great importance to using a risk-based approach to set maximum limits in this Regulation. For the Council, amendments 21 and 40 go against the need to provide a high level of protection of human health. The Council considered that a general exclusion, as suggested by amendment 46, in respect of the application of Annex III B to compound food to which only herbs and spices have been added is too broad and would not provide sufficient protection the consumers. The Council considers, in line with the principle of proportionality, that the exclusion from maximum levels set in Annex III B is justified for the use of herbs and spices under the condition that they are used in compound foods which are prepared and consumed on the same site and thus will not affect cross-boarder trade.

#### IV. **Conclusions**

The Council believes that the Common Position represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation ensuring a high level of human health and consumer protection.

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