



COMMISSION OF THE EUROPEAN COMMUNITIES

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Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1576/89, Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

I. PROCEDURE

1. On 28th July 2006, the Commission adopted the proposal for a European Parliament and Council Regulation on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1576/89, Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC [Document (COM (2006)0427 final)] as part of a package of four proposals on food improvement agents. The proposal was submitted to the Council and the European Parliament on 28th July 2006.
2. The Economic and Social Committee adopted its opinion on 25th April 2007
3. The general approach agreed in the Council at the EPSCO meeting on 31st May 2007 on the other text of the package does not apply to the text on flavourings.
4. The European Parliament has given in first reading a favourable opinion on the proposal on 9 July 2007.
5. The present proposal amends the original proposal [COM (2006)0427 – 2006/0147(COD)] so as to take into account the amendments of the European Parliament that were accepted by the Commission.
6. With regard to the original proposal, the European Parliament adopted 43 amendments. Commissioner Kyprianou had indicated to the plenary meeting on 9 July 2007 that the Commission could accept many of the amendments, wholly or in part, and subject to rewording. From the adopted amendments the following cannot be accepted by the Commission 2, 11, 13, 16, 17, 19, 20, 21, 23, 26, 31 (second part), 32, 37, 40, 43, 44, 46, 49, 52.
7. The amendments in the revised proposal are in **bold and underlined**. A number of amendments have been reformulated so as to ensure consistency of the terminology used throughout the proposal and the other proposals of the package, or to bring the text in line with the approach of the Council where similar amendments have been proposed.
8. The numbering of the Articles has been adapted to take into account a number of amendments.

II. OBJECTIVES OF THE PROPOSAL

9. The proposed Regulation aims at replacing current Council Directive 88/388/EEC in order to take into account technological and scientific developments in the area of flavourings and the developments of the food legislation in the European Community.

The main objectives are:

- to clarify the scope of legislation on flavourings;
- to modernise and adapt the existing legislation on flavourings to technological and scientific developments;
- to establish clear evaluation and authorisation procedures;
- to better inform the consumer about the use of natural flavourings;
- to adapt to the requirements of Regulation (EC) N° 882/2004 on official controls performed to ensure the verification with feed and food law, animal health and animal welfare rules.

III. OVERVIEW OF THE AMENDMENTS OF THE EUROPEAN PARLIAMENT

10. Technical/editorial amendments

Amendments 4, 5, 6, 7, 8, 9, 12, 15, 27, 28, 29, 30, 31 (first part), 35, 36, 39, 41, 42, 45 aim to improve the proposal from a technical and editorial point of view and have been taken over by the Commission, in some cases subject to some editorial changes.

11. Legal basis

Article 37 is deleted as legal basis for the Regulation. The same reasoning as for enzymes applies for which the Parliament voted in favour of this deletion, because the agricultural aspects of the proposal (amendments to vertical agricultural texts) are only secondary objectives of the proposed Regulation.

12. Comitology

Since the package was adopted around the time that Decision 2006/512/EC amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission was adopted, the Commission proposal referred to the normal regulatory procedure. Therefore the alignment of the amended proposal with Decision 2006/512/EC is generally endorsed by the Commission.

The amendments **11, 23 and 32** concern the introduction of the regulatory procedure with scrutiny. The decisions referred to in these amendments will not add new elements to the Regulation, scrutiny is therefore not required.

Amendment **16** removes the possibility to decide (with the assistance of the Standing Committee) to which category a flavouring belongs and is therefore not acceptable, as the Commission is of the opinion that such a decision may be needed.

Amendments **24, 33 and 34** are partially accepted, the urgency procedure should however be allowed in case there is a risk for the safety of the consumer.

13. Definitions (Article 3)

Amendment **14** defines that food ingredients with flavouring properties contribute *significantly* to the presence of the substances in Annex III part B. In practice, this may be the case, however, such a concept does not belong to the legal text and is already mentioned in recital 5.

Amendment 13 changes the term "*other flavouring*" to "*flavourings not elsewhere specified*". Even though both terms have the same meaning the first is preferred.

Amendment **49** restricts the production of "flavouring substances" to appropriate 'natural' processes or chemical synthesis. There may however be other ways to produce flavouring substances e.g. extraction from smoke condensates or from thermal process flavourings. The amendment is therefore not acceptable.

14. Prohibition of non-compliant flavourings

This amendment is introduced in order to bring the text in line with the amended proposals on food additives and food enzymes. The proposed text clarifies that a flavouring or a food in which a flavouring is used should not be placed on the market, if the flavouring or its use does not comply with the proposed Regulation. This clarification is introduced in the amended proposal with the inclusion of Article 5.

15. General conditions of use

The Commission proposal sets general conditions of use of flavourings or food ingredients with flavouring properties. They must be safe and their use must not mislead the consumer. In recital 6 a clarification is introduced explaining what is meant by misleading the consumer (amendment **1**).

Amendment **19** requires that the use of flavourings must have advantages and benefits for the consumer and amendment **20** requires that there should be a technological need. These amendments are not needed as technological need and benefit for the consumer are implicit in the definition of flavourings

Amendment 2 and 17 require the authorisation of flavourings to be based on the precautionary principle. The precautionary principle and the conditions for its application are already laid down in the General Food Law (Regulation (EC) No 178/2002) and it should not be repeated in the proposed Regulation on flavourings.

16. Presence of certain substances

Amendment 46 concerns the maximum limits for substances of toxicological concern in Annex III Part B. These maximum limits would not apply to compound foods to which no flavourings have been added and the only food ingredients with flavouring properties added are spices and herbs. This is unacceptable as a safety concern is not excluded.

Amendments 21 and 40 introduce a blank Annex III Part B, and only when there is a justified scientific concern, maximum levels could be included by comitology. This amendment is not in line with recent scientific opinions which confirm the need for maximum limits as proposed in Annex III Part B.

17. Relation with Regulation 1829/2003 on GM food and feed (Article 12)

Flavourings or source materials which fall within the scope of Regulation (EC) No 1829/2003 will be subject to that Regulation with regard to the safety assessment of the genetic modification, while the other aspects of safety, the consideration of the other criteria and the final authorisation will, where appropriate, be dealt with under the flavourings Regulation. The two evaluations and authorisations can run in parallel.

Amendments 41 and 42 clarify that the two procedures may run simultaneously in accordance with good administrative practice. The proposed clarification is endorsed by the Commission subject to some drafting changes in order to make the provision compatible with Regulation 1829/2003.

Amendments 52 introduces a definition of the term "*produced by GMO's*". If such a definition is needed it should be covered by Regulation (EC) No 1829/2003.

18. Labelling

Amendment 29 concerns the labelling of natural flavourings, where the 90 % rule is replaced by 95 % when referring to a natural source. The proposed change is acceptable as it corresponds better to consumer expectations and will have limited impact on current practices.

Amendment 26 requires that for trade between food business operators, an address in the EU should be provided. This is not accepted as it could lead to barriers to trade with third countries.

A description of smoke flavourings such as "smoked salmon flavour" (amendment 37) is not acceptable as this could be misleading for the consumer; in practice the flavouring could be a mixture of smoke flavouring with salmon flavouring.

Labelling of flavourings obtained from GMO's should be covered by Regulation 1829/2003 and not by this Regulation (amendment 38).

Finally the Commission can not accept amendment 43 as it is a basic principle of the proposal to name the source of the natural flavouring to ensure correct consumer information.

In its original proposal the Commission aligned furthermore the labelling provisions of flavourings with those additives and enzymes. The European Parliament made a number of amendments to the latter proposals to ensure a new presentation and simplification of the labelling provisions for additives and enzymes sold from business to business or to the final consumer. The Commission has therefore taken on board the spirit of these amendments also in this amended proposal on flavourings.

19. Reporting by food business operators

Amendment 31 is partly accepted, as a producer or user of a flavouring substance should inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the flavouring substance. An addition that it concerns *information which is known and accessible to him* is not acceptable as this restricts the responsibility of the producer

The **second part of Amendment 31**, which lays down what information should be requested is not acceptable as it restricts the Commission proposal and pre-empts the contents of the implementation measure.

20. Pursuant to Article 250(2) of the EC-Treaty, the Commission amends it proposals in accordance with the lines set out above.

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on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1576/89, Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 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 Articles ~~37~~ and 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

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 production³ 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 the present 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 flavourings⁴ 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 production⁵ lays down rules on the labelling of flavourings. These rules are being replaced by the present Regulation and the Directive should now be repealed.

¹ OJ C [...], [...], p. [...].

² OJ C **168, 20.7.2007, p 34.**

³ 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).

⁴ OJ L 184, 15.7.1988, p. 67.

⁵ 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 the scope of 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 ('food ingredients with flavouring properties'), their source material and foods containing them.
- (6) Flavourings and food ingredients with flavouring properties may 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. They should 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.**
- (7) Since 1999, the Scientific Committee on Food and subsequently the European Food Safety Authority has expressed opinions on a number of substances occurring naturally in source materials for flavourings and food ingredients with flavouring properties⁶ 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.
- (8) 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.
- (9) Provisions should be established at Community level in order to prohibit or restrict the use of certain plant or animal materials which raise concern for human health in the production of flavourings and food ingredients with flavouring properties and their applications in food production.
- (10) Risk assessments should be carried out by 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 safety⁷.

⁶ http://europa.eu.int/comm/food/food/chemicalsafety/flavouring/scientificadvice_en.htm

⁷ 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).

- (11) 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 [...]establishing a common approval procedure for food additives, food enzymes and food flavourings⁸.
- (12) Flavouring substances are chemically defined substances with flavouring properties. 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 foodstuffs⁹. 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 [...].
- (13) Flavouring preparations are flavourings other than chemically defined substances obtained from materials of vegetable, animal or mineral 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 prior to approval.
- (14) 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 hitherto there is significant evidence of use for the production of flavourings, are considered as food materials for this purpose, even though some of these source materials, such as rose wood, oak wood chips and strawberry leaves, may not have been used for food as such. They do not need to be evaluated.
- (15) Likewise, thermal process flavourings produced from food under authorised 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 produced under non-authorised conditions should be evaluated prior to approval.
- (16) Regulation (EC) No 2065/2003/EC of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods¹⁰, 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.

⁸ OJ L [...], [...], p [...].

⁹ OJ L 299, 23.11.1996, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

¹⁰ OJ L 309, 26.11.2003, p. 1.

- (17) Flavour precursors impart flavour to food by chemical reactions occurring 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 prior to approval.
- (18) 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.
- (19) 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.
- (20) A flavouring or a source material which falls under 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 feed¹¹ should be **subject to the authorization procedure under that Regulation with regard to the safety assessment of the genetic modification, while the final authorization should be granted under this Regulation.** ~~authorised according to that Regulation, prior to its approval under this Regulation.~~
- (21) Flavouring substances or flavouring preparations should only be labelled as ‘natural’ if they comply with certain criteria which ensure that consumers are not misled.
- (22) Specific information requirements should ensure that consumers are not misled concerning the source material used for the production of natural flavourings. ~~The source of vanillin obtained from wood will, for example, have to be mentioned.~~
- (23) **Flavourings should remain subject to the general labelling obligations as provided for in Directive 2000/13/EC and, where appropriate, in Regulation (EC) No 1829/2003. In addition, specific provisions on labelling of flavourings sold as such to the manufacturer or to the final consumer should be included in this Regulation.**
- (24) Consumers should be informed if the smoky taste of a particular food is due to the addition of smoke flavourings. In accordance with Article 5 of 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 foodstuffs¹², the name under which the product is sold should not confuse the consumer as to whether the product is smoked conventionally with fresh smoke or treated with smoke flavourings. This Directive needs to be adapted to the definitions of flavourings, smoke flavourings and the term ‘natural’ for the description of flavourings laid down in the present Regulation.

¹¹ OJ L 268, 18.10.2003, p. 1.

¹² OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

- (25) 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.
- (26) 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 Commission¹³.
- (27) **In particular power should be conferred on the Commission 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, and/or to supplement it by the addition of 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.**
- (28) Annexes II to V to this Regulation should be adapted to scientific and technical progress.
- (29) In order to develop and update Community legislation 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 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 rules¹⁴ and consequently the legal basis for the financing of the above measures will be Regulation (EC) No 882/2004.
- (30) 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 [procedural Regulation]. However the time periods provided for in that Regulation for the Authority to adopt its opinion and for the Commission to submit a draft Regulation updating the Community list to the Standing Committee on the Food Chain and Animal Health should not apply, because priority should be given to the ongoing evaluation programme.

¹³ OJ L 184, 17.7.1999, p. 23. **Decision as amended by Decisions 2006/512/EC (OJ L 200, 22.7.2006, p.11).**

¹⁴ OJ L 165, 30.4.2004, p. 1. Corrected version (OJ L 191, 28.5.2004, p. 1).

- (31) Since the objective of the action to be taken, 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, by reason of market unity and 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 those objectives.
- (32) Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks¹⁵ 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 cocktails¹⁶ need to be adapted to certain new definitions laid down in the present Regulation.
- (33) Regulations (EEC) No 1576/89, (EEC) No 1601/91 and (EC) No 2232/96 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 to ensure **a high level of human health protection and consumer protection and** the effective functioning of the internal market ~~and a high level of human health protection and consumer protection.~~

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 ('the Community list');
- (b) conditions of use of flavourings and food ingredients with flavouring properties in and on foods;
- (c) rules on labelling of flavourings.

¹⁵ OJ L 160, 12.6.1989, p. 1. Regulation as last amended by the 2003 Act of Accession.

¹⁶ OJ L 149, 14.6.1991, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003.

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 ~~the exception of smoke flavourings falling within the scope of~~ 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 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.**
 - ~~(b) raw or non-compound foods.~~
3. Where necessary, it may be decided in accordance with the procedure referred to in Article 18~~20~~(2) whether or not a given substance or mixture of substances, material or type of food falls within the scope of this Regulation.

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. 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;

(iii) which may contain food including additives as permitted by Regulation (EC) No XXX/2007¹⁷ of the European Parliament and of the Council of ... on food additives;

- (b) 'flavouring substance' shall mean a chemically defined 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;
- (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 appropriate physical processes;

and/or
 - (ii) material of vegetable, animal or microbiological origin, other than food, obtained by one or more of the traditional food preparation processes listed in Annex II and/or appropriate physical, enzymatic or microbiological processes;
- (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:

¹⁷

OJ C [...], [...], p. [...].

- (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 the 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;
- (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 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, are considered as food.
4. Where necessary, it may be decided in accordance with the procedure referred to in Article 18~~20~~(2) whether or not a given substance falls within a specific category listed in paragraph 2(b) to (j).

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 concern to the health of the consumer;
- (b) their use does not mislead the consumer.

Article 5

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

No flavouring and/or any food in which such a flavouring has been used may be placed on the market, if the flavouring or its use does not comply with this Regulation and its implementing measures.

Article 56

Presence of certain substances

1. Substances listed in Part A of Annex III shall not be added as such to food.
2. Maximum levels of certain substances, naturally present in flavourings and 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 food ingredients with flavouring properties in and on those foods.

The maximum levels shall apply to the compound foods as offered ready for consumption or as prepared according to the instructions of the manufacturer.

3. Detailed rules for the implementation of paragraph 2 may be adopted in accordance with the procedure referred to in Article ~~48~~**20**(2).

Article 67

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 food ingredients with flavouring properties.
2. Flavourings and food ingredients with flavouring properties produced from source materials listed in Part B of Annex IV may only be used under the conditions indicated in that Annex.

Article 78

Flavourings for which an evaluation and approval is not required

1. The following flavourings may be used in or on foods without an 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) and 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 European Food Safety Authority ('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 [procedural Regulation] 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 20(3).** ~~in accordance with the procedure referred to in Article 18(2).~~ Such measures shall be laid down in Annexes III, IV and/or V as appropriate. **On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 20(4).**

CHAPTER III

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

Article 89

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

The present Chapter applies 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 under Article 3(2)(e)(ii) or for which the conditions for the production of thermal process flavourings and 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 ~~9~~**10***
Community list of flavourings and source materials

Of the flavourings and source materials referred to in Article ~~8~~**9**, only those included in the Community list may be placed on the market as such and used in or on foods.

*Article ~~10~~**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 [common procedure], only if it complies with the conditions set out in Article 4.
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 [...] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

*Article ~~11~~**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 the present Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.** ~~only after it has been authorised in accordance with the procedure referred to in Article 7 of Regulation (EC) No 1829/2003.~~

CHAPTER IV

LABELLING

SECTION 1

~~LABELLING OF FLAVOURINGS NOT INTENDED FOR SALE TO THE FINAL CONSUMER~~

~~Article 12~~**13**

Labelling of flavourings not intended for sale to the final consumer

1. Flavourings not intended for sale to the final consumer may be marketed only if **they comply with the labelling** ~~if their packaging, containers or accompanying documents bear the information~~ provided for in Articles 13~~4~~ and 14~~5~~, which must be easily visible, clearly legible and indelible. **The information provided for in Article 14 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 rules of the Treaty, stipulate that this information shall be given in one or more 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 13~~**14**

*General information requirements for labelling of 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 to which other substances are added in accordance with Article 3(2)(a)(iii), their** packaging or containers ~~of flavourings not intended for sale to the final consumer~~ shall bear the following information:
 - (a) the sales description: either the word ‘flavouring’ or a more specific name or description of the flavouring;
 - (~~e~~**b**) the statement either ‘for use in food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use;
 - (~~f~~**c**) if necessary, the special conditions for storage and use;
 - (~~h~~**d**) a mark identifying the batch or lot;

- (~~d~~e) a list in descending order of weight of:
 - (i) the categories of flavourings present; and
 - (ii) the names of each of the other substances or materials contained in the product or, where appropriate, their E-number and **an indication a accordance with Regulation (EC) No 1829/2003;**
 - (~~b~~f) the name or business name and address of the manufacturer or packager, or of a seller;
 - (~~e~~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 legislation, **including Regulation (EC) No 1829/2003;**
 - (~~h~~) the net quantity.
 - (~~g~~i) a date of minimum durability;
 - (i) **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~~e) to (g) and (i) 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 'intended for the manufacture of food and 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 of this article, 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 ~~14~~**15***

Specific information requirements for the sales description of flavourings

1. The term 'natural' may only be used to describe a flavouring in the sales description referred to in Article ~~13~~**14**(1)(a) as provided for in paragraphs 2 to 6.
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 at least ~~90~~**95**% [by w/w] of the flavouring component has been obtained from the source material referred to.

The flavouring component may contain flavouring preparations and/or natural flavouring substances.

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 and can easily be recognised.

The flavouring component may contain flavouring preparations and/or natural flavouring substances.

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.

The flavouring component may contain flavouring preparations and/or natural flavouring substances.

~~SECTION 2~~

~~LABELLING OF FLAVOURINGS INTENDED FOR SALE TO THE FINAL CONSUMER~~

*Article ~~15~~**16***

Labelling of flavourings intended for sale to the final consumer

1. Without prejudice to Directive 2000/13/EC, **Directive 89/396/EEC and where appropriate, Regulation (EC) No 1829/2003**, flavourings **sold singly or mixed with each other and/or to which other substances have been added** intended for sale to the final consumer may be marketed only if their packaging contains the statement either ‘for use in food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use, which must be easily visible, clearly legible and indelible.
2. The term ‘natural’ shall be used to describe a flavouring in the sales description referred to in Article ~~13~~**14**(1)(a) only as provided for in Article ~~14~~**15**.

Article 17
Other labelling requirements

Articles 13 to 16 shall apply 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.

CHAPTER V

PROCEDURAL PROVISIONS AND IMPLEMENTATION

Article ~~16~~18
Reporting by the food business operators

- 1. A producer or user of a flavouring substance shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the flavouring substance.**
- ~~12.~~ The food business operators or their representatives shall report to the Commission the annual amounts of flavouring substances added to foods in the Community and the use levels for each food category in the Community.
- ~~23.~~ Detailed rules for the implementation of paragraph ~~12~~ shall be adopted in accordance with the procedure referred to in Article ~~18~~20(2).

Article ~~17~~19
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 and report their findings each year to the Commission and to the Authority.
2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on the consumption and use of flavourings set out in the Community list and of the substances listed in Annex III may be adopted in accordance with the procedure referred to in Article ~~18~~20(2).

Article ~~18~~20
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health (hereinafter referred to as ‘the Committee’).

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.**
5. ~~The Committee shall adopt its Rules of Procedure.~~

*Article ~~19~~**21***

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 20(3).** ~~shall be adopted in accordance with the procedure referred to in Article 18(2).~~

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 20(4).

*Article ~~20~~**22***

Community financing of harmonised policies

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

CHAPTER VI

TRANSITIONAL AND FINAL PROVISIONS

*Article ~~21~~**23***

Repeals

1. Directive 88/388/EEC, Decision 88/389/EEC and Directive 91/71/EEC are repealed.

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

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

Article 2224

Establishment of the Community list of flavourings and source materials and transitional regime

1. The Community list shall be established by placing the list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 in Annex I to this Regulation at the time of its adoption.
2. Until the establishment of the Community list, Regulation (EC) No [...] [the common procedure] 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 time periods of ~~six~~**nine** months and ~~nine months~~ referred to in Article 5(1) and Article 7 of Regulation (EC) No [...] [the common procedure] 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 20(3).** ~~may be adopted in accordance with the procedure referred to in Article 18(2).~~

Article 2325

Amendment to Regulation (EEC) No 1576/89

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

1. Article 1(4)(m) is 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 [...], 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) 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 [...] and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation so that the taste is predominantly that of juniper.”

- (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 as defined in Article 3(2)(b) of Regulation (EC) No [...] and/or flavouring preparations as specified at (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 [...] 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 [...] 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 [...] 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)(b) and (d) of Regulation (EC) No [...] 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 [...] and flavouring preparations as defined in Article 3(2)(d) of that Regulation shall be authorized in liqueurs except those mentioned below:”

Article ~~24~~26
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 [...], and/or”
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 [...], 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 [...], and/or”

Article ~~25~~27
Amendment to Regulation (EC) No 2232/96

In Article 5 of Regulation (EC) No 2232/96, paragraph 1 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 ~~26~~28
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 [...] of the European Parliament and of the Council* [Regulation on flavourings];

- “smoke flavouring(s)” if the flavouring component contains flavourings as defined in Article 3 (2) (f) of Regulation EC No [...] [Regulation on flavourings] and imparts a smoky flavour to the food.
2. The term ‘natural’ for the description of flavourings shall be used as laid down in Article ~~14~~**15** of Regulation (EC) No [...] [Regulation on flavourings].”
- * OJ L [...], [...], [...]

*Article ~~27~~**29***
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 [please insert date] [*24 months after entry into force*]. However, Articles ~~9~~**10**, ~~23~~**25** and ~~24~~**26** shall apply from the date of application of the Community list.

Foods lawfully placed on the market or labelled prior to [24 months after the entry into force of this Regulation] which do not comply with this Regulation may be marketed until their date of minimum durability.

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

ANNEX I

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

ANNEX II

List of traditional food preparation processes by which natural flavouring substances and natural flavouring preparations are obtained

Chopping	Coating
Cooking, baking, frying (up to 240°C)	Cooling
Cutting	Distillation / rectification
Drying	Emulsification
Evaporation	Extraction, incl. solvent extraction
Fermentation	Filtration
Grinding	Heating
Infusion	Maceration
Microbiological processes	Mixing
Peeling	Percolation
Pressing	Refrigeration/Freezing
Roasting / Grilling	Squeezing
Steeping	

ANNEX III

Presence of certain substances

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

Agaric acid

Capsaicin

Hypericine

Beta-asarone

1-Allyl-4-methoxybenzene

Hydrocyanic acid

Menthofuran

4-Allyl-1,2-dimethoxybenzene

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 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	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 ¹⁸	3000
	Chewing gum	1000
	Mint/peppermint containing alcoholic beverages	200
4-Allyl-1,2-dimethoxybenzene,	Dairy products	20
	Meat and meat products, including poultry and game	15
	Fish and fish products	10
	Soups and sauces	60
	Ready-to-eat savouries	20
	Non-alcoholic beverages	1
Pulegone	Mint/peppermint containing confectionery, except micro breath freshening confectionery	250
	Micro breath freshening confectionery ¹⁸	2000
	Chewing gum	350
	Mint/peppermint containing non-alcoholic beverages	20
	Mint/peppermint containing alcoholic beverages	100

¹⁸ Candies with intensive taste; weight per candy not more than 1 g.

Quassin	Non-alcoholic beverages	0,5
	Bakery wares	1
	Alcoholic beverages	1.5
1-Allyl-3,4-methylene dioxy benzene, safrole	Meat and meat products, including poultry and game	15
	Fish and fish products	15
	Soups and sauces	25
	Non-alcoholic beverages	1
Teucrin A	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

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>	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) <i>Kotl. et Pouz</i> 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>	St Johns wort	
<i>Teucrium chamaedrys</i>	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