Basic information

2006/0147(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Flavourings and food ingredients with flavouring properties for use in and on foods Repealing Regulation (EC) No 2232/96 1993/0478(COD) Amending Directive 2000/13/EC 1999/0090(COD) Amending Regulation (EC) No 110/2008 2005/0028(COD) **Subject** 3.10.10 Foodstuffs, foodstuffs legislation 3.40.13 Food industry 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	DRČAR MURKO Mojca (ALDE)	14/09/2006

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	DRČAR MURKO Mojca (ALDE)	07/11/2006

Former committee for opinion	Former rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
General Affairs	2858	2008-03-10
Employment, Social Policy, Health and Consumer Affairs	2803	2007-05-30
Agriculture and Fisheries	2841	2007-12-17

	Agriculture and Fisheries	2904	2008-11-18

European Commission	Commission DG	Commissioner
	Health and Food Safety	VASSILIOU Androulla

Key events

Date	Event	Reference	Summary
28/07/2006	Legislative proposal published	COM(2006)0427	Summary
05/09/2006	Committee referral announced in Parliament, 1st reading		
08/05/2007	Vote in committee, 1st reading		Summary
15/05/2007	Committee report tabled for plenary, 1st reading	A6-0185/2007	
30/05/2007	Debate in Council		Summary
09/07/2007	Debate in Parliament		
10/07/2007	Decision by Parliament, 1st reading	T6-0323/2007	Summary
10/07/2007	Results of vote in Parliament		
24/10/2007	Modified legislative proposal published	COM(2007)0671	Summary
10/03/2008	Council position published	16677/3/2007	Summary
13/03/2008	Committee referral announced in Parliament, 2nd reading		
06/05/2008	Vote in committee, 2nd reading		Summary
13/05/2008	Committee recommendation tabled for plenary, 2nd reading	A6-0177/2008	
07/07/2008	Debate in Parliament		
08/07/2008	Decision by Parliament, 2nd reading	T6-0331/2008	Summary
08/07/2008	Results of vote in Parliament		
18/11/2008	Act approved by Council, 2nd reading		
16/12/2008	Final act signed		
16/12/2008	End of procedure in Parliament		
31/12/2008	Final act published in Official Journal		

Technical information

Procedure reference	2006/0147(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation

Legislative instrument	Regulation
Amendments and repeals	Repealing Regulation (EC) No 2232/96 1993/0478(COD) Amending Directive 2000/13/EC 1999/0090(COD) Amending Regulation (EC) No 110/2008 2005/0028(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095 EC Treaty (after Amsterdam) EC 037
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/58918

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE384.469	28/02/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0185/2007	15/05/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0323/2007	10/07/2007	Summary
Committee draft report		PE402.786	06/03/2008	
Amendments tabled in committee		PE404.638	07/04/2008	
Committee recommendation tabled for plenary, 2nd reading		A6-0177/2008	13/05/2008	
Text adopted by Parliament, 2nd reading		T6-0331/2008	08/07/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	06734/2008	03/03/2008	
Council position	16677/3/2007	10/03/2008	Summary
Draft final act	03661/2008/LEX	16/12/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2006)0427	28/07/2006	Summary
Document attached to the procedure	SEC(2006)1042	28/07/2006	
Document attached to the procedure	SEC(2006)1043	28/07/2006	
Commission response to text adopted in plenary	SP(2007)4170	29/08/2007	
Modified legislative proposal	COM(2007)0671	24/10/2007	Summary
Commission communication on Council's position	COM(2008)0142	11/03/2008	Summary

Commission opinion on Parliament's position at 2nd reading	COM(2008)0606	17/10/2008	Summary

Additional information		
Source	**Document**	**Date**
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act	
Regulation 2008/1334 OJ L 354 31.12.2008, p. 0034	Summary

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 17/10/2008 - Commission opinion on Parliament's position at 2nd reading

The European Parliament voted, in second reading, a consolidated text which contains a number of amendments to the text of the common position. The text is the result of negotiations between the Council, the EP and the Commission. The amendments are mainly of technical nature and are generally in line with and strengthen the key principles of the initial proposal. Of particular note are the amendments which will exempt certain aspects of the legislation from applying when only herbs and spices have been added to food.

Other amendments concern the clarification of the interplay between the proposed Regulation on food additives and Regulation (EC) No 1829/2003 on genetically modified food and feed and also creating more legal certainty for producers and users of flavourings by extending the deadline for the adoption of the community list of flavouring substances. Other amendments strengthen the precautionary principle and further clarify the principle of not misleading the consumer.

Additionally a number of technical changes have been introduced as a result of the replacement of the spirit drink Regulation (EEC) No 1576/89 by a new Regulation (EC) No 110/2008.

The Commission **accepts all the amendments** voted by the European Parliament and amends its proposal as set out above.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 30/05/2007

Pending the European Parliament first reading opinion, the Council reached general approaches on three draft Regulations concerning: common authorisation procedure; food additives; food enzymes. It took note of a progress report regarding a draft Regulation on flavourings.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 16/12/2008 - Final act

PURPOSE: to lay 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 human health protection and consumer protection.

LEGISLATIVE ACT : Regulation (EC) No 1334/2008 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 1601/91, Regulations (EC) No 2232/96 and (EC) No 110 /2008 and Directive 2000/13/EC.

CONTENT: the Council adopted this Regulation having accepted all the amendments made by the European Parliament at second reading. This Regulation lays down rules on flavourings and food ingredients with flavouring properties for use in and on foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

The approval of flavourings should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors, the **precautionary principle** and the feasibility of controls.

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.

It provides for:

- a Community list of flavourings and source materials approved for use in and on foods, set out in Annex I ('the 'Community list');
- conditions of use of flavourings and food ingredients with flavouring properties in and on foods;
- rules on the labelling of flavourings.

The main objectives of the Regulation 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 inform better 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.

The Regulation provides that only flavourings or food ingredients with flavouring properties which meet the following conditions may be used in or on foods:

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

(b) their use does not mislead the consumer.

The Regulation contains maximum levels for undesirable substances in food. The conditions for the use of the term "natural" in describing flavourings are made stricter. The use of flavourings must not mislead the consumer, particularly as regards the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product.

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

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

The text also makes reference to natural flavouring substances and smoke flavouring(s) produced from food(s) or food category or source(s) (e.g. smoke flavouring produced from beech).

It should be noted that the Regulation forms part of the package of proposals on 'food improvement agents'. This package of proposals refers to food additives, food enzymes and flavourings. It contributes to the Commission's simplification programme and also provides for harmonisation not only in their respective fields but also promotes consistency between the three related areas. An additional fourth act within the package will establish a single common authorisation procedure for the evaluation and approval of these substances.

ENTRY INTO FORCE: 20/01/2009.

APPLICATION: It shall apply from 20 January 2011.

Article 10 (Community list of flavourings and source materials) shall apply from 18 months after the date of application of the Community list.

Articles 26 (Amendments to Regulation (EEC) No 1601/91) and 28 (Amendments to Regulation (EC) No 110/2008) shall apply from the date of application of the Community list.

Article 22 (Amendments to Annexes II to V) shall apply from 20/01/ 2009. Foods lawfully placed on the market or labelled prior to 20/01/2011 which do not comply with this Regulation may be marketed until their date of minimum durability or use-by-date.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 10/07/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Mojca Drcar **Murko** (ALDE, SI), and made some amendments to the Commission's proposal. Parliament felt that the use of flavourings should be permitted where they do not, on the basis of the scientific evidence available and the precautionary principle, pose a safety concern to the health of the consumer. Their use must have advantages and benefits for the consumer, and there must be a reasonable technological need. The main amendments were as follows:

- the precautionary principle introduced stricter conditions of use;

- a new part recital states that attention should be given to whether or not there could be any negative consequences for vulnerable groups, including the development of taste preferences in children, in the use of flavourings and food ingredients with flavouring properties;

- Parliament added that 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;

- food 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;

- where necessary, it may be decided in accordance with the regulatory procedure with scrutiny whether or not a given substance or mixture of substances, material or type of food falls within the scope of the Regulation. On several issues, detailed implementing rules are to be adopted in accordance with the regulatory procedure with scrutiny;

- Parliament amended the definitions of "flavouring substance" "flavouring not elsewhere specified ", food ingredient with flavouring properties", "appropriate physical process", and added a definition for "produced by GMOs";

- when there is a justified scientific concern that certain substances, naturally present in flavourings and food ingredients with flavouring properties, in compound foods may pose a safety concern to the health of the consumer, the Commission may, on its own initiative or on the basis of information provided by Member States, and following the opinion of the Authority, set maximum levels for these substances. By way of derogation, the maximum levels shall not apply where a compound food contains no added flavourings and the only food ingredients with flavouring properties which have been added are fresh, dried or frozen herbs and spices;

- Parliament clarified that a flavouring or source material falling within the scope of Regulation (EC) No 1829/2003 and not already included in the Community list in Annex I may be included in that list in accordance with this Regulation only if it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003;

- labelling must contain where appropriate , the indication "produced from GMOs"

- 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 95% (and not 90% as proposed by the Commission) of the flavouring component has been obtained from the source material referred to;

-better traceability is ensured by specifying that the seller must be established within the EU;

- a producer or user of a flavouring substance shall inform the Commission immediately of any new scientific or technical information which is known and accessible to him which might affect the assessment of the safety of the flavouring substance. The food industry user of the flavouring containing the flavouring substance and the producer of the flavouring shall in cooperation, at the request of the Commission, inform it of the actual use of the flavouring substance. The information provided in this context shall be treated as confidential data;

- for flavourings produced from a source material falling under the scope of Regulation (EC) No 1829/2003, the indication "produced from GMOs" shall appear on the label. For flavourings produced by an organism falling under the scope of Regulation (EC) No 1829/2003, no specific labelling shall be required;

- flavourings and food placed lawfully on the market before the date of application of the Regulation may continue to be used until stocks have been exhausted.

Lastly, Parliament made some amendments for the sake of clarity and precision.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 08/07/2008 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution amending the Council's common position for adopting 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

Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC. The recommendation for second reading (under the codecision procedure) had been tabled for consideration in plenary by Mojca **DRCAR MURKO** (ALDE, SI) on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments were the result of a compromise between the Council and the Parliament. The main amendments – adopted under the 2nd reading of the codecision procedure – are as follows:

Vulnerable groups: a new part recital states that, where possible, attention should be given to whether or not there could be any negative consequences for vulnerable groups. The use of flavourings must not mislead the consumer.

Consumer protection: Parliament stressed that the objectives are the effective functioning of the internal market, a high level of protection of human health and a high level of consumer protection.

Herbs and spices: non-compound foods and mixtures such as, but not exclusively, fresh, dried or frozen spices and/or herbs, mixtures of tea and mixtures for infusion as such are outside the scope of the Regulation.

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

Reporting by the food business operators: a producer or user of a flavouring substance must, if required, inform the Commission of the amount of the substance added to foods in the Community in a period of 12 months. The information provided in this context shall be treated as confidential data insofar as this information is not required for the safety assessment.

Spirit Drinks Regulation: Parliament inserted an amendment which is intended to adapt the new spirit drinks regulation (EC) No 110/2008. It replaces the Common position text adapting the old regulation (EEC) No 1576/89. The deletion of the category “nature-identical“ category must allow the producers of the traditional spirits aquavit and väkevä glögi to only use natural flavouring substances for the sake of their quality image. Regarding the latter, flavouring substances and preparations must be allowed;

Smoke flavourings: Parliament inserted an amendment providing the opportunity for referring to specific smoke flavourings so that consumers would be properly informed about salmon flavouring, bacon flavouring, barbecue flavouring and so on.

Lastly, Article 10 (the content of the Community lists of food additives) shall apply from 18 months after the date of application of the Community list.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 24/10/2007 - Modified legislative proposal

To recall, the European Parliament adopted 43 amendments to the original proposal, of which many were accepted. 19 amendments were not.

Technical/editorial amendments: Most of the amendments proposed by Parliament (in this case 19) seek to improve the proposal from a technical and editorial point of view. In such cases the Commission has amended its initial proposal accordingly.

Legal basis: The Commission has decided to delete Article 37 of the TEU as the legal basis for the Regulation, as proposed by Parliament.

Comitology: The Commission has agreed to align the implementing powers with Decision 2006/512/EC (regulatory procedure with scrutiny) in cases where scrutiny is required.

Definitions: On the question of definitions, the Commission has decided not to accept amendments that i) change the definition of flavouring properties that contribute *significantly* to the presence of the substances in Annex III part B; ii) to change the term *other flavourings* to *flavourings not elsewhere specified* and iii) to restrict the production of flavouring substances to appropriate *natural* processes or chemical synthesis.

Prohibition of non-compliant flavourings: The Commission has accepted an amendment specifying that food additives and enzymes that do not conform with the provisions of the proposed Regulation should not be placed on the market.

General conditions of use: The Commission has accepted proposed amendments that clarify provisions that seek to prevent the consumer from being mislead. However, amendments that would require the use of flavourings needing to have an advantage plus consumer benefit linked to technological need have been rejected. Further, amendments requiring the authorisation of flavourings to be based on the precautionary principle have been rejected given that such provisions are already set out in the General Food Law Regulation.

Presence of certain substances: The Commission has decided not to accept an amendment concerning the maximum limits for substances of toxicological concern in Annex III part B. Similarly, an amendment that introduces a blank Annex III part B has been rejected.

Proposed Regulation’s relation with GM food and feed: The Commission has decided to endorse an amendment stating that GMO procedures should run simultaneously. The proposed definition “produced by GMO’s” has been rejected though on the ground that should such a definition be needed it should be covered by Regulation (EC) No 1829/2003.

Labelling: The Commission has decided to accept an amendment regarding the labelling of natural flavourings from 90% to 95% when referring to a natural sources. On the other hand, it rejected an amendment which required 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. The description of smoke flavourings has not been accepted on the grounds that it could be misleading to the consumer. The labelling of flavourings obtained from GMO's should be covered by Regulation 1829/2003 and not by this Regulation. On a final point, the Commission has decided to accept Parliamentary proposals to simplify labelling provisions for additives and enzymes sold from business to business or to the final consumer.

Food business operator reporting: The Commission has decided to accept an amendment requiring producers to inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of flavouring substances. The requirement that "information which is known and accessible to him" be provided is not, however, accepted as this restricts the responsibility of the producer.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 17/12/2007

The Council reached an overall political agreement on a legislative package on food improvement agents (food additives, food enzymes and food flavourings).

After finalisation of the text, a common position will be adopted at a forthcoming Council meeting and forwarded to the European Parliament for a second reading, in accordance with the codecision procedure.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 28/07/2006 - Legislative proposal

PURPOSE : to lay 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 human health protection and consumer protection.

PROPOSED ACT : Regulation of the European Parliament and of the Council.

CONTENT : the European Commission has adopted a package of legislative proposals which aim to introduce harmonised EU legislation on food enzymes and upgrade current rules for flavourings and additives (refer to **COD/2006/0144** and **COD/2006/0145**).

The texts aim to clarify and update current legislation in this area and to create a simplified common approval procedure for food additives, flavourings and enzymes, based on scientific opinions from the European Food Safety Authority (EFSA) (refer also **COD/2006/143**).

At present, Council Directive 88/388/EEC sets out the definition of flavourings, general rules for their use, requirements for labelling and maximum levels for substances which raise concern for human health. It provides that Community Legislation relating to flavourings should take account primarily of human health requirements. However, the Directive needs to be substantially amended, to take into account technological and scientific developments in the area of flavourings. In addition, as a result of the adoption of Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety, certain provisions need to be adapted and others need to be newly introduced.

In the interest of clarity and efficiency Directive 88/388/EEC shall be replaced by the present proposal.

This Regulation provides for:

- a Community list of flavourings and source materials approved for use in and on foods, set out in Annex I ('the Community list');

- conditions of use of flavourings and food ingredients with flavouring properties in and on foods;

- rules on labelling of flavourings.

Lastly, the new legislation proposed sets out clearer rules on maximum levels for undesirable substances, in line with EFSA opinions. Definitions of flavourings (e.g. flavouring substance, flavouring preparation, thermal process flavouring) are clarified and stricter conditions are also introduced for the use of the term "natural" when describing flavourings. Consumers must be informed if the smoky taste of food is due to the presence of smoke flavourings.

For more details of the financial implications of this proposal, please refer to the financial statement.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 11/03/2008 - Commission communication on Council's position

The Commission supports the common position, which was adopted unanimously by the Council. The changes made by Council are in line with the objectives set out in the initial proposal as well as reflecting the core principles of several Parliamentary amendments tabled at first reading.

Amendments made by the Parliament accepted by the Commission and which are in line with the common position:

Criteria for authorising flavourings: taking account of Parliament's concerns, the common position clarifies what is meant by misleading the consumer in Recital 6.

Labelling natural flavourings: in line with Parliament's amendments, the common position modifies the initial proposal so that at least 95% of the flavouring component (and not 90% as originally proposed) must be obtained from the source referred to. This change corresponds better to consumer expectations and will have a limited impact on current practices.

Regulatory procedure with scrutiny: the European Parliament, the Council and the Commission agree that measures to amend non-essential elements of the Regulation by supplementing it will be subject to the regulatory procedure with scrutiny. However, both the Council and the Commission introduced the option for an urgency procedure.

Amendments made by Parliament accepted by the Commission but not incorporated in the common position:

Four Parliamentary amendments accepted by the Commission have not been incorporated into the Common position. They refer to the labelling of flavourings falling within the scope of Regulation (EC) No 1829/2003; and defining an "appropriate physical process" for the production of natural flavouring substances or flavouring preparations. In the amendment the Parliament sought to avoid traditional preparation processes being considered physical processes. The Commission accepted this amendment, given that it clarifies the situation and in case of doubt, a comitology decision can be adopted.

Commission's position on new provisions introduced by the Council:

Several new provisions have been introduced by the Council. Most of which seek to clarify the text or are in line with the objective's proposed in the initial proposal. In summary, they refer to:

- clarifying the meaning of "raw foods" and "non-compound food";
- justifying the risk based approach for the establishment of maximum levels for substances of toxicological concern, referred to in Article 5, that may be present in flavourings. It furthermore emphasizes the responsibilities of the producers in relation to those substances;
- clarifying the principle already included in the General Food Law (Regulation (EC) No 178/2002) that the rules on flavourings take into account, where appropriate, the protection of the environment. This change is consistent with the proposed Regulation on food additives and food enzymes and relevant EP amendments on the proposal on food additives;
- adding to the definition of natural flavouring substance that they correspond to substances that are naturally present and have been identified in nature. This is to void that some flavouring substances that are not present in materials of vegetable r animal origin, but that are obtained by artificial enzymatic processes, would be considered as natural;
- adding to that the definition of source materials considered as food for the production of flavourings is valid for the purpose of this Regulation only;
- clarifying that flavourings and/or foodstuffs in which flavourings are used should not be placed on the market, if the flavouring or its use does not comply with the proposed Regulation;
- introducing the option for an urgency procedure into the regulatory procedure with scrutiny;
- clarifying labelling requirements and aligning them with the proposals on food additives and food enzymes;
- clarifying that the maximum of 5% of the flavouring component derived from other source materials shall not reproduce the flavour of the source material referred to;
- in Annex III Part A, aloin and coumarin remain included in the list of substances that shall not be added as such to food, as already established in the current legislation. Scientific consideration on potential carcinogenicity of aloin is still ongoing and there are concerns that the exposure to coumarin via the use of food ingredients with flavouring properties (cinnamon) could be already too high;
- clarifying that maximum levels will not apply to compound foods which are prepared and consumed on the same site (restaurants), that contain no added flavourings and contain only herbs and spices as food ingredients with flavouring properties;
- setting maximum levels for coumarin in certain food categories;
- increasing the maximum levels for teucrine A in alcoholic beverages from 2 to 5 mg/kg in bitter tasting spirit drinks and liqueurs with bitter taste. This change was introduced at the request of Italy which has concerns about some local traditional drinks in Italy that otherwise could no longer be maintained on the market. The Commission can accept this increase, as these spirit drinks will have a limited impact on the total exposure to teucrine A.

Major problems encountered in adoption of the Common Position:

New analytical data from Germany demonstrated that the actual levels in certain foodstuffs to which cinnamon is added, are much higher than the current maximum levels and that the Tolerable Daily Intake (TDI) was likely to be exceeded. Germany therefore requested to reintroduce maximum levels. The Member States agreed with this reintroduction. However there was major concern about traditional cinnamon containing products that could be affected by too strict levels. The Commission organised two technical meetings with Member State experts and stakeholders and, following these consultations, possible maximum levels were identified. The Commission, therefore, asked the EFSA to assess this information. The conclusions of EFSA's additional assessment are expected to be available in May 2008. The Council has in the mean time adopted maximum levels that will be reconsidered in the light of these conclusions and a joint statement of Council and Commission has therefore been prepared.

To conclude, the Commission supports the common position as adopted unanimously by the Council.

Flavourings and food ingredients with flavouring properties for use in and on foods

2006/0147(COD) - 10/03/2008 - Council position

The Council has introduced a number of modifications to the text of the initial proposal with many of these based on amendments proposed by the European Parliament. Some of the Parliamentary amendments were introduced by Council on its own initiative. Of the 43 amendments proposed by Parliament, the Council has decided to adopt either in principle or in full, 27 amendments.

In summary, the modifications made by Council are as follows:

A single legal base: accepting Parliamentary suggestions, the Council has decided to retain Article 96 of the TEU as the sole legal base for the proposal agreeing that agricultural aspects are merely incidental and not core to the proposed Regulation's objectives.

Misleading the consumer: the Council has decided to included, in accordance with Parliamentary amendments, references to "misleading the consumer" in recital 7.

Environmental protection: the Council has modified the proposal so that prior to an authorisation being granted, scientific evaluators should take any environmental impacts into consideration when authorising flavourings.. Environmental protection is also listed as one of the Regulation's objectives.

Scope: the Council clarifies that smoke flavourings are not completely excluded from the scope of the proposed Regulation. The common position, therefore, opts for the complementary application of two Regulations namely: the proposed Regulation, in the absence of more specific rules set out in Regulation (EC) No 2065/2003 on smoke flavourings.

The common position specifies that the proposed Regulation will not apply to mixtures of herbs and/or spices, mixtures of tea and mixtures for infusions, on condition that they are not used as food ingredients. This is in line with a Parliamentary amendment on the matter.

Definitions: the Council has given particular attention to the accuracy of definitions and their consistency with other Community legislation. Thus, the term "flavourings not elsewhere specified" has the same meaning as the formulation proposed by the Commission namely "flavourings" not defined elsewhere. The Council favours the latter interpretations given that it is more consistent with Article 3.

Regulatory procedure with scrutiny: the proposal has been modified in order to apply the regulatory procedure with scrutiny when adopting measures that supplement the Regulation. The Council has also introduced the urgency procedure to allow the Commission to restrict, on grounds of emergency, the use of flavourings and food ingredients with flavouring properties for which an approval is not required. The urgency procedure will also allow for amendments to Annexes II and V.

Interpretation decisions: all provisions relating to interpretations have been regrouped into a new single article. Given that they do not supplement the Regulation they have been made subject to the regulatory comitology procedure without scrutiny.

Prohibiting the use of non compliant flavourings or food containing such flavourings: for reasons of clarity, legal certainty and the correct functioning of the internal market, the Council has inserted an article that prohibits producers from placing non-compliant food enzymes on the market. This is consistent with the proposals concerning enzymes and food additives.

Use of the term "natural" flavouring: in order to safeguard consumer interests, the Council agrees with Parliamentary proposals that the term "natural" should only be sued in reference to a food, food category or a vegetable or animal flavouring source, on condition that at least 95% by w/w has been obtained from the source material (as opposed to 90% proposed in the Commission's initial proposal). Further, the common position adds that the remaining 5% flavouring component, derived from other sources materials, should not reproduce the flavour of the source material referred to.

Authorising flavourings that fall within the scope of Regulation (EC) 1829/2003 on genetically modified food and feed: the Council agrees that two authorisation procedures can be carried out simultaneously. Some drafting changes to the text have been made in order to make these provisions compatible with Regulation (EC) No 1829/2003.

Labelling: the common position streamlines labelling provisions in a bid to harmonise them with provisions already laid down by Directive 2000/13/EC. A distinction is drawn between "business to business" labelling and the labelling of products intended for the final consumer. Although, the structure of the Chapter on Labelling is different to that proposed by Parliament, the underlying principles, nevertheless, remain the same.

Transitional measures for products already on the market: The Council has allowed for a two year transition phase, from the entry into force of the Regulation. Thus, food lawfully placed on the market or labelled during this two-year period may be marketed until their date of minimum durability or use-by-date.

Amendments not incorporated in the common position include, *inter alia*:

Precautionary principle: given that this principle already applies to general food law, the Council has decided there is no specific need to refer to it in the proposed Regulation. Further, and taking account of the risk analysis framework, the precautionary principle can only be taken into account within the context of risk management, never in the risk assessment phase, as suggested by Parliament.

Defining "appropriate physical process": the Council does not wish to confuse the traditional food preparation processes listed in Annex II with the "appropriate physical process".

Defining "flavouring substance": the Council indicates, in recital 14, which flavouring substances can be considered products. Defining this term would restrict the methods that may be used.

Decisions submitted to the regulatory comitology procedure: decisions on whether or not a given substance should fall within the scope of the Regulation are of an interpretive nature and as a result do not fall under the regulatory comitology procedure with scrutiny – in this case i) rules on implementing Annex IIIB and the common methodology for monitoring the consumption and use of flavourings – are of an interpretive nature and therefore do not supplement the Regulation. As a result they do not fall within the scope of the regulatory comitology procedure with scrutiny.

Labelling of GMOs: food additives remain subject to the labelling provisions as defined in Directive 2000/13/EC on the approximation of the laws relating to labelling, presentation and advertising foodstuffs, as well as Regulation (EC) No 1829/2003 on genetically modified food and feed. Any amendments that could potentially interfere with the scope of the horizontal Regulations in force have not been accepted by Council.

Conditions for use: the Council has decided not to include a reference to "benefiting the consumer" and "the technological need as a general condition for the use of flavouring" as suggested by Parliament given that the implementation of these provisions would not be possible.

Labelling: although the Council has reorganised the Chapter on Labelling, the principles underlying the provisions remain fundamentally the same. However, the Council is unable to accept proposals to label GMOs. This is due to the fact that it would not be consistent with related EU legislation on both labelling and GMOs.

Entry into force: Parliament's proposals to change the dates for the entry into force of certain provisions have been rejected by Council on the grounds that they can only apply after the Community list of authorised flavourings and source materials has become applicable. Further the date of application of the Community list can only be determined after it has been adopted through the comitology procedure with scrutiny and pending the outcome of an EFSA evaluation.

Presence of toxic substances: The Council attaches great importance to using a risk-based approach to the setting of maximum limits in the proposed Regulation. As a result certain Parliamentary suggestions on the presence of toxic substances go against the need to provide a high level of protection to human health. Further, the Council is of the view that a general exclusion, as suggested by on amendment, regarding 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 to consumers. On the grounds of proportionality, the Council concludes that the exclusion from maximum levels set in Annex III B is justified for the use of herbs and spices on condition that they are used in compound foods which are prepared and consumed on the same site and thus will not affect cross-border trade.

To conclude, the Council believes that the common position offers a balanced approach as well as incorporating many of Parliamentary suggestions.