



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.3.2008  
COM(2008) 142 final

2006/0147 (COD)

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT**

**pursuant to the second subparagraph of Article 251 (2) of the EC Treaty**

**concerning the**

**common position of the Council on the adoption of a Regulation of the European  
Parliament and 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**

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**1. BACKGROUND**

Date of transmission of the proposal to the EP and the Council (document COM(2006) 427 final – 2006/0147 COD):	28 July 2006.
Date of the opinion of the European Parliament, first reading:	10 July 2007
Date of transmission of the amended proposal:	24 October 2007
Date of political agreement by the Council	17 December 2007
Date of formal adoption of the common position by the Council	10 March 2008
Date of the opinion of the European Economic and Social Committee:	25 April 2007

**2. OBJECTIVE OF THE COMMISSION PROPOSAL**

The proposed Regulation aims at replacing the 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 rules for evaluation and authorisation;

- 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 for food and feed.

### **3. COMMENTS ON THE COMMON POSITION**

#### **3.1. General comment**

The Commission supports the common position as adopted by the Council at unanimity. It is in line with the objectives and the approach taken in the Commission's original proposal and reflects the principles of several amendments proposed by the European Parliament.

#### **3.2. Outcome of Parliament's amendments at first reading**

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

The common position reflects the spirit of 17 of the 21 amendments which were acceptable by the Commission in full, in part, in principle or subject to drafting changes. Most of these amendments bring further clarification to the text.

In relation to the criteria for the authorisation of flavourings, the common position clarifies what is meant by misleading the consumer (recital 6) which addresses some of the considerations of the EP amendment 1.

Amendment 29 concerns the labelling of natural flavourings. At least 95 % of the flavouring component must be obtained from the source referred to. This change corresponds better to consumer expectations and will have limited impact on current practices.

Amendments 12, 24, 34 and 35 introduce the regulatory procedure with scrutiny on measures to amend non-essential elements of the regulation by supplementing it. There is agreement between the European Parliament, the Council and the Commission on these amendments; however the Council and the Commission introduced the option for an urgency procedure.

##### **Amendments made by the European Parliament accepted by the Commission and not incorporated in the common position.**

4 amendments that were accepted by the Commission have not been incorporated into the Common position.

Amendments 27 and 28 concern further clarification of the labelling of flavourings falling within the scope of Regulation (EC) No 1829/2003.

Amendment 7 concerns rewording of Article 1 on the subject matter. In the amendment the Parliament proposes to place the high level of health protection before the effective functioning of the internal market, as otherwise this may give the impression that protection of human health is secondary to the functioning of the internal market.

Amendment 15 concerns the definition of an "appropriate physical process" for the production of natural flavouring substances or flavouring preparations. In the amendment the Parliament want to avoid that traditional preparation processes can be considered as physical processes that are not appropriate. Commission accepted this amendment, as it clarifies the situation and in case of doubt, a comitology decision can be adopted.

### **Points of diversion between the Commission's modified proposal and the Council common position.**

With exception of the Commission position on amendments 7, 15, 27 and 28 (see above), there are no divergences between the Commission and the Council.

### **3.3. Commission's position on new provisions introduced by the Council**

Several new provisions have been introduced by the Council. Most of them aim at further clarifying the text or are in line with the general objective of the original Commission proposal. The Commission can therefore accept these changes.

Recital 5a (new) clarifies the meaning of "raw foods" and "non-compound food" to which the proposed Regulation does not apply.

Recital 8a (new) justifies 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.

Article 1 clarifies 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 keeps also consistency with the proposed Regulation on food additives and food enzymes and relevant EP amendments on the proposal on food additives.

Art 3 (2) c, adds 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 avoid that some flavouring substances that are not present in materials of vegetable or animal origin, but that are obtained by artificial enzymatic processes, would be considered as natural.

In Art 3 (3) the Common Position completes the definition of source materials considered as food for the production of flavourings, as proposed by the Commission, by adding that the definition is valid only for the purpose of this Regulation.

Art 4a (new) clarifies 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.

Article 7 (2), Article 18 (4) and Article 19 introduce the option for an urgency procedure into the regulatory procedure with scrutiny.

For reasons of clarity the interpretation decisions have been moved from Articles 2 and 3 to a separate new Article 11.

Article 12, 13 and 15 (new), bring further clarification of labelling requirements and alignment with the proposals on food additives and food enzymes.

Article 14 (4) concerns the labelling of natural flavourings. 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.

Annex III Part B:

- For reasons of proportionality, it has been clarified in the title that the maximum levels shall not apply to compound foods which are prepared and consumed on the same site (restaurants), contain no added flavourings and contain only herbs and spices as food ingredients with flavouring properties.
- Maximum levels for coumarin have been introduced in certain food categories.
- The maximum level for teucrine A in alcoholic beverages has been increased 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 had concern 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.

### **3.4. Major problems encountered in adoption of the Common Position**

Directive 88/388/EEC lays down maximum levels for coumarin in foodstuffs. The Commission did not maintain maximum levels for coumarin in the proposed new Regulation, because in its opinion on coumarin of 6 October 2004, the European Food Safety Authority (EFSA) concluded that the intake of the substance was not of concern compared to the Tolerable Daily Intake. 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.

Furthermore, since the opinion of EFSA was adopted in October 2004, additional scientific information has been made available, that suggests that the TDI should be reviewed. The Commission asked therefore 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.

#### **4. CONCLUSIONS / GENERAL OBSERVATIONS ON THE COMMON POSITION**

The Commission takes the view that the common position fully reflects the key elements of its initial proposal and the spirit of many of the amendments of the European Parliament made in the first reading.

The Commission therefore supports the common position as adopted by the Council by unanimity.

#### **5. STATEMENT**

Following the discussion on coumarin (see 3.4) the following joint statement has been annexed to the Common Position:

*The Council and the Commission undertake to reconsider the maximum levels for coumarin set out in Annex III B as soon as the advice (expected in the first half of 2008) of the European Food Safety Authority becomes available.*

*To this end, the Council invites the Commission to convene a meeting of experts without delay after the advice of the Authority is issued in order to examine the technical aspects.*