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**STATEMENT OF THE COUNCIL'S REASONS**

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Subject : COMMON POSITION adopted on 10 March 2008 by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on food additives

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**STATEMENT OF THE COUNCIL'S REASONS**

## **I. INTRODUCTION**

On 28 July 2006, the Commission adopted the proposal for a Regulation on food additives<sup>1</sup>. The proposal is based on Article 95 of the Treaty establishing the European Community.

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

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

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

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

## **II. OBJECTIVE**

The proposed Regulation, as part of four proposals designed to overhaul the Community's rules on food improvement agents, would update and simplify the existing Community legislation with regard to food additives.

Through the proposed Regulation, a Community list of food additives and of food additives approved for use in food additives, food enzymes and food flavourings including their conditions of use, will be established. The proposed Regulation will also establish rules on the labelling of food additives.

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<sup>1</sup> 12181/06.

<sup>2</sup> 11640/07.

<sup>3</sup> 14419/07.

<sup>4</sup> EESC/2007/604, OJ C 168, 20.7.2007, p. 29.

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

### **III. ANALYSIS OF THE COMMON POSITION**

#### **1. Introductory remarks**

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

- "Misleading the consumer" (in line with amendments **3** and **26**).  
The Council included, in recital 7 and Article 6, elements integrating the notion of misleading the consumer.
- Protection of the environment (in line with amendments **1** and **7**).  
The Council considered that, apart from scientific evidence, the authorisation of the food additives should also take into account other relevant factors, such as the protection of the environment. The Council also included a reference to the protection of the environment among the objectives of the proposed Regulation.
- Protection of consumers with a food intolerance or allergy (in line with amendment **1**).  
The Council recognised that the use and maximum levels of food additives should take into account the exposure of special groups of consumers, e.g. consumers with allergies.

- Regulatory comitology procedure with scrutiny (in line with amendment **48, 51, 64/rev , 67/rev, 68/rev, 79 and 80**).

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

The Council decided, on grounds of efficiency, to use the regulatory procedure with scrutiny with curtailed time limits for the establishment of Community lists of additives and for transitional measures, until the establishment of Community lists, to amend Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC.

- Interpretation decisions.

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

- Provision prohibiting the placing on the market of non compliant food additives (in line with amendments **9 and 22**).

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

- Authorisation of additives falling within the scope of Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>5</sup> (in line with amendment **4**).

The Council agrees that the two authorisation procedures for any substance can be carried out simultaneously, although the final authorisation should be granted under the additives Regulation. The Council subjected that principle to some drafting changes in order to make the provision more compatible with Regulation (EC) No 1829/2003.

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<sup>5</sup> OJ L 268, 18. 10.2003, p.1.

- Transitional measures for products already on the market (in line with amendment **56**).  
The Council provided for a 1 year transition period from the date of entry into force of the regulation. Foods lawfully placed on the market or labelled during this year may be marketed until their date of minimum durability or use-by-date.
- Labelling.  
The Council streamlined the labelling provisions in order to duplicate the provisions already laid down by Directive 2000/13/EC, respecting the distinction between "business to business" labelling and labelling requirements for products intended for the sale to the final consumer. Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are in line with amendments **42** and **44**.
- Nanotechnology (in line with amendment **35**).  
Similar to the proposal of the European Parliament, the Council considered that a new evaluation of a food additive is necessary if a food additive is produced by production methods significantly different from those included in the previous risk assessment. Different conditions of use can be imposed in consequence of the new evaluation.

The Commission has accepted the common position agreed by the Council.

## **2. The amendments of the European Parliament**

In its Plenary vote, on 10 July 2007, the European Parliament adopted **59** amendments to the proposal.

In its common position, the Council, incorporated, in full or in principle, **33** amendments.

a) Amendments incorporated in the common position

In addition to amendments already mentioned in part 1. above, the common position incorporates other European Parliament's first reading amendments, either in full or in part, that are of a technical/editorial nature and aimed at improving the clarity of the text of the proposal (amendments **8, 13, 14, 18, 19, 21, 36, 37, 39, 46, 55, 57, 58, 59, 60**).

b) Amendments not introduced<sup>6</sup>

The Council was not able to accept all the amendments, for the following reasons:

– Precautionary principle (amendment **78** – recital 10).

The precautionary principle is one of the general principles underlying the general food law<sup>7</sup>. Consequently, it applies to the proposed regulation with no need for a specific reference to it. Moreover, in the risk analysis framework, the precautionary principle can only be taken into account in the context of risk management, never in the risk assessment phase, as suggested by the European Parliament.

– Food additives not to be used with other food additives (amendment **34** – article 10(2)).

Articles 1 and 10(2)(c) already stipulate that conditions of use of food additives have to be specified in the Community list, hence amendment 34 is superfluous.

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<sup>6</sup> Numbering of Articles in this part refers to the text of the common position

<sup>7</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4. 2006, p. 34).

- Re-evaluation programme to review authorisations (amendments **5, 54** – recital 14, Article 30(2a new)).

For the Council, a system of continuous observation and of re-evaluation whenever necessary in the light of changing conditions and of new scientific information, will guarantee food safety. An additional review would represent an unnecessary administrative burden for producers, users, EFSA, the Commission and the Member States.

- Review of existing authorisations (amendment **6, 52, 69rev** – recital 21, Article 30(1) and (2)).

The Council maintains that the additives already authorised shall be transferred into the list of authorised additives after review of the criteria other than safety. However, EFSA is tasked to undergo the re-evaluation of currently authorised food additives with respect to their safety. It is not appropriate to link these two reviews.

- Definition of food additives and scope of the proposed Regulation

- to include in the scope post-harvest plant protection products (amendment **10** – Article 2(b)):

Plant protection products used for post-harvest treatment are subject to Directive 91/414/EEC, which already provides that if a plant protection product falls under the definition of other Community law, the latter will be applicable.

- to exclude from the scope microbial cultures (amendment **11** – Article 2(da) new):

Some cultures are added to foods towards the end of their manufacture for an intended preservation effect and therefore could be considered to be food additives. For that reason, they should not be excluded from the scope of the proposed Regulation.

- Blood protein not to be considered as an additive (amendment **16** – Article 3(2)(a)(viii)): At present substances consisting of blood proteins are considered as falling under the scope of Community law on food additives. The Council considers that the exclusion of blood protein as an additive in article 3(2) is not appropriate.
  
- Decisions submitted to the regulatory comitology procedure (amendment **12, 40, 47** – Articles 2(5), 18(c) introduction, 25(2))  
Decisions on whether or not a given substance falls within the scope of the Regulation are of merely interpretative nature. Therefore, they do not fall within the scope of the regulatory comitology procedure with scrutiny.
  
- Definitions and exclusions (additional technological effect)(amendment **15** – Article 3(2)(a)(ii)).  
The Council considers that the addition of "an additional technological effect" in Article 3 (2)(a)(ii) is too broad and may exclude from the definition substances used as food additives.
  
- Food reduced in sugars (amendment **20, 29** – Articles 3(2)(i), 7(a)).  
The introduction of this concept into the Regulation would result in an increase in variety of products in which sweeteners may be used and may lead to the increased consumption of such additives, which would not benefit the consumers.
  
- Benefits to the consumer (amendment **24** – Article 6(1)(b)).  
Amendment 24 provides that one of the conditions for including a food additive into the Community list should be a reasonable technological need in terms of benefits to the consumer. However, Article 6(2) already stipulates that an additive needs to have benefits and advantages for the consumers in order to be included in the Community list. Amendment 24 is therefore not necessary.

- Explanation of the basis for the final decision (amendment **28** – Article 6(3a new)).  
The decision whether or not to include food additives in the Community list is taken through the regulatory procedure with scrutiny on the basis of the proposal from the Commission. These proposals include recitals explaining their background, thus amendment 28 is superfluous.
  
- Specific conditions for sweeteners (amendment **73** - Article 7(b)).  
The Council considered that the deletion of the sentence would be too restrictive.
  
- Additives potentially misleading the consumers (e.g. colors) (amendment **30** – Article 8(1a new)).  
The provision in Article 6 concerning general conditions for authorisation of food additives provide that an additive should not mislead the consumer. In addition the Council, in order to define the term “misleading the consumers” clarified this notion in recital 7.
  
- Specifications in the Community lists:
  - Identification of the additive group (amendment **33** – Article 10(2)(a)): Article 9 provides that a food additive will be allocated to a functional class. As an additive can fall into several functional classes, the Council could not support such an amendment requiring the identification of all the classes to which an additive can belong.
  - Specification of the substances to which additives can be added (amendment **33** – Article 10(2)(b)): The amendment is not necessary as enzymes, flavourings and additives are considered as food.

- Labelling of genetically modified organisms (GMO's) (amendment **38** and **63** – Article 12).

As mentioned in recital 16, food additives remain subject to the labelling provisions defined in Directive 2000/13 of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>8</sup> and in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>9</sup> (The labelling of food ingredients, including additives, produced from, containing and consisting of GMO's, is provided for in Articles 12 and 13 of Regulation (EC) No 1829/2003). The Council adopted a prudent approach, not accepting amendments that could interfere with the scope of the horizontal Regulations in force.

- Labelling (amendments **43** and **45** – Articles 21(4), 22(3a new)).

First of all, the Council considered that only certain information can be provided by the accompanying documents supplied with or prior to the delivery. Secondly, as there are already provisions on the labelling of allergens, which are listed in Annex IIIa of Directive 2000/13/EC, the Council considered that it is not appropriate to go beyond those provisions in this legislative act.

#### **IV. Conclusions**

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

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<sup>8</sup> OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p.11).

<sup>9</sup> OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p.34).