COMMISSION OF THE EUROPEAN COMMUNITIES

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2006/0143 (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 of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings

(presented by the Commission)

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1. BACKGROUND

Date of transmission of the proposal to the EP and the Council (document COM((2006)0423 final – 2006/0143(COD):	28 July 2006.
Date of the opinion of the European Economic and Social Committee:	25 April 2007.
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	17 December 2007.
Date of adoption of the common position:	10 March 2008.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

As part of the efforts undertaken to improve Community legislation on the basis of the "farm to table" concept, in the White Paper on Food Safety, the Commission announced its intention to update and complete existing legislation with regard to food additives and flavourings and to lay down specific provisions in respect of food enzymes.

This proposal aims to ensure the proper functioning of the internal market, while also ensuring a high level of protection of human health as regards food additives, food enzymes and food flavourings.

In order to do this, it aims to establish a common authorisation procedure that is centralised, effective, expedient and transparent and that is based on risk assessment carried out by the European Food Safety Authority (EFSA) and a risk management system in which the Commission takes action within the framework of a regulatory committee procedure (comitology). It assigns to the Commission, on the basis of the EFSA's scientific assessments, the task of creating, maintaining and updating a general Community list for each category of substances concerned. The inclusion of a substance on one of these lists means that its use is authorised in general for all operators in the Community.

3. COMMENTS ON THE COMMON POSITION

3.1. General comment

The Commission supports the common position as adopted by the Council on 10 March 2008. It is in line with the aims and the approach taken in the Commission's original proposal and reflects the principles of several amendments proposed by the European Parliament.

3.2. Amendments made by the European Parliament at first reading

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

With regard to the scope of the proposed Regulation on the common authorisation procedure, the common position (Article 1) clarifies that this does not apply to smoke flavourings falling within the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. This covers amendment 12 made by the European Parliament (EP) during its first reading.

In relation to confidentiality, the common position clarifies that all information related to the safety of a substance, including toxicological data, safety studies and raw data as such, should not be confidential (recital 16). This change includes the considerations of amendment 8 by the EP.

The common position (Article 6(3)) clarifies that the deadline for the EFSA opinion may be extended even when applicants submit additional information on their own initiative, but this should be limited to exceptional circumstances in accordance with Article 10. This change is coherent with EP amendment 25.

Articles 8, 10 and 12(3) in the common position have been modified to strengthen transparency and these changes cover EP amendments 27, 28 and 32.

Recitals 21, 22, 23 and 24 and Articles 7 and 14 in the common position have been modified in order to introduce the regulatory procedure with scrutiny and to align in general the proposed Regulation with Council Decision 2006/512/EC amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. These provisions are coherent with the EP amendments 34, 35, 36 and 37 on this subject, however the difference is that the common position includes the use of the curtailment of time periods in some cases. This aspect was not reflected in the Commission's amended proposal apart from the urgency procedure which was introduced for the cases of particular risk to human health.

Amendments not incorporated in the common position, which are nevertheless accepted by the Commission in the amended proposal as such or subject to rewording:

The EP clarified in amendment 1 that a high level of protection of the environment must also be ensured in the pursuit of Community policies. This principle is already included in the General Food Law (Regulation (EC) No 178/2002) and the amendment has been accepted in the Commission amended proposal.

EP amendments 3, 9, 10, 19, and 21 strengthen the transparency and information provisions, which were already underling principles of the Commission proposal; they have been therefore endorsed in the amended proposal.

EP amendment 22 increases the time for EFSA to give its opinion, from six to nine months. This has been accepted in the amended proposal.

Amendments 2 and 6 are mainly editorial and amendments 4 and 5 clarify respectively that the criteria set by each sectoral food law must be fulfilled for the authorisation of a substance and that the scientific assessment of a substance must be independent. These amendments have been taken over by the Commission in the amended proposal.

3.3. New provisions introduced by the Council

Contrary to the EP, the Council has retained the 9 months deadline for the Commission to present a draft measure to update the Community list, after the EFSA opinion has been issued. However, to clarify the need for this period of time, the Council has introduced in the common position the recital 9 which specifies that the nine months period is necessary, in some cases, for the Commission to ensure adequate consultation of stakeholders. This time of course could be shorter depending on the nature of the draft measure. Recital 10 of the common position clarifies further the deadlines of the procedure. These amendments are in line with the Commission proposal and can be accepted.

The common position (recital 12) clarifies further that the other legitimate factors to be considered during the risk management decision for the inclusion or not of a substance in the Community list, include societal, economic, traditional, ethical and environmental factors and the feasibility of controls. These factors are already mentioned in the General Food Law, therefore their reiteration in the proposed Regulation reinforces the initial proposal and it can be accepted by the Commission.

Several changes in Articles 2, 3, 6, and 9 are mainly editorial and clarify practical aspects of the authorisation procedure and the role of the different actors. Some changes in Articles 12 and 15 are of technical nature and add precision to the proposed Regulation. These changes are consistent with the spirit of the proposal and they can be accepted.

4. CONCLUSION

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 agrees with the common position as adopted by the Council by unanimity.