



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.3.2008
COM(2008) 144 final

2006/0144 (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 on food enzymes and amending Council
Directive 83/417/EEC,
Council Regulation (EC) No 1493/1999, Directive 2000/13/EC,
Council Directive 2001/112/EC and Regulation (EC) No 258/97**

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1. BACKGROUND

Date of transmission of the proposal to the EP and the Council (document COM((2006)0425 final – 2006/0144(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

The Commission announced in the White Paper on Food Safety a proposal amending the framework Directive 89/107/EEC on food additives to lay down specific provisions in respect of food enzymes. In-depth assessment of the situation has led to the development of a specific proposal for food enzymes.

Currently the scope of Directive 89/107/EEC only covers enzymes used as food additives. The remaining enzymes are not regulated at all or are regulated as processing aids under the legislation of the Member States, which is diverse. With respect to safety, there is neither safety evaluation nor authorisation of food enzymes at European level, except for those that are considered as food additives. The proposal aims to establish harmonised rules for food enzymes at Community level, in order to promote fair trading and effective functioning of the internal market and to ensure protection of human health and consumers' interest.

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:

Regarding the legal basis of the proposed Regulation, the Common position has deleted Article 37 of the Treaty and this is in line with amendment 35 made by the European Parliament (EP) during its first reading.

In relation to the criteria for the authorisation of food enzymes the common position clarifies what is meant by misleading the consumer (recital 6) which addresses some of the considerations of the EP amendments 4 and 16.

The common position has introduced a definition of 'food enzyme preparation' (Article 3) similarly to a request of the EP under amendment 14.

The new Article 5 of the common position has clarified that a food enzyme or a food in which an enzyme is used should not be placed on the market, if the enzyme or its use does not comply with the proposed Regulation. This clarification has been also requested by the EP in amendment 15.

Concerning the interplay between the proposed Regulation on food enzymes and Regulation (EC) No 1829/2003 on GM food and feed, the EP had clarified in amendments 7 and 34 that the evaluation and authorisation procedures under the two Regulations should run simultaneously. The principle of these amendments is reflected in the common position (recital 11 and Article 8).

Recitals 20 and 21 and Articles 15 and 17 of the common position were 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 10, 28 and 30.

As regards the labelling of food enzymes sold from business to business or directly to the final consumer, the EP adopted in first reading a number of amendments with a view to simplifying the labelling provisions. The common position incorporated a similar simplification. Despite the differences in structure and wording the labelling requirements for food enzymes are largely the same, with the exception of the provision of amendment 21 of the EP which requires information on the "side effects of their use in excessive quantities", which is not endorsed in the common position. The scope of the EP provision under amendment 21, that requires food enzymes to be added to foods only in a dose strictly necessary to achieve the purpose for which they are used, has been taken on board in the common position under Article 7(2), where the principle of the *quantum satis*, as defined in the proposed Regulation on food additives, has been introduced. The common position has also gone further in simplifying the labelling provisions for food enzymes sold directly to the final consumer, as these enzymes are considered food and hence covered by the labelling provisions of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs (Article 12). The Commission amended proposal took over the main ideas of the EP amendments and reflects the labelling provisions endorsed by the Council in the common position.

EP amendment 31 amends Regulation (EC) No 258/97 on novel foods in order to clarify that food enzymes which are covered by the proposed Regulation on food enzymes will be excluded from the scope of the novel food Regulation. This amendment is endorsed in Article 23 of the common position.

The additional transitional measures incorporated in Article 18 of the common position reflect totally the EP amendment 36.

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

EP amendments 2, 8 and 17 improve the proposal from a technical (e.g. introduction of definition of enzyme) and editorial point of view and are incorporated in the Commission amended proposal.

The EP clarified that the proposed Regulation does not apply to food enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids. This clarification is in line with the Commission proposal and it has therefore been endorsed in the amended proposal. The Council has not introduced similar clarification in the common position.

Regarding food enzymes which are already on the market, the EP proposed them to be transferred directly to the Community list ('fast track authorisation'), if the European Food Safety Authority (EFSA) is satisfied with the previous safety assessment carried out at Community or national level. The Commission considered that an automatic transfer of food enzymes into the Community list, without a previous evaluation by EFSA, is not appropriate. However, it is usual practice that when EFSA evaluates substances they consider any relevant scientific assessments undertaken by other bodies. The Commission has therefore introduced in the amended proposal wording to clarify that EFSA could consider existing opinions as part of their evaluation.

3.3. New provisions introduced by the Council

The common position (Article 2) excludes from the scope of the proposed Regulation, food enzymes used exclusively in the production of processing aids, while on the other hand it includes within the scope enzymes used in the production of novel foods and in the production of flavourings. The Council considered that the initial proposed exclusion of enzymes for flavourings is not justified because some flavourings, such as flavouring preparations from food sources, are not evaluated for their safety. The Commission raised concerns that such a measure would be disproportionate taking into account the small quantity of enzymes used in the production of flavourings which themselves are added in small amounts into the food. However, as most of the enzymes used in the production of flavourings seem to be the same as the enzymes used in other foods, this amendment would not have a major practical impact, considering the small number of enzymes concerned and can be accepted by the Commission.

The common position strengthened the requirement set already in the Commission proposal that enzymes produced from different production methods should be evaluated for their safety before they can be used. The common position strengthens the proposal by reiterating the text of a recital in an article (Article 14(2)). The amended Commission proposal has included a new Article to this effect.

The Council clarified in the common position the principle already included in the General Food Law (Regulation (EC) No 178/2002) that the rules on food enzymes will ensure the effective functioning of the internal market and a high level of protection of human health and protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of the environment. This change keeps also consistency with the proposed Regulation on food additives and relevant EP amendments on that proposal. The Commission can accept this change.

Concerning the interplay between the proposed Regulation on food enzymes and Regulation (EC) No 1830/2003 with regard to the unique identifier attributed to a GMO, the EP clarified the relevant provision of the proposal. The Commission has accepted this clarification in the amended proposal. The Council has deleted the provisions relevant to the unique identifier from recital 8 and Article 7(2) of the common position. This deletion is technically correct and it can be supported by the Commission.

The Council has also included in the common position a new Article 9 to provide, where necessary, for interpretation decisions under the regulatory procedure as to whether a given substance is a food enzyme or if a particular food belongs to a food category in the Community list.

Finally the common position modified further Directive 2000/13/EC to exclude from labelling in the final food of substances used in quantities strictly necessary as solvents or media for enzymes, as it is the case currently for additives and flavourings. This change is technically correct.

4. CONCLUSION

The Commission takes the view that the common position fully reflects the key elements of its initial proposal and of 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.