Food enzymes

2006/0144(COD) - 11/03/2008 - Commission communication on Council's position

The Commission supports the common position, adopted by the Council in March 2008 given that it is in line with the initial proposal. Further, the common position takes on board a number of amendments proposed by Parliament at first reading.

Amendments accepted by the Commission:

Legal base: The common position deletes Article 37 of the Treaty as the legal base for the proposal and thus is fully in line with an amendment made by Parliament during first reading.

Criteria for the authorisation of food enzymes: The common position clarifies what is meant by misleading the consumer and takes account of Parliamentary concerns.

Definitions: A definition on “food enzyme preparation” reflects that of a Parliamentary proposal. Further, the new Article 5 of the common position clarifies 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 was a clarification sought by the European Parliament.

Interplay with Regulation (EC) No 1829/2003 on GM food and feed: The common position has adopted Parliamentary amendments that the evaluation and authorisation procedures under the two Regulations should run simultaneously.

Regulatory procedure with scrutiny: The Council has agreed to use the “regulatory procedure with scrutiny” and to align, in general, the proposed Regulation with that of Council Decision 2006/512/EC laying down procedures for the exercise of implementing powers conferred on the Commission.

Labelling of food enzymes sold from business to business or directly to final consumer: The common position has adopted, albeit with slightly different wording, many of the amendments adopted by Parliament at first reading relating to the labelling of food enzymes. Two elements, however, have not been adopted by the Council. They concern, information on the “side effects of their use in excessive quantities” and a requirement that “food enzymes be added to foods only in a dose strictly necessary to achieve the purpose for which they are used.” In addition, the common position has gone further in simplifying the labelling provisions, given that these enzymes are considered to be food and hence covered by the labelling provisions of Directive 2000/13/EC.

Novel Foods: A Parliamentary amendment that seeks to amend the Novel Food Regulation, in order to clarify that food enzymes are excluded from the scope of that Regulation, has been endorsed by Council.

Transitional measures: An amendment on additional transition measures has been accepted, in full, and incorporated into the common position.

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

Definitions: Parliamentary amendments that improve, from a technical point of view the term “enzyme” have been incorporated in the Commission’s amended proposal.

Enzymes used for nutritional purposes or enzymes used as digestive aids: The Commission has decided to fully incorporate a Parliamentary amendment clarifying that the proposed Regulation will 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 fully in line with the Commission's initial proposal and has therefore been endorsed. The Council, however, has not introduced a similar clarification in its common position.

Fast track authorisation: On the matter of food enzymes which are already on the market, Parliament proposed to transfer them directly onto the Community list through a fast track authorisation procedure – on condition that the EFSA is satisfied with the previous safety assessment carried out at either Community or national level. The Commission is of the view that an automatic transfer of food enzymes on to the Community list (without a previous evaluation by the EFSA) would not be appropriate. In short, therefore, the Commission has decided to accept the amendment subject to some rewording clarifying that the EFSA should consider existing opinions as part of their evaluation.

New provisions introduced by Council:

Scope: In its common position, the Council decided to exclude food enzymes used exclusively in the production of processing aids, from the scope of the proposed Regulation. What it does include in the scope though are enzymes used in the production of novel foods and in the production of flavourings. The Commission is of the view, however, that most of the enzymes used in the production of flavourings seem to be the same as the enzymes used in other foods. As a result, the Parliamentary amendment would not have a major practical impact, considering the small number of enzymes involved.

Different production methods: The Commission has accepted a new requirement, set out in the common position, concerning enzymes produced from different production methods. The Commission agrees that they should be evaluated for their safety before they can be used.

Environment: The Council has clarified the principle that the rules on food enzymes should ensure the effective functioning of the internal market as well as offering a high level of protection to human health and the environment. The Commission has accepted this change.

Interplay of the proposed Regulation with 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 decided to accept this clarification. Similarly, the Commission has accepted a Council deletion on provisions relating to the unique identifier from recital 8 and Article 7(2).

Interpretation decisions: The common position includes a new Article 9 to provide, where necessary, for "interpretation decisions" under the regulatory procedure on matters concerning whether a given substance is a food enzyme or if a particular food belongs to a food category in the Community list.

To conclude, the Commission is of the view that the common position fully reflects the key elements of its initial proposal as well as adopting many of the amendments made by Parliament at first reading. The Commission therefore agrees with the common position, as adopted unanimously by the Council.