Food enzymes

2006/0144(COD) - 24/10/2007 - Modified legislative proposal

The Commission has amended its initial proposal to take account of Parliamentary amendments adopted under the first reading. To recall, Parliament adopted 33 amendments in total of which most were accepted by the Commission either in whole or in part, subject to some rewording. Seven were not adopted.

In summary, the Commission modified its proposals as follows:

Technical/ Editorial amendments: Amendments deemed to improve, from a technical and editorial point of view, the proposal have been adopted by the Commission. They include, in particular, an amendment concerning Regulation (EC) No 258/97 on novel foods which seeks 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.

Legal Basis: The Commission has agreed to delete Article 37 from the TEU as the legal basis of the proposed Rewgulation given that agricutlrual aspects of the proposal are a secondary objective only.

Scope: The Commission has accepted amendments (with some re-working regarding their positioning in the text) that clarify the proposal will not apply to food enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids. The principle of these amendments is in line with the Commission proposal. The Commission, however retains the exclusion of cultures that are "traditionally" use in the production of foods such as cheese, wine etc and which may incidentally produce enzymes. The deletion of the word "traditionally" would enlarge the scope to the exclusion and could result in cultures, which are added to food for the technological function of the enzyme that they produce (e.g. preservation) not being regulated.

Definitions: The new definitions (as proposed by Parliament) on "enzyme" and "food enzyme preparation" have been adopted with some editorial changes. However, the definition of "produced by GMOs" is considered unnecessary for the scope of the proposed Regulation which covers all food enzymes regardless of whether it falls into the scope of Regulation (EC) No 1829/2003. The Commission, as a result, has not incorporated the new definition into the amended proposal. Similarly, the Commission has not included the definition of "*quantium satis*" in the proposal given that it is a repetition of provisions set down in the proposal for "food additives".

Prohibition of non-compliant food enzymes: An amendment stating that a food enzyme or a "food in which an enzyme is used", should not be placed on the market in cases where they do not comply with the proposed Regulation, has been endorsed by the Commission.

General criteria for inclusion and use of food enzymes in the Community list. Amendments relating to misleading the consumer have been incorporated into the revised proposal. Amendments concerning: authorisation of food enzymes based on the precautionary principles and requiring food enzymes to bring a clear benefit to the consumer before they can be authorised, however, have not been adopted.

Proposals relationship with GM food and feed: The Commission endorses an amendment clarifying that two GMO procedures can run simultaneously and in accordance with good administrative practice.

Comitology: The Commission has agreed to modify its initial proposal so that the implementing powers will be in line with Decision 2006/512/EC – the new regulatory procedure with scrutiny. An amendment which would apply the new regulatory procedure with scrutiny to deciding whether or not a given

substance falls within the scope of the Regulation, however, has not. The normal regulatory procedure should apply in the later case.

10 Year review: An amendment requiring a ten year review has not been accepted by the Commission on the grounds that it would impose a significant administrative burden.

Fast track authorisation: An amendment whereby enzymes, which are already on the market, could be transferred direct to the Community list, if the EFSA is satisfied with the previous safety assessment carried out at Community or national level, has not been adopted. The Commission has, however, introduced new wording that clarifies the EFSA could consider existing opinions as part of their evaluation.

Labelling: The Commission has taken over the main ideas concerning the simplification of labelling provisions sold from business to business or to the final consumer. However, the provisions requiring information on the "side-effects of their use in excessive quantities" is deemed irrelevant and therefore has not been adopted. An amendment requiring that food enzymes should be added to foods only in a dose which is strictly necessary has been incorporated into the revised proposal on the grounds that it is in line with the *quantum satis* principle. A further amendment, which was not accepted by the Commission, refers to requiring the labelling of the technological function of the food enzyme sold directly to the final consumer.

Labelling of food enzymes in food: The Commission has decided not to accept two amendments concerning the labelling of food enzymes in food. Specifically they refer to i) introducing labelling of all food enzymes present in the final food, irrespective of the level of residues and whether they continue to function or not and ii) requiring information on all food enzymes used in the production process to be made available to consumers – if not on the label at least through other information channels. The Commission has decided not adopt these amendments given that they are not compatible with Directive 2000/13/EC.

Transitional measures: The Commission has endorsed an amendment that introduces transitional measures for food enzymes, food enzyme preparations and food containing food enzymes, which were put on the market or labelled before the date of application.

Changes to production process or starting materials of a food enzyme. **New Article 8**: The amended Commission proposal includes a new Article 8 introducing requirements for food enzymes already included in the Community list which are prepared by production methods or starting material significantly different form those included in the risk assessment of the Authority. This Article reflects the principle of the initial Commission proposal and is consistent with the proposal on food additives, where the same text has been introduced in order to address an amendment concerning "nano" substances.