Food enzymes

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In adopting the report drafted by Ms Avril **DOYLE** (EPP, IE), the Committee on the Environment, Public Health and Food Safety amended in first reading the proposal for 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, and Council Directive 2001/112/EC.

At present, there is a lack of harmonised rules at Community level controlling the use of enzymes in food processing. This creates not only barriers to trade and legal uncertainty, but also differing standards of health and consumer protection among the Member States.

Enzymes perform many useful functions such as improving texture, appearance and nutritional values. Currently, EU legislation only covers enzymes used as food additives under the scope of Directive 89/107 /EEC and just two enzymes, E 1103 Invertase and E1105 Lysozyme, are authorised under this Directive. In recent years, the use of food enzymes in food production has significantly increased, and improved technology has allowed the development of new and more complex enzymes. This raises issues about the potential risks to human health such as allergenicity, toxicity and residual microbiological activity. Enzymes are also being produced from genetically modified micro-organisms. There is therefore a clear need for uniform safety evaluation at European level to ensure effective protection for consumers.

The Committee welcomes the proposal from the Commission, and notes that both industry and consumer associations also welcome the prospect of harmonising legislation for food enzyme use in the EU. The main focus of its amendments has been on clarification and coherence, particularly in relation to the definitions of food enzymes and food enzyme preparations, labeling requirements for products not intended for sale to the final consumer and on food enzymes derived from genetically modified micro-organisms.

The main amendments are as follows:

- **legal base**: whereas the Commission’s proposal cited two legal bases Articles 37 and 95, the Committee does not agree that Article 37 is appropriate because the use of enzymes in the context of agricultural legislation is just a very minor aspect of the proposed regulation. However, because the proposal is aiming at a high level of consumer protection, which would be achieved by harmonising regulations of the Member States within the internal market. Article 153 should therefore be used as legal base, along with Article 95.

- **scope**: the Committee felt that it should be made clear that this Regulation should only cover enzymes that are added to food to perform a technological function and not enzymes intended for human consumption, such as enzymes used as digestive aids. This new point 1a in Article 4 ensures that all eligible food enzymes are covered by this Regulation.

- **definitions**: the Committee clarifies the meaning of enzyme as being any protein of vegetable, animal or microbial origin, capable of catalysing a specific biochemical reaction, without changing its own structure in the process; this definition should, for the purposes of this Regulation, also include "pro-enzymes", i.e. compounds that are inactive or nearly inactive precursors of enzymes and can be converted to active enzymes if subjected to a specific catalytic change; it then goes on to clarify the terms ‘food enzyme’, ‘food enzyme preparation’, ‘produced by GMOs’ as well as ‘quantum satis’. The Committee also agreed on new wording regarding misleading the consumer.

In its Opinion, the Committee on Industry, Research and Energy introduced an amendment to ensure that, if possible, the most accurate enzyme name, based on the International Union of Biochemistry (IUB)'s Nomenclature should be used. In cases of complex enzymes, the name should be based on the enzyme activity (active principle) that is exerting the functionality in the food processing. It also amended the title of Article 7 to read 'Inclusion in the Community list of food enzymes from genetically modified micro organisms' because it considers that the term "genetically modified enzymes" could lead to misunderstandings.

- **GMOs:** It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM-derived foods and food ingredients would be adopted. The requirement in this draft regulation for a GM-derived food enzyme to be authorised in accordance with Regulation 1829/2003 /EC before it may be assessed for inclusion in the Community list of the proposed food enzymes Regulation, in the Committee's view, appears to go against this approach, and may result in the enzyme having to undergo two separate authorisation procedures. While, in practice, the European Food Safety Authority (EFSA) may look at a GMO-derived enzyme in light of both pieces of legislation, in accordance with good administrative practice, the Committee considers it is better to make this clear from the outset.

- **consistency with other legislation**: MEPs have approved amendments bringing Regulation (EC) No 258 /1997 on novel foods and Regulation 1829/2003/EC on GM food and feed (the concept of "last living organism") in line with this proposal.

- **precautionary principle**: MEPs consider that the precautionary principle should be in the centre of the risk assessment of food enzymes and to this end amended Article 5.

- **simplification**: in simplifying business-to-business labelling by replacing Articles 8, 9, 10, 12 and 14 with one single article containing all the requirements for labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer, the Committee considers it has improved the logic of the text and made it easier to read and understand. MEPs want the labelling intended for professional users to give precise information regarding the nature and activity of the enzyme and consider it is important for food producers to know the durability of food enzymes in order to ensure food safety. The conditions under which specific enzymes sensitive to changes in temperature, humidity levels, etc. are transported can have an effect on the quality of the end product. Information on the effects of a potential overdose of enzymes can protect consumers against avoidable diseases.

As EFSA's resources are already limited and therefore should not be wasted in performing risk assessments of food enzymes which have already been appropriately evaluated within the EU, specifically in Denmark, France or the UK, where well-established national authorization procedures exist for food enzymes, the Committee on Industry, Research and Energy has inserted an amendment to the effect that EFSA should be allowed to decide on a "fast track" authorization procedure for such food enzymes.

- **comitology**: on several occasions, the Committee amended provisions of the draft regulation to align the text to the provisions of the new comitology decision (Decision 2006/512/EC) which lays down the procedures for the exercise of implementing powers conferred on the Commission.