Food enzymes

2006/0144(COD) - 28/07/2006 - Legislative proposal

PURPOSE: to authorise the use of food enzymes at Community level.

PROPOSED ACT: Regulation of the European Parliament and of the Council

CONTENT: this Commission proposal is being forwarded to the Parliament and the Council within the context of the White Paper on Food Safety and alongside three other related proposed Regulations. They are on:

- Establishing a common authorisation procedure for food additives, food enzymes and food flavourings. (for a summary refer to COD/2006/0143)

- Food additives; (for a summary refer to COD/2006/0145)

- Certain food ingredients with flavouring properties for use in and on food. (For a summary refer to COD/2006/0147).

Enzymes are currently authorised based on the principles established Directive 89/107/EEC and are classified as a "food additive". Only 2 of the estimated 200 enzymes on the market are classified this way. The remaining are either not regulated at all or are regulated as "processing aids" under national law. The present situation is such that, at a Community level, there is scant provision for the regulation of enzymes, whilst at a national level, the provisions that do exist vary considerably resulting in a fragmented market.

Although, historically speaking, enzymes are deemed non-toxic, the development of food enzymes in recent years has expanded considerably, resulting in complex and sophisticated processing techniques. Experts warn of potential hazards arising from their chemical make-up such as allergenicity, activity-related toxicity, residual microbiological activity and chemical toxicity.

The purpose of this proposal, therefore, is two-fold. Firstly, it is designed to create harmonised standards applicable across the internal market and secondly, to offer a high level of consumer protection. In order to achieve these objectives, the proposed Regulation sets the conditions for the use of food enzymes; for a positive list of Community approved enzymes; and labelling requirements.

The Regulation will apply to enzymes used for a *technological purpose* in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including enzymes used as *processing aids* . A distinction is made between enzymes used for a *technological purpose* and enzymes used as *processing aids* when it comes to labelling requirements, with the later group being exempt.

The Commission proposes that all food enzymes be evaluated for their safety, technological need and benefits. Safety evaluations will be carried out by the European Food Safety Authority (EFSA). As far as the labelling requirements are concerned it is proposed that food enzymes be classified as ingredients, along the same lines as additives are classified in Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs. In most cases, food enzymes will be used as processing aids (i. e. they will be present in food in the form of a residue, if at all) and hence have little or not effect on the finished product. Hence, this category of enzyme will not be subject to the food labelling requirements. Food enzymes used to exert a technological function in the final food (such as stabilisers) however, will have to label their specific name and function.

Producers of food enzymes will be obliged to inform the Commission of any new information which may affect the safety assessment of the food enzyme. Implementation will be based on the regulatory procedure. In order to allow manufacturers and producers of food enzymes time to adjust to the new legislation, the Commission is proposing an initial period of 24 months (following the date of application), during which applications can be submitted.

Lastly, the Community list will be established in a “single-step” procedure following an opinion on all products from the EFSA and within the 24 month submission period. Until the finalisation of the list food enzymes and products already on the market may be used in accordance with national rules. A transitional period is also foreseen for the labelling requirements.

The proposal will have some impact on the Community’s budget. In order to develop and update Community legislation on food enzymes, in a proportionate and effective way, studies and the collection of data will need to be undertaken. Support for such action is foreseen by Regulation 882/2004/EC on official feed and food controls and is within the amounts set aside for the 2007/2013 period.