

# Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

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In adopting the report drafted by Ms Asa **WESTLUND** (PES, SE), 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 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

The main amendments were as follows:

- **the legal base** : the committee proposes that Article 175 together with Article 95 of the EC Treaty should be used as the legal basis for the proposal for a regulation. Members are of the opinion that the aims of protecting human health and the environment and the establishment and functioning of the internal market are indissolubly linked with each other without one being secondary and indirect in respect of the other. They have concluded that the proposal evidently has both aims connected with the protection of human health, and aims designed to improve the functioning of the internal market. This view point also received the unanimous support of the Legal Affairs Committee;

- **comitology**: due to the fact that most modifications and updates of the Community list (products that are authorised to be placed on the Community market) have in the past been subject to controversial debates both in the European Parliament and in Council, and despite the fact that first reading agreements could often be achieved, Members introduced amendments to ensure that these decisions would not be left to the Commission and its comitology procedure;

- **transparency**: in the Committee's view, transparency is a crucial factor if consumers are to feel confident in the EU's way of managing food-related issues. For this reason, it introduced an amendment requiring the Commission to ensure the transparency of the authorisation procedure by making public all applications and making all relevant material in the matter available to the public. Producers applying for authorisation must always be informed directly on matters concerning their application.

The Commission, furthermore, should be able, without difficulty, to explain the considerations on which its decision is based. This would benefit consumers, industry and the Member States' authorities. The Commission should, therefore, always make public its proposals for decisions, justify its proposal and explain the considerations on which its decision is based. Decisions not to take decisions must also be made public. In addition, where the adopted regulation departs from the Commission's original proposal to the Committee on the Food Chain and Animal Health, the Commission would also be required to explain the background to the final decision;

- **European Food Safety Authority opinions**: Members consider that the requirement in the Commission's proposal that the EFSA should give its opinion within six months of receipt of a valid application is not reasonable given the resources at the EFSA's disposal and the quality standards required of its opinion. They therefore proposed that this period be extended to nine months;

- **information submitted by applicants to the EFSA** : Members also tightened up the provisions of Article 6 to ensure that there are no incentives for applicants to submit additional information once the deadline has expired;

- **regular reviews:** the Environment Committee has introduced an amendment to ensure that all authorisations for use of food additives, enzymes and flavourings are reviewed on a regular basis because it considers that it is important that the use of substances in food is consistent with the latest scientific research. Moreover, it is important for certain groups of consumers that substances which are not used are deleted from the list, along with uses which are no longer current;

- **scientific data and toxicological studies :** Committee members introduced new provisions in Article 12 to ensure that scientific data and other information provided by applicants may not be used for the benefit of a subsequent applicant for a period of 5 years from the date of authorization unless the subsequent applicant has agreed with the prior applicant that such data and information may be used and costs are shared accordingly where i) the scientific data and other information were designated as proprietary by the prior applicant at the time the prior application was made, ii) the prior applicant had exclusive rights of reference to the proprietary data at the time the prior application was made, iii) the food additive could not have been authorized without the submission of the proprietary data by the prior applicant;

- **scope:** Members introduced an amendment whereby this Regulation would not apply to products permitted under Regulation (EC) No 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods because they consider that they are already adequately and appropriately governed under that Regulation.-