

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

2006/0143(COD) - 10/07/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Asa WESTLUND (PES, SE), and made some amendments to the Commission's proposal:

- **scope:** an amendment was introduced whereby the Regulation would not apply to products permitted under Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods;
- **Community list:** the Community list will be **updated by the Commission in accordance with the regulatory procedure with scrutiny** provided for in Article 5a of Decision 1999/468/EC. Substances included on the Community list may be used by all food business operators subject to the conditions applicable to them, provided their use is not restricted under the terms of the legislation. When updating the Community list, the Commission must justify its draft regulation and explain the considerations on which it is based. Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the reasons for its decision;
- **transparency:** an application to update the Community list will be made available by the Commission to the European Parliament, to the Member States and to stakeholders. Where it initiates the procedure on its own initiative, the Commission shall inform the Member States and make public the fact. The opinion shall also be made public, subject to certain provisos;
- **time limits:** the Authority shall give its opinion within nine months (rather than six) of receipt of a valid application. Within six months of the Authority giving its opinion, the Commission shall submit a draft regulation updating the Community list. The regulation will be adopted in accordance with the regulatory procedure with scrutiny. Where the Commission asks for further information, it may extend the time limit, and must inform the Member States of the extension;
- **scientific data and toxicological studies :** new provisions in Article 12 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 authorisation 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.