

Food safety: smoke flavourings used on foods, authorisation procedure (Directive 88/388/EEC, Regulation (EC) No 178/2002)

2002/0163(COD) - 10/11/2003 - Final act

PURPOSE : to harmonise national rules on the authorisation and use of smoke flavourings.

LEGISLATIVE ACT : Regulation 2065/2003/EC of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods. **CONTENT** : the Council adopted by a qualified majority - the United-Kingdom delegation abstained - a Regulation on smoke flavourings used or intended for use in or on foods. The European Parliament adopted amendments corresponding to the changes proposed by the Council. They include the deletion of the Annex to the Regulation regarding the traditional smoking methods and natural reserves of woods for the production of smoke and provisions on public access to documents regarding the European Food Safety Authority (EFSA). In order to ensure a high level of protection of human health and protection of consumers' interests and to ensure fair trading practices, this Regulation establishes a safety assessment and authorisation procedure for primary smoke condensates and primary tar fractions which can be used as such in and on foods and/or for the production of derived smoke flavourings. The primary products for which no health concern is expressed during evaluation and their conditions of use will be included in a positive list of products authorised to the exclusion of all others in the Community. Authorisations shall be restricted to a period of 10 years after which they will have to be renewed. This provision ensures that products are regularly re-assessed in the light of the latest scientific and technical knowledge and that authorised products that are no longer used are removed from the Community positive list. Anyone applying for authorisation of a primary product, must provide detailed information on production methods and on the further steps to be taken in the production of derived smoke flavourings, the intended uses in or on specific food or food categories, chemical specifications, toxicological studies and recognised methods for sampling and detecting primary products and derived smoke flavourings. The evaluation will be carried out by the European Food Safety Authority according to a specific time-limit and on the basis of transparent procedures. The regulation stipulates that the Authority must inform the Commission and the Member States of the receipt of an application and provide a summary or the full dossier. If requested by the applicant, sensitive data must remain confidential. The United Kingdom delegation issued a statement expressing its concerns about the legal basis for the Regulation - qualified majority based on the approximation of laws (Article 95) rather than unanimity (Article 308) - concerning the authorisation procedure. **ENTRY INTO FORCE** : 16/12/2003. Article 4 (2) shall apply from 16 June 2005. Until this date, national provisions in force concerning smoke flavourings and their use in and on foods continue to apply in the Member States.