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

2002/0163(COD) - 15/07/2002 - Legislative proposal

PURPOSE: to establish Community procedures for the safety assessment and the authorisation of smoke flavourings intended for use in or on foods in order to ensure a high level of protection of human health and protection of consumers' interest, as well as to ensure fair trade practices. CONTENT: the current situation in the Member States concerning the authorisation of smoke flavourings is diverse. Some Member States have a very strict authorisation procedure, others have none at all. Thus, there is a need for harmonisation at Community level. The objective of the present proposal is to establish Community procedures for the safety assessment and the authorisation of smoke flavourings intended for use in or on foods in order to ensure a high level of protection of human health and protection of consumers' interests, as well as to ensure fair trade practices. The present draft proposes to establish 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 revealed 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. It is proposed to restrict the authorisations to a period of 10 years after which the authorisations will need to be renewed. This provision ensures that products are regularly reevaluated according to the latest scientific and technical knowledge and ensures also that authorised products which are no longer used will disappear from the Community positive list. For an application for authorisation of a primary product, detailed information on the production method of this product as well as on the further steps in the production of derived smoke flavourings, the intended uses in or on specific food or food categories, chemical specifications, toxicological studies and validated methods for sampling and detection of the primary product and derived smoke flavourings have to be provided by the applicant. The evaluation will be done by the European Food Safety Authority according to a defined time limited and transparent procedure. The Authority has to inform the Commission and the Member States about the receipt of an application and has to provide a summary thereof or the whole dossier. Confidentiality for sensitive data is provided if requested by the applicant. After the European Food Safety Authority has completed its scientific evaluation, the Commission will propose a risk management decision to be adopted by the regulatory procedure laid down by Council Decision 1999/468/EC. Since many smoke flavourings are already on the market in the Community, the transition to a Community positive list should be smooth and should not lead to unfair conditions for smoke flavouring producers. Therefore, the proposal foresees an initial period of 18 months during which applications for existing and new products can be submitted to the European Food Safety Authority. The establishment of the Community list will take place in a single step procedure after the European Food Safety Authority has expressed opinions on all products for which applications have been submitted during the 18-month period.