Novel foods

2008/0002(COD) - 14/01/2008 - Legislative proposal

PURPOSE: to establish harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of human health and consumers? protection, whilst ensuring the effective functioning of the internal market.

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

BACKGROUND: the authorisation and use of novel foods and food ingredients is harmonised in the European Union since 1997 when Regulation (EC) No 258/97 on novel foods and novel food ingredients was adopted. The current legislation consists of the novel food Regulation and one Commission Regulation.

As part of the framework to improve and bring coherence to Community legislation from "farm to table", the Commission announced in the White Paper on Food Safety its intentions to examine the application of the novel food legislation and to make the necessary adaptations to the existing legislation in the light of the conclusions of the report on the implementation of the Regulation (EC) No 258/97 and in accordance with the regulatory framework of Directive 90/220/EEC on GMOs. This was partly done by adopting the Regulation (EC) No 1829/2003 on GM food and feed. The novel food Regulation now needs to be clarified after removal of GM food from the scope.

CONTENT: the current proposal aims to:

- streamline the authorisation procedure, develop a safety assessment system that is better adjusted for traditional food from third countries, which is considered as novel food under the current Regulation;
- clarify the definition of novel food, including new technologies with an impact on food, and the scope of the novel food Regulation;
- improve the efficiency, transparency and application of the authorisation system, which also contributes to better implementation of the Regulation, and empower consumers by informing them about food;
- ensure legal clarity by making necessary changes and updating the legislation.

The main elements of the proposed Regulation are as follows:

- novel foods shall be subject to safety evaluation and approval via Community procedure. The definitions are clarified and updated following legal developments. A procedure to collect information on the novelty of a food may be laid down. It may be determined with the comitology procedure if a food falls within the scope of the Regulation;
- all novel foods and their use in food shall be evaluated for the following criteria: they should not present a danger to or mislead the consumer nor, in the case of replacement, present nutritional disadvantages for the consumer;
- all applications for the approval of novel food shall be submitted to the Commission and then directed to the European Food Safety Authority (EFSA) which will carry out the safety evaluations;
- the final decision to include a novel food in the Community list of novel foods shall be made by the Commission in accordance with the comitology procedure. The applicant-linked authorisation shall be replaced and the simplified procedure abolished by authorisation decisions addressed to the Community as a general rule. Protection of data could be granted in justified cases concerning newly developed scientific evidence and/or proprietary data in order to support innovation in the agri-food industry. The Decision on inclusion shall include, where appropriate, specific additional labelling for novel foods sold to the consumer;
- for traditional food from third countries, a safety assessment and management based on the history of safe food use in the country of origin shall be introduced. If a history of safe food use in the country of origin has been demonstrated, and the Member States and EFSA do not present reasoned safety objections, based on scientific evidence, the food could be placed on the market on basis of a notification of the food business operator intending to market the food;
- for every authorised novel food a specification, labelling, conditions of use and, where appropriate, a requirement of post-market monitoring may be laid down;
- to ensure that novel foods once authorised are kept under continuous observation and re-evaluated wherever necessary, producers of novel foods will be obliged to inform the Commission of any new information which may affect the safety assessment of the novel food;
- the Member States shall lay down rules on penalties applicable to infringements of the provisions of the proposed Regulation;
- already authorised novel foods shall continue to be marketed and included in the Community list of novel foods;
- the Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings (see COD/2006/0143) must be amended to include novel foods in the scope of the Regulation and to enable the applicant to present one single application for foods regulated under different sectoral food laws.