Novel foods

2008/0002(COD) - 15/03/2010 - Council position

The Council position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced several changes in the text, some of them inspired by the

amendments proposed by the European Parliament. In its plenary vote on 25 March 2009, the European Parliament adopted 76 amendments to the proposal. The Council incorporated in its common position 30 amendments, of which 20 in full, 5 in part and 5 in principle.

The main modifications introduced by the Council in the proposal, with reference to European Parliament?s amendments are as follows:

Objectives of the Regulation: the Council added the protection of the environment and animal welfare.

Scope: the Council clarified that, pending the respective amendments to Regulation (EC) 1925/2006, Directive 2002/46/EC and Directive 89/398/EEC, those vitamins and minerals obtained from new sources or using a production process, which were not taken into account at the moment of their authorisation and which give rise to significant changes in the composition or structure of food which affect its nutritional value, metabolism or level of undesirable substances should be within the scope of the novel food Regulation.

Definition of novel foods: the basic criterion for assessing the novelty of the food remains whether it has been used for human consumption to a significant degree within the Union before 15 May 1997. In order to provide legal clarity, the Council agreed that further criteria for assessing human consumption to a significant degree within the Union before 15 May 1997 must be developed before the date of application of the Regulation. The adoption of these criteria has been delegated to the Commission according to Article 290 TFEU.

In order to ensure better clarity, the following changes of definition have been made: a distinction has been made between food of animal and food of plant origin; addition of the definition of "offspring" and "engineered nanomaterial"; the definition of the "traditional food from a third country" has been specified. The Council also agreed that the Commission may, through the regulatory comitology procedure, adopt further criteria to clarify definitions.

Food produced from animals obtained by non-traditional breeding techniques and their offspring: the Council agreed that foods produced from animals obtained by non-traditional breeding techniques (e.g. cloning) and their offspring shall fall within the scope of the Regulation. The Commission shall forward, within one year from the date of entry into force of this Regulation, to the European Parliament and the Council a report on all aspect of food production from cloned animals and their offspring, followed, if appropriate, by a legislative proposal. The Council considered that it was necessary to keep food produced from cloned animals within the scope of the proposed Regulation until any specific legislation has been proposed by the Commission and adopted.

Nanomaterials: the Council recognized the need for systematic safety evaluation and authorisation of foods containing or consisting of engineered nanomaterials irrespective of any changes that the nanomaterials might cause in the properties of such foods. Therefore, the Council made clear that such foods are considered to be novel and added the definition of "engineered nanomaterial". A Recital highlights the need for an internationally agreed definition of nanomaterial. The Council followed the thrust of the amendments on the necessity to have appropriate risk assessment methods for engineered nanomaterials.

Determination of the status of food: the Council agreed that the determination of the status of food to be placed on the Union market with respect to the definition of novel food would be a responsibility of food business operators, who must consult their national authority in case of doubt.

Authorisation of novel foods:the Council agreed that the authorisation of novel foods should be carried out according to the Regulation (EC) No 1331/2008, unless there is provision for a specific derogation in the present Regulation. The Council clarified that ethical, environmental, animal welfare factors and the precautionary principle should be taken into account in authorisation of novel foods. These factors should be considered on a case-by-case basis according to the content of the application.

Authorisation of traditional foods from third countries: the Council did not accept the "notification procedure" as proposed by the Commission. In order to ensure food safety, any authorisation should be based on the EFSA opinion and subsequent authorisation adopted by the Commission through the regulatory comitology procedure. The EFSA evaluation should primarily focus on the evidence of safe food use and the information on the composition of traditional food. In order to speed up the procedure, shorter deadlines should apply - 6 months for EFSA opinion and 3 months for the draft measure submitted by the Commission to SCFCAH. A separate list of authorised traditional foods from third countries would be established.

Technical guidance: the Commission must before the date of application of the Regulation (i.e. 2 years after its entry into force) make available technical guidance and tools to interested parties, in particular food business operators and SMEs.

European Group on Ethics in Science and new Technologies ? EGE: an additional provision was added on the possibility for the Commission to consult the EGE, on its initiative or at the request of a Member State, on ethical issues concerning the novel foods.

Data protection: in order to promote innovation in industry, the need for the protection of new scientific evidence and/or proprietary scientific data for the period of 5 years was accepted by the Council. Such protected data cannot be used for the benefit of another application without the agreement of the prior applicant and the authorisation is limited to the prior applicant during the period of 5 years unless a subsequent applicant obtains authorisation without reference to that proprietary data.

Information to the public: summaries of applications, findings of any consultations for determination of the status of food and lists of authorised novel foods must be made available to the public, in the latter case on the single dedicated web page.

Adaptation to the Lisbon Treaty: given the entry into force of the Treaty on the Functioning of the European Union on the 1 December 2009, the Council had to adapt the regulatory procedure with scrutiny related provisions of the Commission's proposal to the TFEU. The Council agreed that the following provisions should confer implementing powers on the Commission (Article 291(2) TFEU) for example: criteria could

be adopted to clarify definitions; the update of the list of traditional foods from third countries; the update of the Union list in case of data protection before the expiry of the 5 years period for data protection; the update of the Union list of novel foods.

The Council did not accept 46 amendments. These amendments concern inter alia the following issues:

- measures aiming to avoid testing on vertebrate animals and sharing of testing results (which do not fall under the scope of this Regulation);
- exclusion of food obtained from cloned animals and their offspring from the scope of the Regulation;
- systematic specific labelling of ingredients in the form of nanomaterials;
- additional criteria for risk assessment by EFSA;
- additional conditions for authorisation of novel foods (risk management);
- precautionary principle (already laid down in Regulation (EC) No 178/2002 is still applicable);
- additional specifications for the entry of novel food in the Union list;
- post-marketing monitoring;
- labelling of novel food.