Novel foods

2008/0002(COD) - 04/05/2010

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading as set out in the report drafted by Kartika Tamara LIOTARD (GUE/NGL, NL) on the Council position at first reading for adopting a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

The committee reinstates almost all of the amendments adopted in the first reading. It recommends that the European Parliament adopts its position at second reading under the ordinary legislative procedure (formerly known as the codecision procedure) which amends the Council's first reading position as follows:

Purpose: this Regulation lays down harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of protection of human life and health, animal health and welfare, the environment and the interests of consumers whilst ensuring transparency and the effective functioning of the internal market and stimulating innovation within the agri-food industry.

Scope: Members intend to **exclude foods derived from cloned animals and their offspring** from the scope of this Regulation. Before the date of application of this Regulation, the Commission should put forward a corresponding legislative proposal on foods derived from cloned animals and their descendants. This proposal shall be presented to the European Parliament and the Council.

This Regulation shall apply to food additives, food enzymes, flavourings and certain food ingredients with flavouring properties to which is applied a new production process not used before 15 May 1997, which give rise to significant changes in the composition or structure of the food such as engineered nanomaterials. Where a novel food can have an effect on the human body comparable to that of a medicinal product, the Commission shall seek an opinion of the European Medicines Agency (EMEA) whether it falls under Regulation (EC) No 726/2004.

Definitions: Members have introduced the definition of "cloned animals", "offspring of cloned animals" and "engineered nanomaterial". In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt these definitions to technical and scientific progress and with definitions subsequently agreed at international level.

Collection of information regarding the classification of a novel food: the Commission shall collect information from the Member States and/or from food business operators or any other interested party to determine whether a food falls within the scope of this Regulation. Member States, business operators and other interested parties shall transmit to the Commission information on the extent a food was used for human consumption within the Union before 15 May 1997. The Commission shall publish those data and the conclusions drawn from the data collection and the non-confidential data supporting it.

Union list of novel foods: only novel foods included in the Union list of novel foods ("the Union list") may be placed on the market. The Commission shall keep and publish the Union list on a publicly accessible page intended for that purpose on the website of the Commission.

Prohibition of non-compliant novel foods: a new provision stipulates that novel foods shall not be placed on the market if their use does not comply with the provisions of this Regulation.

Conditions for the entry of novel foods in the Community list: Members have included a broader set of conditions to prevent that unexpected drawbacks appear from the use of a novel food:

- the novel food may not be included in the list if it does not, on the basis of the scientific evidence available, and after application of the precautionary principle, pose a safety concern to the health of the consumer and of **animals**;
- a novel food that may have any adverse effects on **particular groups of the population** will be authorised only where specific measures preventing such adverse effects have been implemented;
- **ethnical and environmental aspects** must be considered as part of the risk assessment during the authorisation procedure. These aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively;
- **foods produced with the aid of nanotechnology** may not be included in the Community list until such specific methods have been approved for use, and an adequate safety assessment on the basis of these methods has shown that the use of the respective foods is safe.

A novel food may be included in the Community list only if the competent authority has submitted an opinion establishing that the food is not harmful to health. In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the **precautionary principle** shall be applied and the food in question shall not be included in the Community list.

Information: the entry of a novel food in the Community list shall include: a specification of the food; the intended use of the food; the conditions of use; the date of entry of the novel food in the Community list and the date of receipt of the application; the name and address of the applicant; the date and results of the last inspection.

Monitoring: in order to be informed about adverse effects from the use of a novel food, the Commission shall impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. This monitoring shall take place five years after the date of inclusion of a novel food in the Community list and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention should be paid to the categories of the population with the highest dietary intakes.

In case a novel food is a substance with a risk linked with consuming too much of it, it should get approval for use with maximum level in certain foods or food categories in order to prevent the risk of over-dosing.

Labelling: all specific data on novel foods shall be indicated and labelled to ensure proper consumer information:

- all new foods placed on the market shall be sold with **clearly distinctive, precise and easily legible labelling** indicating that they are novel foods;
- all the **characteristics or properties** of novel foods such as their composition, nutritional value and proper use, should appear clearly, precisely and in an easily legible and comprehensible manner on their packaging;
- were a novel food contains a substance which may pose a high risk to human health in the event of **excessive consumption**, the consumer must be informed of this by means of clear, precise and easily legible labelling on the packaging of the food;
- all ingredients present in the form of **nanomaterials** shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets;
- products produced from animals fed with **genetically modified feeding stuffs** must be labelled with the words “produced from animals fed with genetically modified feeding stuffs”.

Traditional food from a third country: a food business operator intending to place a traditional food from a third country on the market in the Union shall notify this to the Commission, indicating the name of the food, its composition and country of origin. The notification shall be accompanied by documented data demonstrating the history of safe food use in any third country.

Obligations on the food business operators: the Commission shall impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. This monitoring shall take place five years after the date of inclusion of a novel food in the Community list and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention should be paid to the categories of the population with the highest dietary intakes. All food business operators shall notify the Commission and the competent authorities of the Member State in which they operate of any health problem of which they have been informed by consumers or consumer protection organisations.

European Group on Ethics and new technologies: where appropriate, on ethical questions relating to science and new technologies of major ethical importance, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies, with a view to obtaining its opinion on ethical issues. The Commission shall make this opinion available to the public.

Data protection: data from research projects partly or completely paid by the EC and/or public institutions and risk studies or data related to risk studies, like feeding studies should be published together with the application and shall be freely available for use by other applicants. In order to avoid the repetition of studies involving vertebrates, reference by a subsequent applicant to studies on vertebrates and other studies that may prevent animal testing shall be allowed. The owner of the data may claim adequate compensation for the use of the data

Harmonised data protection: where an applicant intends a novel food to carry a health claim authorised in accordance with Regulation (EC) No 1924/2006, and where the novel food and health claim applications are introduced at the same time and both include a request for the protection of proprietary data, at the request of the applicant the periods of data protection should start together and run concurrently.

Inspection and control measures: in order to enforce compliance with this Regulation, official controls are to be carried out in accordance with Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Penalties: in view of increasing legal certainty, Members set a clear deadline for notification (12 months) by which the Member States must announce rules for imposing sanctions for infringement of this regulation.

Privileges of Member States: a new article states that where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.

Review: no later than three years and six months after the date of application of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation. It shall forward to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a cloning technique and from their offspring followed, where appropriate, by any legislative proposals.