Novel foods

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The Committee on the Environment, Public Health and Food Safety adopted the report drawn up by Kartika Tamara LIOTARD (GUE/NGL, NL) amending, under the first reading of the codecision procedure, the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No xxx/xxxx [common procedure].

The main amendments adopted by the committee are as follows:

Purpose: the report states that the regulation aims to ensure a high level of food safety, consumer protection, environmental protection and protection of animal health while providing high transparency for stakeholders and consumers and supporting innovation in the food industry in order to ensure the smooth operation of the internal market.

Definitions: MEPs have clarified the existing definitions and where necessary supplemented them with new ones. For example, a definition of foods derived from cloned animals and foods produced using nanotechnology.

Scope: MEPs intend to exclude foods derived from cloned animals and their offspring from the scope of this Regulation. They should be dealt with in a specific regulation, adopted under the codecision procedure, and not be subject to the common procedure. Pending the entry into force of this Regulation, the Commission should put forward a corresponding legislative proposal. Pending the entry into force of a regulation on cloned animals, a moratorium should be imposed on the placing on the market of foods manufactured from cloned animals and their offspring.

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. It shall publish these data and the conclusions drawn from the data collection and the non-confidential data supporting it. It shall keep and publish the Community 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: MEPs 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. These methods must not entail the use of vertebrate animals.

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. It is important to require this information from all novel foods, including those imported from a third country.

Monitoring: in order to be informed about adverse effects from the use of a novel food, monitoring shall take place after five years and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Where a novel food contains a substance which may pose a risk to human health in the event of excessive consumption, it shall require approval for use within maximum limits in certain foods or food categories.

Labelling: like any other foodstuff placed on the European market, a novel food must be labelled in accordance with the provisions of Directive No 2000/13/EC, currently under review, but also in accordance with the specific provisions of this article, taking account of the specific qualities of novel foods and novel food ingredients:

- 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;
- where 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;
- products produced with the aid of nanotechnologies and food produced from animals fed with genetically modified feeding stuffs must be labelled as such.

Traditional food from a third country: according to the MEPs, when assessing the safety of novel foods, the authority should also consider such aspects as the composition, allergenicity and toxicity of novel foods.

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. Moreover, MEPs also add that the owner of a test or study cannot prevent it being used by another person where this would avoid animal testing.

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, MEPs 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 has been inserted stating 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: not later than 31 December 2013 (instead of 1 January 2015 as proposed by the Commission) 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.