Novel foods

2013/0435(COD) - 28/10/2015 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 359 votes to 202 with 127 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on novel foods.

Parliaments position adopted in first reading following the ordinary legislative procedure amends the Commission proposal as follows:

Purpose and scope: Parliament specified that the purpose of the Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

In order to adapt the Regulation to scientific and technological developments that have occurred since 1997, Parliament adopted amendments to review, clarify and update the categories of food which constitute novel foods. These categories should include:

- food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
- food consisting of, isolated from or produced from microorganisms, fungi or algae;
- food consisting of, isolated from or produced from material of mineral origin;
- food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
- food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
- food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
- food containing engineered nanomaterials as defined in the Regulation.

In order to determine whether or not a food falls within the scope of the Regulation, Member States may consult the other Member States and the Commission.

The Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts, whether or not a particular food falls within the definition of novel food.

Union list: only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

Parliament specified that the Commission shall only authorise and include a novel food in the Union list if the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value.

Updating of the Union list may consist of, inter alia, adding, removing or changing the specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a novel food in the Union list.

With regard to the placing on the market within the Union of a traditional food from a third country, the entry in the Union list shall specify that it concerns a traditional food from a third country.

Authorisation procedure: the Commission and the Authority must respect certain time limits in order to ensure the harmonious treatment of applications for authorisation. However, in certain cases, the Commission and the Authority may extend the time limits.

The Commission shall make the application available to the Member States without delay and make the summary of the application publicly available.

The application for an authorisation shall include the name and address of the applicant; the description of the production process; the detailed composition of the novel food; and where appropriate, the analysis method(s).

Upon request by the Commission, the European Food Safety Authority shall give its opinion as to whether the update is liable to have an effect on human health.

When test methods are applied to engineered nanomaterials, the applicants shall provide an explanation of their scientific appropriateness for nanomaterials

Opinion of the Authority: where the Commission requests an opinion from the Authority, it shall forward the valid application to the Authority without delay, and not later than one month after having verified its validity. The Authority shall adopt its opinion within nine months from the date of receipt of a valid application.

Within seven months from the date of publication of the Authority's opinion, the Commission shall submit a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list

Authorisation procedure in case of a parallel application for the authorisation of a health claim: the amended text states that on request by the applicant, the Commission shall stay an authorisation procedure for a novel food started following an application, where the applicant has submitted: (i) a request for data protection; and (ii) an application for the authorisation of a health claim on the same novel food in accordance with Regulation (EC) No 1924/2006, in conjunction with a request for data protection.

The Commission shall inform the applicant about the date of effect of the stay. The authorisation procedure shall resume when the Commission has received the opinion of the Authority on the health claim. The Commission shall inform the applicant about the date of resumption of the authorisation procedure.

Cloned animals: until specific legislation on food from animal clones enters into force, food from animal clones should fall under the scope of this Regulation as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with the Union legislation in force.