Novel foods

2013/0435(COD) - 25/11/2015 - Final act

PURPOSE: to lay down rules for the placing of novel foods on the market within the Union while providing a high level of protection of human health.

LEGISLATIVE ACT: Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

CONTENT: this Regulation lays down **rules for the placing of novel foods on the market** within the Union. The purpose of this Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

Scope: ‘novel food’ shall mean any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union. However, on the basis of scientific and technological developments that have occurred since 1997, the Regulation **reviews, clarifies and updates the categories of food which constitute novel foods**.

The following are considered as **novel foods** under this Regulation:

- food with a new or intentionally **modified molecular structure**;
- food consisting of, isolated from or produced from microorganisms, fungi or algae or from material of mineral origin, **cell culture or tissue culture** derived from animals;
- 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 **engineered nanomaterials**;
- **vitamins, minerals** and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
- food used exclusively in **food supplements** within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements.

Animal clones: 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.

Procedure for determination of novel food status: in order to determine whether or not a food falls within the scope of this 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.

Placing novel food on the market: only novel foods authorised and included in the **Union list,** established by the Commission, may be placed on the market within the Union. The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

- the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;

- 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;
- where the food is intended to **replace another food**, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Authorisation procedure: the procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list shall be **efficient, time-limited and transparent**. It shall start either on the Commission's initiative or following an application to the Commission by an applicant. The Commission shall make the application available to the Member States without delay.

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

Opinion of the Authority: 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 forward the valid notification without delay, and not later than one month after having verified its validity, to the Member States and to 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.

Traditional foods from third countries: the placing on the market within the Union of traditional foods from third countries should be facilitated where the **history of safe food use** in a third country has been demonstrated. Those foods should have been consumed in at **least one third country for at least 25 years** as a part of the customary diet of a significant number of people. The history of safe food use should not include non-food uses or uses not related to normal diets.

Data protection: in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation.

The Regulation stipulates that on request by the applicant, and where supported by appropriate and verifiable information included in the application, **newly developed scientific evidence or scientific data supporting the application** shall not be used for the benefit of a subsequent application during a period of **five years** from the date of the authorisation of the novel food without the agreement of the initial applicant.

ENTRY INTO FORCE: 31.12.2015.

APPLICATION: from 01.01.2018 with the exception of certain provisions which shall apply from 31.12.2015 or from the date of application of certain implementing acts.

DELEGATED ACTS: the power to adopt delegated acts should be delegated to the Commission in respect of the adjustment and adaptation of the definition of engineered nanomaterial to technical and scientific progress or to definitions agreed at international level. It shall be conferred on the Commission

for a period of **five years** (renewable) from 31 December 2015. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification (this period may be extended by two months). If the European Parliament or the Council objects, the delegated act shall not enter into force.