Novel foods

2013/0435(COD) - 18/12/2013 - Legislative proposal

PURPOSE : to ensure food safety, to protect public health and secure the functioning of the internal market for food, while supporting innovation for the food sector.

PROPOSED ACT : Regulation of the European Council and of the Parliament.

ROLE OF THE EUROPEAN PARLIAMENT : the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND : Union rules on novel foods were set out in Regulation (EC) n° 258/97 of the European Parliament and Council and Commission Regulation (EC) n° 1852/2001. Those rules need to be updated **to simplify the current authorisation procedures** and to take account of recent developments in Union law.

In January 2008, the Commission adopted a proposal aiming to simplify the authorization procedure set out in Regulation (EC) 258/97 on novel foods. The legislative discussions under the ordinary legislative procedure mainly focused on the provisions applicable to: (i) nanomaterials; (ii) the cloning of animals for food production; (iii) traditional foods from third countries; (iv) the criteria to be examined for the risk assessment, and (v) risk management and to the procedure for the authorisation of novel foods in accordance with the Treaty on the Functioning of the European Union (Lisbon Treaty).

However, the proposal was not adopted after the Conciliation Committee failed to reach an agreement in March 2011.

The Commission considers that issues related to cloning of farm animals should be addressed in a **separate proposal**, based on an impact assessment.

IMPACT ASSESSMENT : the 2008 impact assessment is still valid, and the rationale for an in-depth revision of the current legislation remains unchanged (the length and cost of the current authorisation procedure, the need for a centralised risk assessment and risk management and for an adjusted procedure for the placing on the EU market of traditional foods from third countries).

CONTENT : the proposal brings together and updates the provisions of the legislation currently in force, which will be repealed at the time of entry into application of the new legislation. It aims to **streamline the authorisation procedure for novel foods**, to improve its efficiency and transparency. It is limited to the safety of novel food and is based on the overall agreement achieved in conciliation.

The main points are as follows:

Subject matter, scope and definitions

- novel foods will be subject to safety evaluation and authorisation through a **fully harmonised procedure;**
- the **definition** of novel foods is clarified, bearing in mind new technologies which have an impact on food.
- a **simplified procedure** is created for marketing of traditional foods from third countries;

- **nanomaterials** which are intended for food uses and covered by the definition of "engineered nanomaterials", as laid down in Regulation (EU) n°1169/2011 on food information to consumers, shall be assessed and authorised under this Regulation before being placed on the EU market.

Requirements for placing novel foods on the market within the Union:

- all novel foods and their use must **not present a danger to human health** and their use should not mislead the consumer;

- for every authorised novel food, specifications, labelling requirements, conditions of use and, where appropriate, a requirement of post-market monitoring may be laid down;

- the current system of individual authorisations is replaced by a **system of generic authorisation;**

- novel foods already authorised shall continue to be marketed and will be included in the Union list of novel foods.

Authorisation procedure for a novel food

- all applications for the authorisation of novel foods shall be submitted to the Commission which may then request a scientific opinion on risk assessment from the European Food Safety Authority (EFSA);

- the inclusion of a novel food in the Union list of novel foods will be considered by the Commission on the basis of the opinion from EFSA.

For **traditional foods from third countries**, a safety assessment and a risk management, based on a history of safe food use, is introduced:

- if the applicant has shown a history of safe food use in a third country for at least 25 years, and if the Member States or EFSA do not present reasoned safety objections based on scientific evidence, the food may be included in the Union list;

- where reasoned safety objections are presented, an EFSA assessment followed by an EU authorisation procedure, similar to the standard authorisation procedure but with shorter deadlines, is required.

Additional procedural rules and other requirements

- the information provided by the applicant should be kept confidential where the disclosure of such information might significantly harm their competitive position.

Data protection

- in order to support innovation in the EU food industry and only in duly justified cases, individual authorisations with data protection may be granted for a maximum period of five years.

Penalties and committee procedure

- rules on penalties applicable to infringements of the provisions of the proposed Regulation will be laid down;

- implementation of the measures proposed in the Regulation will be mainly adopted by the Commission. This relates to the conditions of use and labelling of a novel food as well as laying down specifications and, where appropriate post-market monitoring requirements.

Transitional provisions

- transitional measures are set out to ensure a smooth transition with on-going applications and notifications, pending the entry into application of this legislation;

- to enhance legal certainty, a food that was legally placed on the market prior to the application of this Regulation, should be allowed to be continued to be marketed until the risk assessment and authorisation procedures have been concluded.

BUDGETARY IMPLICATIONS : operational resources necessary for implementation of the proposal will be covered by redeployment within the contribution granted to EFSA during the annual budgetary procedure.

The estimated impact on appropriations of an administrative nature is **EUR 2.750 million** for the period 2014-2020.