

Collaboration

New regulation on novel foods in the European Union

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Abstract

The new Regulation (EU) 2015/2283 on novel foods has included new categories in the concept of novel food. These include engineered nanomaterials, whole animals (including insects) and food from material of mineral origin. However, the definition of novel food as such has not undergone any significant changes with respect to the previous definition, keeping the date from which it is considered that a food product that has not been used for human consumption to a significant degree must be subject to assessment.

The application of Regulation (EU) 2015/2283 implies a significant change in the regulation and authorization procedure for novel foods. The new criteria applicable from 2018 include the requirement that the assessment should no longer be conducted by the Member States but should be carried out by the European Food Safety Authority (EFSA), the establishment of a specific procedure for traditional foods from third countries when a history of safe food use has been demonstrated for at least 25 years, and the establishment of time periods for consultation, assessment and authorization. In addition, data protection is offered when the scientific evidence or data on which the application is based are essential for the assessment of the safety of the novel food such that the data shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorization of the novel food without the agreement of the initial applicant.

In any case, and in spite of the changes introduced, experience obtained to date will be essential for improving the authorization procedures for novel foods, making the authorization process more efficient, and stimulating innovation in the food sector and, at the same time, guaranteeing the safety of European consumers and increasing the variety of available food products.

Key words

Novel foods, authorization, Regulation (EU) 2015/2283, application, notification, traditional foods.

1. Introduction

“Novel foods” are those foods and food ingredients which have not been used for human consumption to a significant degree in the European Union prior to 15 May 1997, when Regulation (EC) No 258/1997 (EU, 1997) came into effect, and with it the first provisions regarding novel foods.

From 1 January 2018, on starting the application of the new Regulation (EU) 2015/2283 (EU, 2015), new categories have been included to the concept of novel food. These include engineered nano-materials, whole animals and food from material of mineral origin. However, the definition of novel food as such has not undergone any significant changes with respect to the previous definition, keeping the date from which it is considered that a food product that has not been used for human consumption to a significant degree must be subject to assessment.

Novel foods may be recently created, innovative food products produced using new technologies and production processes, and food products which are consumed or have traditionally been consumed outside the European Union.

The application of Regulation (EU) 2015/2283 implies a significant change in the regulation and authorisation procedure for novel foods. Previously, all novel foods were treated in the same way, regardless of whether they were completely new or there was a history of safe use outside the European Union. The authorisations were given to the applicant such that they held full rights over the ownership of the same. Moreover, the initial assessment was conducted in the country in which the novel food was to be placed on the market for the first time, establishing two procedures:

- Simplified: in which it was necessary to prove that the food in question was “substantially equivalent” to foods or food ingredients already available on the market.
- Ordinary: applicable in those cases in which it was not possible to apply the concept of substantial equivalence, and which sought to demonstrate that the novel food or food ingredient did not present a danger for the consumer nor mislead them, and would not be nutritionally disadvantageous for the consumer with respect to their conventional counterparts.

The new Regulation is intended to improve the efficiency and transparency of the novel food authorisation procedure, establishing time limits for the assessment of its safety and for its authorisation, in order to reduce the time required before it is placed on the market.

2. Scope

New categories of food have been included in the concept of novel food, thus increasing the scope of application with respect to the previous Regulation.

The categories of novel foods included in Regulation (EU) 2015/2283 are as follows:

- 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 consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

- Traditional propagating practices which have been used for food production within the Union before 15 May 1997.
- Non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not 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, microorganisms, fungi or algae.
- Food resulting from a new production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.
- Food consisting of engineered nanomaterials as defined below.
- 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:
 - a production process not used for food production within the Union before 15 May 1997 has been applied; or
 - they contain or consist of engineered nanomaterials.
- 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 as defined in point (a) of Article 2 of Directive 2002/46/EC.

Unlike in the former Regulation (EC) No 258/1997, whole animals are now considered in the scope of application of the new Regulation. These are included in the transitional measures reflected in the new Regulation in Article 35, point 2, that is, those species of whole animals which were lawfully placed on the market by 1 January 2018, date on which the new Regulation came into force, in certain countries, which previously tolerated them (Belgium, the United Kingdom, Finland, the Netherlands, Denmark and Austria), may continue to be placed on the European market on the condition that an application is submitted in accordance with the new Regulation before 1 January 2019.

Another difference to the previous Regulation is the inclusion in the scope of application of foods of mineral origin, and engineered nanomaterials, defined as “any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale”.

Regulation (EU) 2015/2283 does not apply to:

- Genetically modified foods included in the scope of application of Regulation (EC) No 1829/2003.

- Foods when and as far as they are used as:
 - Food enzymes included in the scope of application of Regulation (EC) No 1332/2008.
 - Food additives falling within the scope of Regulation (EC) No 1333/2008.
 - Food flavourings falling within the scope of Regulation (EC) No 1334/2008.
 - Extraction solvents used or intended for use in the production of food or food ingredients and included within the scope of Directive 2009/32/EC.

3. Authorisation procedure

The new legislation which regulates novel foods aims to make the authorisation procedure more efficient, in turn stimulating innovation in the food sector, while also guaranteeing the safety of European consumers and increasing the variety of marketable foods.

Only authorised novel foods may be placed on the market in the European Union. The authorisation procedure for a novel food involves a safety assessment prior to the authorisation to place it on the European Union market and these authorisations are applicable in all the Member States.

3.1 Procedure for determination of novel food status

Food business operators shall verify whether or not the food which they intend to place on the market within the Union is a novel food. Where they are unsure, they may consult the Member State of the European Union where they first intend to place the novel food in the market. Previously, the competent authorities were also consulted but Regulation (EU) 2015/2283 has standardised the consultation procedure, which has been established under Implementing Regulation (EU) 2018/456 (EU, 2018).

The consultation request shall be submitted electronically and shall consist of:

- A) A cover letter.
- B) A technical dossier containing the information necessary to enable a conclusion to be reached regarding the novel food status
- C) Supporting documentation.
- D) An explanatory note clarifying the purpose and relevance of the submitted documentation.

Implementing Regulation (EU) 2018/456 provides templates of the cover letter and technical dossier.

The recipient Member State may request the applicant provide additional information and may also consult other Member States and the Commission. The conclusion must be justified and sent to the applicant, the other Member States and the European Commission within 4 months, and only in duly justified cases, may the recipient Member State extend the time period by a maximum of 4 more months.

3.2 General procedure

If the novel food status of a product is confirmed, the product must undergo a safety assessment conducted by the European Food Safety Authority (EFSA) prior to authorising its placing on the market.

Food business operators may place a novel food on the market in the European Union only after submitting an application for a novel food authorisation to the European Commission, and after the Commission has adopted an implementing act which authorises the placing on the market of the novel food and the Union list has been updated.

The applicant must submit the application for authorisation to the Commission in accordance with the requirements of Article 10 of the new Regulation. These requirements have been developed in Implementing Regulation (EU) 2017/2469 (EU, 2017b).

If the novel food may have an effect on human health, the Commission will request the EFSA conduct a risk assessment and the EFSA shall adopt its opinion within 9 months from the date of receipt of a valid application.

Within 7 months from the date of publication of the EFSA's opinion, the Commission shall submit to the Standing Committee on Plants, Animals, Food and Feed, a draft implementing act authorising the placing on the market of a novel food and updating the Union list. Once the implementing act has been approved by the Standing Committee and adopted and published by the Commission, the novel food may legally be placed on the market in the European Union.

This is therefore a simplified and centralised authorisation procedure, managed by the European Commission, using an online system for sending applications.

3.3 Procedure for traditional foods from a third country

Foods from third countries which are regarded as novel foods in the European Union should only be considered as traditional foods from third countries when they are derived from primary production as defined in Regulation (EC) No 178/2002 (EU,2002), regardless of whether or not they are processed or unprocessed foods.

In the interest of facilitating the placing on the market within the Union of traditional foods from third countries 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.

The authorisation of the placing on the market of these traditional foods may follow two paths. The first consists in a notification according to that established in Article 14 and the second path may be adopted in the case of safety objections to the notification submitted in the first instance. In the second case, the applicant may submit an application in accordance with Article 16.

As for the other novel foods, traditional foods from a third country may only be placed on the market in the European Union after the European Commission has validated a notification, adopted a regulation which authorises the placing on the market of the novel food and updated the Union list. Therefore, prior to placing a traditional food from a third country on the market in the Union, the applicant must submit a notification for the authorisation to the Commission in accordance with the requirements of Article 14 of the new Regulation. These requirements are developed in the Implementing Regulation (EU) 2017/2468 (EU, 2017a).

On receipt of a notification, the Commission validates the application, its integrity and the presence of the information required. The Commission shall forward the valid notification to the Member

States and to the EFSA which, within 4 months, may submit to the Commission duly reasoned safety objections to the placing on the market of the traditional food concerned.

Where no duly reasoned safety objections have been submitted, the Commission shall submit to the Standing Committee on Plants, Animals, Food and Feed, a draft implementing act authorising the placing on the market of the traditional foods and updating the Union list. Once the implementing act has been approved by the Standing Committee and adopted and published by the Commission, the traditional food may legally be placed on the market in the European Union.

If one or more Member States or the EFSA submit duly reasoned safety objections, the Commission shall not authorise the placing on the market of the traditional foods concerned or update the Union list. In that case, the applicant may submit an application to the Commission, including, in addition to the information already provided, documented data relating to the duly reasoned safety objections submitted in accordance with Article 16 of Regulation (EU) 2015/2283.

3.4 Union list of novel foods

One of the new features of Regulation (EU) 2015/2283 is the way in which authorisations to place a product on the market are made public.

Previously, authorisations were published in letters of authorisation from the competent authorities of a Member State or, if objections had been raised by a Member State or the European Commission, via Commission Rulings published in the Official Journal of the European Union.

Now however, from January 2018, authorisations for novel food are included in the so-called Union list published in Commission Implementing Regulation (EU) 2017/2470 (EU, 2017c).

The Union list of novel foods includes information about the name of the novel food authorised, the conditions of use (foods and maximum content in which they may be used), additional specific labelling requirements and other requirements. It will also include the specifications for each novel food.

3.5 Situation of novel foods authorised in accordance with Regulation (EC) No 258/97

The authorisations of novel foods under the scope of the previous Regulation (EC) No 258/1997 are specifically directed to the applicant and they are granted exclusive rights over the novel food.

With the new Regulation (EU) 2015/2283, although the authorisations, conditions of use, specifications and labelling of the previously authorised novel foods continue to be valid, they are no longer specific to the applicant but are general for the food after its inclusion in the Union list.

This allows any food business operator to place the already authorised novel foods on the market in the European Union, provided the applicable specifications are met. There is no longer a specific recipient of the authorisation unless there is a need for data protection.

3.6 Data protection

At the request of the applicant, and if the European Commission considers that the scientific evidence or data on which the application is based are essential for the assessment of the safety of the novel food, this data shall not be used for the benefit of a subsequent application during a period

of 5 years from the date of the authorisation of the novel food without the agreement of the initial applicant. Therefore, if another operator wishes to place the same product on the market, they should submit a complete dossier including proprietary scientific data. This means that the Union list should be modified in accordance with the data protection, including:

- The date of inclusion of the novel food in the Union list.
- The end date of the data protection.
- The name and address of the applicant.

4. Procedure for assessment

Following the application of the new Regulation (EU) 2015/2283, the assessment of novel foods will be carried out by the EFSA. Previously, the assessment of the novel food was carried out by the Member State in which the novel food was to be placed on the market for the first time, and the EFSA only conducted a complementary assessment at the request of the European Commission.

This is intended to improve the efficiency and transparency, establishing time limits for the assessment of its safety and the authorisation procedure, in order to reduce the total time required for the approval procedure.

The EFSA has published guidance documents on novel food and traditional food from third countries to help ensure that these foods are safe before risk managers decide whether they can be marketed in Europe.

The new guidance documents explain in detail the kind of information applicants need to provide for risk assessment. They also clarify how to present this information before EFSA can assess the safety of the novel or traditional food from third countries.

These guides are:

- Guidance for the preparation and presentation of an application for a novel food under Regulation (EU) 2015/2283 (EFSA, 2015a).
- Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 (EFSA, 2015b).
- Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (EFSA, 2015c).

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