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► **B** REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 25 November 2015

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

(Text with EEA relevance)

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CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and purpose

1. This Regulation lays down rules for the placing of novel foods on the market within the Union.
2. 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.

Article 2

Scope

1. This Regulation applies to the placing of novel foods on the market within the Union.
2. This Regulation does not apply to:
 - (a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;
 - (b) foods when and in so far as they are used as:
 - (i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;
 - (ii) food additives falling within the scope of Regulation (EC) No 1333/2008;
 - (iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;
 - (iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.

Article 3

Definitions

1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 apply.

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2. The following definitions also apply:
- (a) ‘novel food’ means 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, and that falls under at least one of the following categories:
- (i) 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;
 - (ii) food consisting of, isolated from or produced from micro-organisms, fungi or algae;
 - (iii) food consisting of, isolated from or produced from material of mineral origin;
 - (iv) 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; or
 - 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;
 - (v) 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;
 - (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
 - (vii) food resulting from a 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;
 - (viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;
 - (ix) 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 as referred to in point (a) (vii) of this paragraph; or

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- they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;
- (x) 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;
- (b) ‘history of safe food use in a third country’ means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification referred to in Article 14;
- (c) ‘traditional food from a third country’ means novel food as defined in point (a) of this paragraph, other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof which is derived from primary production as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country;
- (d) ‘the applicant’ means the Member State, the third country or the interested party, which may represent several interested parties and has submitted to the Commission an application in accordance with Article 10 or 16 or a notification in accordance with Article 14;
- (e) ‘valid’ in respect to an application or a notification means an application or a notification which falls within the scope of this Regulation and contains the information required for risk assessment and authorisation procedure;
- (f) ‘engineered nanomaterial’ means 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.

Properties that are characteristic of the nanoscale include:

- (i) those related to the large specific surface area of the materials considered; and/or
- (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

*Article 4***Procedure for determination of novel food status**

1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.

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2. Where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, food business operators shall consult the Member State where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation.

3. 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.

4. The Commission shall, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraphs 2 and 3 of this Article, including deadlines and the means to make the status publicly available. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*Article 5***Implementing power concerning the definition of novel food**

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, as laid down in point (a) of Article 3(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

CHAPTER II

REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN THE UNION*Article 6***Union list of authorised novel foods**

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 ('the Union list').

2. 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.

*Article 7***General conditions for inclusion of novel foods in the Union list**

The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

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

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- (c) 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.

*Article 8***Initial establishment of the Union list**

By 1 January 2018 the Commission shall, by means of an implementing act, establish the Union list by including in it the novel foods authorised or notified under Article 4, 5 or 7 of Regulation (EC) No 258/97, including any existing authorisation conditions.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 30(2).

*Article 9***Content and updating of the Union list**

1. The Commission shall authorise a novel food and update the Union list in accordance with the rules laid down in:

- (a) Articles 10, 11 and 12 and, where applicable, Article 27; or
- (b) Articles 14 to 19.

2. The authorisation of a novel food and updating of the Union list provided for in paragraph 1 shall consist of one of the following:

- (a) adding a novel food to the Union list;
- (b) removing a novel food from the Union list;
- (c) 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.

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include the specification of the novel food and, where appropriate:

- (a) the conditions under which the novel food may be used, including in particular any requirements necessary to avoid possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;
- (b) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;
- (c) post-market monitoring requirements in accordance with Article 24.

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CHAPTER III
AUTHORISATION PROCEDURES FOR A NOVEL FOOD

SECTION I

General rules

Article 10

Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list

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1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States without delay. The Commission shall make a summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.

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2. The application for an authorisation shall include:

- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (c) the description of the production process(es);
- (d) the detailed composition of the novel food;
- (e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
- (f) where appropriate, the analysis method(s);
- (g) a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

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3. Where the Commission requests an opinion from the European Food Safety Authority (the 'Authority'), the Authority shall make public the application in accordance with Article 23 and shall give its opinion as to whether the update is liable to have an effect on human health.

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4. When test methods are applied to engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2), an explanation shall be provided by the applicants of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.

5. The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 9 shall end with the adoption of an implementing act in accordance with Article 12.

6. By way of derogation from paragraph 5, the Commission may terminate the procedure at any stage, and decide not to proceed with an update, where it considers that such an update is not justified.

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In such cases, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.

The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified. The Commission shall make the list of such applications publicly available.

7. The applicant may withdraw its application at any time, thereby terminating the procedure.

*Article 11***Opinion of the Authority**

1. 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.

2. In assessing the safety of novel foods, the Authority shall, where appropriate, consider whether:

- (a) the novel food concerned is as safe as food from a comparable food category already placed on the market within the Union;
- (b) the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;
- (c) a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

3. The Authority shall forward its opinion to the Commission, to the Member States and, where applicable, to the applicant.

4. In duly justified cases, where the Authority requests additional information from the applicant, the nine-month period provided for in paragraph 1 may be extended.

After consulting the applicant, the Authority shall specify a period within which that additional information is to be provided and shall inform the Commission thereof.

Where the Commission does not object to the extension within eight working days of being informed by the Authority, the nine-month period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

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5. Where the additional information referred to in paragraph 4 is not provided to the Authority within the additional period referred to in that paragraph, the Authority shall draw up its opinion on the basis of the available information.

6. Where an applicant submits additional information on its own initiative, it shall send that information to the Authority.

In such cases, the Authority shall give its opinion within the nine-month period provided for in paragraph 1.

7. The Authority shall make the additional information provided in accordance with paragraphs 4 and 6 available to the Commission and to the Member States.

*Article 12***Authorisation of a novel food and updates of the Union list**

1. Within seven months from the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list, taking into account the following:

- (a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, in point (c) of that Article;
- (b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;
- (c) the Authority's opinion;
- (d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2. Where the Commission has not requested an opinion from the Authority in accordance with Article 10(3), the seven-month period provided for in paragraph 1 of this Article shall start from the date on which a valid application is received by the Commission in accordance with Article 10(1).

*Article 13***Implementing acts laying down administrative and scientific requirements for applications**

By 1 January 2018, the Commission shall adopt implementing acts concerning:

- (a) the content, drafting and presentation of the application referred to in Article 10(1);
- (b) the arrangements for verifying the validity, without delay, of those applications;

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- (c) the type of information to be included in the opinion of the Authority referred to in Article 11.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*SECTION II**Specific rules for traditional foods from third countries**Article 14***Notification of a traditional food from a third country**

Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within the Union a traditional food from a third country, may opt to submit a notification of that intention to the Commission.

The notification shall include the following information:

- (a) the name and address of the applicant;
- (b) the name and description of the traditional food;
- (c) the detailed composition of the traditional food;
- (d) the country or countries of origin of the traditional food;
- (e) documented data demonstrating the history of safe food use in a third country;
- (f) a proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or a verifiable justification why those elements are not necessary.

*Article 15***Procedure for notifying the placing on the market within the Union of a traditional food from a third country**

1. The Commission shall forward the valid notification provided for in Article 14 without delay, and not later than one month after having verified its validity, to the Member States and to the Authority.

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2. Within four months from the date on which a valid notification is forwarded by the Commission in accordance with paragraph 1 of this Article, a Member State or the Authority may submit to the Commission duly reasoned safety objections to the placing on the market within the Union of the traditional food concerned. Where the Authority submits duly reasoned safety objections, it shall make public, without delay, the notification, pursuant to Article 23, which shall apply *mutatis mutandis*.

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3. The Commission shall inform the applicant of any duly reasoned safety objection as soon as it is submitted. The Member States, the Authority and the applicant shall be informed of the outcome of the procedure referred to in paragraph 2.

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4. Where no duly reasoned safety objections have been submitted in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update the Union list without delay.

The entry in the Union list shall specify that it concerns a traditional food from a third country.

Where applicable, certain conditions for use, specific labelling requirements, or post-market monitoring requirements shall be specified.

5. Where duly reasoned safety objections have been submitted to the Commission in accordance with paragraph 2, the Commission shall not authorise the placing on the market within the Union of the traditional food concerned or update the Union list.

In that case, the applicant may submit an application to the Commission in accordance with Article 16.

*Article 16***Application for the authorisation of a traditional food from a third country**

Where the Commission, acting in accordance with Article 15(5), does not authorise the placing on the market within the Union of a traditional food from a third country or update the Union list, the applicant may submit an application including, in addition to the information already provided in accordance with Article 14, documented data relating to the duly reasoned safety objections submitted in accordance with Article 15(2). ►**M1** The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. ◀

The Commission shall, without delay, forward the valid application to the Authority and make it available to Member States. ►**M1** The Authority shall make public the application, relevant supporting information and any supplementary information supplied by the applicant in accordance with Article 23. ◀

*Article 17***Opinion of the Authority on a traditional food from a third country**

1. The Authority shall adopt its opinion within six months from the date of receipt of a valid application.

2. In assessing the safety of a traditional food from a third country, the Authority shall consider the following matters:

- (a) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant in accordance with Articles 14 and 16;
- (b) whether the composition of the food and the conditions of its use do not pose a safety risk to human health in the Union;
- (c) where the traditional food from the third country is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

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3. The Authority shall forward its opinion to the Commission, the Member States and the applicant.

4. In duly justified cases, where the Authority requests additional information from the applicant, the six-month period provided for in paragraph 1 may be extended.

After consulting the applicant, the Authority shall specify a period within which that additional information is to be provided and shall inform the Commission thereof.

Where the Commission does not object to the extension within eight working days of being informed by the Authority, the six-month period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

5. Where the additional information referred to in paragraph 4 is not provided to the Authority within the additional period referred to in that paragraph, the Authority shall draw up its opinion on the basis of the available information.

6. Where an applicant submits additional information on its own initiative, it shall send that information to the Authority.

In such cases, the Authority shall give its opinion within the six-month period provided for in paragraph 1.

7. The Authority shall make the additional information provided in accordance with paragraphs 4 and 6 available to the Commission and to Member States.

Article 18

Authorisation of a traditional food from a third country and updates of the Union list

1. Within three months of the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of the traditional food from a third country and updating the Union list, taking into account the following:

- (a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, point (c) of that Article;
- (b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;
- (c) the Authority's opinion;
- (d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2. By way of derogation from paragraph 1, the Commission may terminate the procedure at any stage and decide not to proceed with an update where it considers that such an update is not justified.

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In such case, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.

The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified.

3. The applicant may withdraw its application referred to in Article 16 at any time, thereby terminating the procedure.

*Article 19***Updates to the Union list as regards authorised traditional foods from third countries**

Articles 10 to 13 apply to removing a traditional food from a third country from the Union list or to adding, removing or changing specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a traditional food from a third country on the Union list.

*Article 20***Implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries**

By 1 January 2018 the Commission shall adopt implementing acts concerning:

- (a) the content, drafting and presentation of the notifications referred to in Article 14 and of applications referred to in Article 16;
- (b) the arrangements for verifying the validity, without delay, of those notifications and applications;
- (c) the arrangements for the exchange of information with the Member States and with the Authority for submitting duly reasoned safety objections as referred to in Article 15(2);
- (d) the type of information to be included in the opinion of the Authority referred to in Article 17.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

CHAPTER IV

ADDITIONAL PROCEDURAL RULES AND OTHER REQUIREMENTS*Article 21***Additional information concerning risk management**

1. Where the Commission requests from an applicant additional information on matters concerning risk management, it shall determine, together with the applicant, the period within which that information is to be provided.

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In such cases, the period provided for in Article 12(1) or (2) or in Article 18(1) may be extended accordingly. The Commission shall inform the Member States of that extension and shall make the additional information available to Member States once it has been received.

2. Where the additional information referred to in paragraph 1 is not received within the additional period referred to in that paragraph, the Commission shall act on the basis of the available information.

*Article 22***Ad hoc extension of time periods**

In exceptional circumstances, the Commission may extend the time periods provided for in Articles 11(1), 12(1) or (2), 17(1) and 18(1) on its own initiative or, where applicable, at the Authority's request, where the nature of the matter in question justifies an appropriate extension.

The Commission shall inform the applicant and the Member States of the extension and the reasons therefor.

▼M1*Article 23***Transparency and confidentiality**

1. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002 and with this Article.

2. The applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification, upon submission of the application.

3. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.

4. In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:

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- (a) where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety;
- (b) where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety.

5. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16 of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 4 of this Article shall apply *mutatis mutandis*.

6. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.

▼ B*Article 24***Post-market monitoring requirements**

The Commission may, for food safety reasons and taking into account the opinion of the Authority, impose post-market monitoring requirements. Such requirements may include, on a case-by-case basis, the identification of the relevant food business operators.

*Article 25***Additional information requirements**

Any food business operator which has placed a novel food on the market shall immediately inform the Commission of any information of which it has become aware concerning:

- (a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food;
- (b) any prohibition or restriction imposed by a third country in which the novel food is placed on the market.

The Commission shall make that information available to the Member States.



CHAPTER V
DATA PROTECTION

Article 26

Authorisation procedure in case of data protection

1. On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1), 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.

2. The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met:

- (a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
- (b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
- (c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.

3. Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.

Article 27

Authorisation of a novel food and inclusion in the Union list based on protected proprietary scientific evidence or scientific data

1. Where a novel food is authorised and included in the Union list pursuant to Articles 10 to 12 based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 26(1), the entry of that novel food in the Union list shall indicate, in addition to the information referred to in Article 9(3):

- (a) the date of inclusion of the novel food in the Union list;
- (b) the fact that that inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26;

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- (c) the name and address of the applicant;
 - (d) the fact that during the period of data protection the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) of this paragraph, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 or with the agreement of the initial applicant;
 - (e) the end date of the data protection provided for in Article 26.
2. Scientific evidence or scientific data protected in accordance with Article 26 or for which the protection period under that Article has expired shall not be granted renewed protection.

*Article 28***Authorisation procedure in case of a parallel application for the authorisation of a health claim**

1. The Commission shall, on request by the applicant, stay an authorisation procedure for a novel food started following an application, where the applicant has submitted:
- (a) a request for data protection in accordance with Article 26; and
 - (b) an application for the authorisation of a health claim on the same novel food in accordance with Article 15 or 18 of Regulation (EC) No 1924/2006, in conjunction with a request for data protection in accordance with Article 21 of that Regulation.

The stay of the authorisation procedure shall be without prejudice to the assessment of the food by the Authority in accordance with Article 11.

2. The Commission shall inform the applicant about the date of effect of the stay.
3. While the authorisation procedure is stayed, time shall cease to run for the purposes of the time-limit laid down in Article 12(1).
4. The authorisation procedure shall resume when the Commission has received the opinion of the Authority on the health claim pursuant to Regulation (EC) No 1924/2006.

The Commission shall inform the applicant about the date of resumption of the authorisation procedure. From the date of resumption, time shall begin to run afresh from the beginning for the purposes of the time-limit laid down in Article 12(1) of this Regulation.

5. In the cases referred to in paragraph 1 of this Article, where data protection has been granted in accordance with Article 21 of Regulation (EC) No 1924/2006, the period of data protection granted in accordance with Article 26 of this Regulation shall not exceed the period of data protection granted in accordance with Article 21 of Regulation (EC) No 1924/2006.

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6. The applicant may withdraw at any time the request for staying the authorisation procedure submitted in accordance with paragraph 1. In that case, the authorisation procedure shall resume and paragraph 5 shall not apply.

CHAPTER VI

PENALTIES AND GENERAL PROVISIONS

*Article 29***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 1 January 2018 and shall notify it without delay of any subsequent amendment affecting them.

*Article 30***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽¹⁾.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

*Article 31***Delegated acts**

For the purposes of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts adopted in accordance with Article 32, adjust and adapt the definition of engineered nano-materials referred to in point (f) of Article 3(2) to technical and scientific progress or to definitions agreed at international level.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).



Article 32

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.
3. The power to adopt delegated acts referred to in Article 31 shall be conferred on the Commission for a period of five years from 31 December 2015. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
4. The delegation of power referred to in Article 31 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or on a later date specified therein. It shall not affect the validity of any delegated acts already in force.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 31 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and to the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER VII

TRANSITIONAL MEASURES AND FINAL PROVISIONS

Article 33

Amendments to Regulation (EU) No 1169/2011

Regulation (EU) No 1169/2011 is amended as follows:

(1) In Article 2(1) the following point is added:

- (h) the definition of “engineered nanomaterials” as established by point (f) of Article 3(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council (*).

(*) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 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 (OJ L 327, 11.12.2015, p. 1).

▼B

(2) Point (t) of Article 2(2) is deleted.

References to the deleted point (t) of Article 2(2) of Regulation (EU) No 1169/2011 shall be construed as references to point (f) of Article 3(2) of this Regulation.

(3) In Article 18, paragraph 5 is deleted.

*Article 34***Repeal**

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 are hereby repealed from 1 January 2018. References to Regulation (EC) No 258/97 shall be construed as references to this Regulation.

*Article 35***Transitional measures**

1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application under this Regulation.

The Commission shall not apply Article 11 of this Regulation, where a risk assessment has already been provided by a Member State on the basis of Regulation (EC) No 258/97 and no other Member State has raised any reasoned objection to that assessment.

2. Foods not falling within the scope of Regulation (EC) No 258/97, which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, but no later than 2 January 2020.

3. The Commission may, by means of implementing acts, adopt measures concerning the requirements referred to in Articles 13 and 20 necessary for the application of paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*Article 36***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2018, except for the following provisions:

- (a) Article 4(4), Articles 8, 13 and 20, Article 23(8), Article 30 and Article 35(3) shall apply from 31 December 2015;
- (b) Article 4(2) and (3) shall apply from the date of application of the implementing acts referred to in Article 4(4);

▼B

- (c) Article 5 shall apply from 31 December 2015. However, implementing acts adopted under Article 5 shall not apply before 1 January 2018;
- (d) Articles 31 and 32 shall apply from 31 December 2015. However, delegated acts adopted under those Articles shall not apply before 1 January 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.