



16.11.2015

## **AGREED TEXT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS**

Subject: Proposal for a regulation on novel foods  
(COM(2013)0894 – C8-0487/2013 – 2013/0435(COD))

The interinstitutional negotiations on the aforementioned proposal for a regulation have led to a compromise. In accordance with Rule 69f(4) of the Rules of Procedure, the provisional agreement, reproduced below, is submitted as a whole to the Committee on the Environment, Public Health and Food Safety for decision by way of a single vote.

REGULATION (EU) No .../2015 OF THE EUROPEAN PARLIAMENT

AND OF THE COUNCIL

*of [...]*

**on novel foods 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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national *parliaments*,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

Whereas:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, **and to** their social and economic interests. Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating **legal uncertainty and** unfair conditions of competition.

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> OJ C [...], [...], p. [...].

- (2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency. *A high level of protection and improvement of the quality of the environment is among the objectives of the Union as established in the Treaty of the European Union. Moreover, it is important that all relevant Union legislation, including this Regulation, take these objectives into account.*
- (2a) *Union legislation applicable to food is also applicable to novel foods placed on the market within the Union, including novel foods imported from third countries.*
- (3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council and by Commission Regulation (EC) No 1852/2001. Those rules need to be updated to simplify the current authorisation procedures and to take account of recent developments in Union law *and technological progress*. Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and replaced by this Regulation.
- (4) Food intended to be used for technological purposes and genetically modified food *which is already covered by other Union acts* should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council, *food* enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council, *food* flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council should be excluded from the scope of this Regulation.
- (5) The existing *definition* of novel food in Regulation (EC) No 258/97 should be clarified and updated with a reference to the general definition of food provided for in Regulation (EC) No 178/2002 of the European Parliament and of the Council.

- (6) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, ***one of the criteria for the food to be considered a novel food should continue to be*** the absence of a use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997. Use within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union.
- (6a) ***The scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) No 258/97. However, on the basis of scientific and technological developments occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. The categories should cover whole insects and their parts. There should be, inter alia, categories for food with a new or intentionally modified molecular structure, as well as food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae, food from microorganisms, fungi or algae and food from material of mineral origin. There should also be a category covering 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. The definition of novel food may also cover food consisting of certain micelles or liposomes.***<sup>1</sup>
- (7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore ***this Regulation should further specify*** that a food should be considered a novel food where ***it results 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.***

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<sup>1</sup> Recital 8a has been merged with this recital.

- (7a) *To ensure a high level of protection of human health and consumers' interests, food consisting of engineered nanomaterials should also be considered a novel food under this Regulation. 'Engineered nanomaterial' is currently defined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council. For consistency and coherence purposes, it is important to ensure a single definition of engineered nanomaterial in the area of food law. The appropriate legislative framework for including such a definition is this Regulation. Accordingly, the definition of engineered nanomaterial, along with the related conferral of delegated powers to the Commission, should be deleted from Regulation (EU) No 1169/2011 and replaced by a reference to the definition set out in this Regulation. Furthermore, this Regulation should provide that the Commission should, by means of delegated acts, adjust and adapt the definition of engineered nanomaterial set out in this Regulation to technical and scientific progress or to definitions agreed at international level.*
- (8) *Vitamins, minerals and other substances intended to be used in food supplements in accordance to Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council or in infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control according to Regulation (EU) No 609/2013 of the European Parliament and of the Council, should also be assessed in accordance with the rules laid down in this Regulation **when they fall within the definition of novel food therein.***
- (9) *When **vitamins, minerals or other substances used in accordance to Directive 2002/46/EC, Regulation (EC) 1925/2006 or Regulation (EU) 609/2013 result 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, or contain or consist of engineered nanomaterials, they** should also be considered novel foods under this Regulation and should be **re-assessed** first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.*

- (10) A food used **before 15 May 1997** exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC, should be **permitted** to be placed on the market within the Union after that date for the same use, **as it should not be** considered **to be** a novel food for the purposes of this Regulation. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than in, or as, a food supplement should be subject to this Regulation.
- (10a) Food from animal clones has been regulated under Regulation (EC) No 258/1997. It is crucial that no legal ambiguity should emerge as regards the placing on the market of food from animal clones during the transition period from the end of the application of Regulation (EC) No 258/97. Therefore, 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.**
- (11) 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 a third country for at least 25 years as a part of the customary diet of a **significant number of people in at least one third country**. The history of safe food use should not include non-food uses or uses not related to normal diets.
- (12) **Foods** from third countries which are regarded as novel foods in the 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, regardless of whether or not they are processed or unprocessed foods.
- (13) Food produced **exclusively** from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or **their** amount, should not be considered **to be a** novel food. However, modifications of a food ingredient that have not **yet** been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.

- (14) Directive 2001/83/EC of the European Parliament and of the Council applies *in cases* where a product, taking into account all its characteristics, may fall both within the definition of "medicinal product" as laid down in that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as laid down in Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.
- (15a) *The Commission and the European Food Safety Authority ("the Authority") should be subject to deadlines to guarantee a smooth processing of applications. However, in certain cases, the Commission and the Authority should have a right to extend those deadlines.***<sup>1</sup>
- (16) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in the Member States. Food business operators should consult Member States if they are unsure of the status of the food *which* they intend to place on the market. *Where* there is no information or *the* information available on human consumption before 15 May 1997 *is insufficient*, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information.
- (17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe *and if their safety cannot be assessed and scientific uncertainty persists, the precautionary principle may be applied*. Their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

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<sup>1</sup> In a Legal-Linguistic revision of this text, this recital could perhaps be placed next to recitals 20 and 20a.

- (18) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, by means of an implementing act, a Union list of novel foods by entering *in it* novel foods already authorised or notified in accordance with Regulation (EC) No 258/97, including any existing authorisation conditions. ***The list should be transparent and easily accessible.***
- (18a) New technologies and innovations in food production should be encouraged as this could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured.***
- (19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use, ***the applicants should be able to opt for*** a faster and simplified procedure to update the Union list if no ***duly*** reasoned safety objections are expressed.
- (20) Criteria for the assessment of the safety risks arising from novel foods should also be ***clearly defined*** and laid down. In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ("the Authority"). ***Under the procedure for authorising a novel food and updating the Union list, the Authority should be requested to render its opinion if the update is liable to have an effect in human health. In its opinion, the Authority should assess, inter alia, all the characteristics of the novel food that may pose a safety risk to human health and consider possible effects on vulnerable groups of the population. In particular, the Authority should verify that, where a novel food consists of engineered nanomaterials, the most up-to-date test methods are used to assess their safety.***



- (20a) The applicant may be requested by the Authority or by the Commission to provide additional information for the purposes of risk assessment or risk management respectively. In case the applicant fails to provide the additional information within the period set by the Authority or by the Commission after consulting the applicant, lack of such information may have consequences for the opinion of the Authority or for a possible authorisation and update of the Union list.*
- (21) As regards the possible use of nanomaterials for food use, the Authority considered in its opinion of 6 April 2011<sup>21</sup> on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. The OECD Council Recommendation from 19 September 2013 concluded that the approaches for the testing and assessment of traditional chemicals are, in general, appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials. In order to better assess the safety of nanomaterials for food use and in order to address the current gaps in toxicological knowledge and measurement methodologies, test methods, including non-animal tests, which take into account specific characteristics of engineered nanomaterials may be needed.*
- (21a) When test methods are applied to nanomaterials, an explanation should be provided by the applicant of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations and adjustments that have been made in order to respond to the specific characteristics of these materials.*

- (22) When a novel food is authorised and included in the Union list, the Commission should have the power to introduce post-market monitoring requirements to monitor the use of the authorised novel food to ensure that the use is within safe limits as established in the safety assessment by *the Authority*. ***Post-market monitoring requirements may therefore be justified by the necessity to gather information on the actual marketing of the food. In any event, food business operators should inform the Commission of any new relevant information regarding the safety of food they have placed on the market.***
- (23) Under specific circumstances, 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 newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the *initial* applicant. The protection of scientific data provided by *an* applicant should not prevent other applicants from seeking the inclusion in the Union list on the basis of their own scientific data or by referring to the protected data with the agreement of the *initial* applicant. However, the overall five year period of data protection which has been granted to the *initial* applicant should not be extended due to the granting of data protection to subsequent applicants.

- (23a) In cases where an applicant requests the protection of scientific data relating to the same food in accordance with this Regulation and with Regulation (EC) No 1924/2006 of the European Parliament and of the Council<sup>1</sup>, it should be possible for the respective data protection periods to run concurrently. Therefore, provision should be made for staying, on request by the applicant, the authorisation procedure for a novel food.**
- (23b) In accordance with Directive 2010/63/EU of the European Parliament and of the Council, tests on animals should be replaced, reduced or refined. Therefore, within the scope of this Regulation, duplication of animal testing should be avoided, where possible. Pursuing this goal could reduce possible animal welfare and ethical concerns with regard to novel food applications.**
- (24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, **its composition** or its conditions of **intended** use to ensure that consumers are sufficiently informed of the nature **and safety** of the novel food, **particularly with regard to vulnerable groups of the population.**
- (24a) Materials and articles intended to come into contact with novel foods are subject to the Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>2</sup> and the specific measures adopted thereto.**

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<sup>1</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

<sup>2</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

***(24b) In line with the Commission's better regulation policy, the Commission should carry out an ex-post evaluation of the implementation of this Regulation, addressing in particular the new procedure on traditional foods from third countries.***

(25) For those applications which have been submitted under Regulation (EC) No 258/97 ***and a final decision has not been taken*** before the date of application of this Regulation, risk assessment and authorisation procedures should be concluded in accordance with this Regulation. Furthermore, a food ***not falling within the scope of Regulation 258/97, which*** was ***lawfully*** placed on the market before the date of application of this Regulation ***and which falls under the scope of this Regulation***, should in principle be allowed to ***continue to*** be placed on the market until the risk assessment and authorisation procedures ***under this Regulation*** have been concluded. Therefore, transitional ***provisions*** should be laid down to ensure a smooth transition to the rules of this Regulation.

***(25a) This Regulation respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union.***

(26) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

***(26a) The power to adopt delegated acts in accordance with Article 290 TFEU for the purposes of achieving the objectives of this Regulation 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 is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.***

- (27) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission ***with regard, in particular, to the procedure for the determination of the novel food status, uniform interpretation of whether a particular food falls within the definition of ‘novel food’, the establishment and subsequent updates of the Union list, the content, drafting and presentation of applications and notifications as well as the arrangements for checking their validity, the rules on confidentiality and the transitional provisions.***

*Those implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.*

- (28a) ***The advisory procedure should be used for the adoption of the implementing act establishing the initial Union list given that it will concern only novel foods that have already been assessed for their safety, legally produced and marketed in the Union and have not given rise to health concerns in the past. The examination procedure should be used for the adoption of implementing acts in all other cases.***

- (29) Since the objective of this Regulation, ***in particular*** laying down rules for the placing of novel foods on the market within the Union, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

**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.
- 1a. 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 1a*  
*Scope*

- 1. This Regulation shall apply to the placing of novel foods on the market within the Union.*
2. This Regulation shall 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 2*  
*Definitions*

1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.
2. The following definitions shall 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 date of accession of the various Member States to the Union and ***that falls under at least one of the following categories:***
    - (-v) ***food with a new or intentionally modified molecular structure, where that structure was not used in or as a food within the Union before 15 May 1997;***
    - (-iv) ***food consisting of, isolated from or produced from microorganisms, fungi or algae;***
    - (-iii) ***food consisting of, isolated from or produced from material of mineral origin;***
    - (-ii) ***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, or isolated 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 and 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.***

- (-i) *food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union.*
- (-ia) *food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;*
- i) 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;
- (ii) food consisting of "engineered nanomaterials" as defined in **point (f) of this paragraph;**
- (iii) 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 (i) of this paragraph; or
  - **they** contain or consist of "engineered nanomaterials" as defined in **point f) of this paragraph;**
- (iv) 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) "traditional food from a third country" means novel food as defined under point (a), other than the novel food as referred to in point (a) (-v), (-iii), (i), (ii), (iii) and (iv) which is derived from primary production as defined in Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country;
- (c) "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 13;
- (d) "the applicant" means the Member State, the third country or the interested party, who may represent several interested parties, who has submitted an application in accordance with Article 9 or 15 or a notification in accordance with Article 13 to the Commission;
- (e) "valid" *in respect to an* application *or a* notification means an application or a notification which falls in 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 3

*[This Article was moved. See Article 4a.]*

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.
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.**
- 2a. **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.**
3. The Commission **shall**, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraphs 2 and 2a, **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 27(3).**

Article 4a

*Implementing power concerning the definition of novel food in Article 2(2)(a)*

***In order to ensure the uniform implementation of this Regulation, the Commission may decide, on its own initiative or upon a Member State request, and by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).***

## **Chapter II**

### **Requirements for placing novel foods on the market within the Union**

#### *Article 5*

##### *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 6, 7 and 8 ("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 and/or used in or on foods **according to** the conditions of use **and to the labelling requirements** specified therein.

#### *Article 6*

##### *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) it does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- b) its **intended** use does not mislead the consumer, **especially when there is a significant change in the nutritional value of a food intended to replace another food.**
- c) where it 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 7*  
*Initial establishment of the Union list*

**By...**<sup>1</sup> the Commission shall, by means of an implementing act, establish the Union list by entering novel foods authorised or notified under Articles 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).

*Article 8*  
*Contents **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 9, 10 and 11 and, where applicable, in accordance with Article 25 or
  - (b) Articles 13 to 18.
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 on the Union list.

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<sup>1</sup> Publications Office: please insert date: 24 months after the entry into force of this Regulation.

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 any requirements necessary*** to avoid, in particular, 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 23.

### **Chapter III** **Authorisation procedure for a novel food**

#### **SECTION I** **GENERAL RULES**

##### *Article 9*

*The **procedure** for authorising the placing on the market within the Union of a novel food and updating the Union list.*

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 8 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. The Commission shall make the summary of the application, based on the information referred to in points (-a), (a) and (c) of paragraph 1a, publicly available.***

- 1a. The application *for an authorisation* shall include:
- (-a) *the name and address of the applicant;*
  - (a) the name and description of the novel food;
  - (aa) *the description of production process;*
  - (b) the *detailed* composition of the novel food;
  - (c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
  - (cc) *where appropriate, the analysis method(s);*
  - (d) 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.*
2. *Upon request by the Commission*, the European Food Safety Authority ("*the Authority*") shall render its opinion if the update is liable to have an effect on human health.
- 2a. *When test methods are applied to engineered nanomaterials as referred to in sub-points (ii) and (iii) of point (a) of Article 2 (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.*
3. 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 8 shall end with the adoption of an implementing act in accordance with Article 11.

4. By way of derogation from paragraph 3, the Commission may **terminate** the authorisation procedure and decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.

Where applicable, it shall take account of the views of Member States, the **Authority's** opinion and any other legitimate factors relevant to the update under consideration.

In such cases, the Commission shall inform the applicant and all Member States directly, indicating the reasons for not considering the update justified. **The Commission shall make the list of such applications publicly available.**

5. The applicant may withdraw its application at any time, thereby terminating the procedure for authorising a novel food and updating the Union list.

#### *Article 10* *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 the validation. The Authority** shall adopt its opinion within nine months from the date of receipt of a valid application.
  - 1a.* In assessing the safety of novel foods, **the Authority** shall, where appropriate, consider the following:
    - (a) whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
    - (b) whether 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) **whether 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.**

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

4. Where the additional information referred to in paragraph 3 is not **provided to the Authority** within the additional period referred to in that paragraph, it shall **draw up** its opinion on the basis of the **available** information.
5. Where applicants submit additional information on their own initiative, they shall send it to **the Authority**.

In such cases, **the Authority** shall give its opinion within the period of nine months provided for in paragraph 1.

6. **The Authority** shall make the additional information referred to in paragraphs 3 **and 5** available to the Commission and to the Member States.



*Article 11*  
*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 27(1) a draft implementing act ***authorising the placing on the market within the Union of a novel food and*** updating the Union list taking account of:
  - (a) the conditions provided for in *points (a) and (b), and, where applicable, in point (c) of* Article 6;
  - (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 27(3).

2. Where the Commission has not requested an opinion from *the Authority* in accordance with Article 9(2), the *seven*-month period provided for in paragraph 1 shall start from the date on which a valid application ***is received by the Commission*** in accordance with Article 9(1).

*Article 12*  
*Implementing acts **laying down** administrative and scientific requirements for applications*

By ...<sup>1</sup> at the latest, the Commission shall adopt implementing acts concerning:

- (a) the contents, drafting and presentation of the application referred to in Article 9(1);

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<sup>1</sup> Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

- (b) the arrangements for checking the validity, *without delay*, of those applications;
- (c) the type of information to be included in the opinion of *the Authority* referred to in Article 10.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

## SECTION II SPECIFIC RULES FOR TRADITIONAL FOODS FROM THIRD COUNTRIES

### *Article 13* *Notification of traditional foods from third countries*

*Instead of following the procedure referred to in Article 9, 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;*
- (a) the name and a description of the traditional food;
- (b) its *detailed* composition;
- (c) its country *or countries* of origin;
- (d) documented data demonstrating the history of safe food use in a third country;
- (e) *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 14*  
*Procedure for notifying **the placing on the market***  
*within the Union of traditional foods from third countries*

1. The Commission shall forward the valid notification provided for in Article 13 without delay **and not later than one month after the validation** to the Member States and to **the Authority**.
2. Within four months from the date on which the valid notification is forwarded by the Commission in accordance with paragraph 1, 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.
3. The Commission shall inform the applicant **of any duly reasoned 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.
4. Where no reasoned safety objections are made 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 are 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 nor update the Union list.

In that case, the applicant may submit an application to the Commission in accordance with Articles 15 **to 17**.

*Article 15*

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

The application provided for in the **second subparagraph of Article 14(5)** shall include in addition to the information already provided in accordance with Article 13, documented data relating to the reasoned safety objections submitted in accordance with Article 14(5).

The Commission shall forward the valid application without undue delay to **the Authority** and make it available to Member States.

*Article 16*

*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 13 and 15;
  - (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, it 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, 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 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, it shall finalise its opinion on the basis of the **available** information.
6. Where applicants submit additional information on their own initiative, they shall send it 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 available to the Commission and to Member States.

#### *Article 17*

#### *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 27(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), and, where applicable, point (c) of Article 6**;

- (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 27(3).

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

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.

In such cases, the Commission shall inform the applicant and all Member States directly, indicating the reasons for not considering the update justified.

3. The applicant may withdraw its application referred to in Article 15 at any time thereby terminating the procedure for authorising a traditional food from a third country and updating the Union list.

#### *Article 18*

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

*Articles 9 to 12 apply for* removing a traditional food from a third country from the Union list or for 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 19*  
*Implementing acts laying down administrative and scientific requirements*  
*concerning traditional foods from third countries*

By ...<sup>1</sup> the Commission shall adopt implementing acts concerning:

- (a) the contents, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5);
- (b) the arrangements for checking the validity, *without delay*, of those notifications and applications;
- (c) the procedural steps for the exchange of information with the Member States and with *the Authority* for submitting reasoned safety objections as referred to in Article 14(2), (4) and (5);
- (d) the type of information to be included in the opinion of *the Authority* referred to in Article 16.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

**Chapter IV**  
**Additional procedural rules and other requirements**

*Article 20*  
*Additional information concerning risk management*

1. Where the Commission requests additional information from an applicant 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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<sup>1</sup> Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

In such cases, the time period provided for in Article 11(1) or (2) or in Article 17(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 extended period referred to in that paragraph, the Commission shall act on the basis of the *available* information.

#### *Article 21*

#### *Ad hoc extension of time periods*

In exceptional circumstances, the Commission may extend the time periods provided for in Articles 10(1), 11(1) or (2), 16(1) and 17(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.

In such cases the Commission shall inform *the applicant and* the Member States of the extension and the reasons for *it*.

#### *Article 22*

#### *Confidentiality of applications for updates of the Union list*

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may harm their competitive position.
2. For the purposes of paragraph 1, applicants shall indicate which *parts* of the information provided they wish to be treated as confidential and provide all the necessary *details* to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.



3. After being informed of the Commission's position on the request, applicants may withdraw their application within three weeks, **during which** the confidentiality of the information provided **shall be observed**.
4. After expiry of the time period referred to in paragraph 3, **if the applicant has not withdrawn the application and in case of disagreement**, the Commission **shall** decide, **which parts of the** information **shall** remain confidential and, in case a decision has been taken, notify the Member States and the **applicant** accordingly.

However, confidentiality shall not apply to the following information:

- (a) the name and address of the applicant;
  - (b) the name and description of the novel food;
  - (c) the proposed **conditions of** use of the novel food;
  - (d) a summary of the studies submitted by the applicant;
  - (da) the results of the studies carried out to demonstrate the safety of the food;**
  - (e) where **appropriate**, the analysis method(s).
  - (ea) any prohibition or restriction imposed in respect of the food by a third country.**
5. The Commission, the Member States and **the Authority** shall take necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation in accordance with paragraph 4, except for information which is required to be made public in order to protect human health.
  6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and **the Authority** shall not disclose confidential information, including the information of which **confidentiality** is the subject of disagreement between the Commission and the applicant.

7. The application of paragraphs 1 to 6 shall not affect the *exchange* of information concerning the application between the Commission, the Member States and *the Authority*.
8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

*Article 23*  
*Post-market monitoring*

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

*Article 23a*  
*Additional information requirements*

*Any* food business operator *who has placed a novel food on the market* shall forthwith inform the Commission of *any information of which he is 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 any 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 24

#### *Authorisation procedure in case of data protection*

1. On request by the applicant, supported by appropriate and verifiable information included in the application provided for in Article 9(1), newly developed scientific evidence or scientific data supporting the application may 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. That data protection shall be granted *by the Commission under Article 25(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 *of traditional foods from third countries* concerning the placing on the market of traditional foods from third countries within the Union.

*Article 25*

*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 9 to 11*** based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 24(1), the entry of a novel food in the Union list shall indicate, in addition to the information referred to in Article 8(3):
  - (a) the date of entry of the novel food in the Union list;
  - (b) the fact that that entry is based on proprietary scientific evidence and scientific data protected in accordance with Article 24;
  - (c) the name and address of the applicant;
  - (d) the fact that the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) during the period of data protection, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data designated as such by the prior applicant or with the agreement of the ***initial*** applicant;
  - (e) the end date of the data protection provided for in Article 24.
2. Scientific evidence or scientific data protected in accordance with Article 24 or for which the protection period under that Article has expired shall not be ***granted renewed protection***.

## **Article 25a**

### **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 24 of this Regulation; and**
  - (b) an application for the authorisation of a health claim on the same novel food in accordance with Article 15 or Article 18 of Regulation (EC) No 1924/2006, in conjunction with a request for data protection in accordance with Article 21 of Regulation (EC) No 1924/2006.**

**The stay of the authorisation procedure shall be without prejudice to the assessment of the novel food by the Authority in accordance with Article 10.**

- 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 11(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 for the purposes of the time-limit laid down in Article 11(1) of this Regulation.**

5. *In the cases referred to in paragraph 1, 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 24 of this Regulation shall not exceed the period of data protection granted in accordance with Article 21 of Regulation (EC) No 1924/2006.*
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 26 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 must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ...<sup>1</sup> at the latest and shall notify it without delay of any subsequent amendment affecting them.

### *Article 27 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 (***'the committee'***). That committee shall be the committee within the meaning of Regulation (EU) No 182/2011.
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.

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<sup>1</sup> Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

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

***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.***

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.

#### ***Article 27a 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 27b, adjust and adapt the definition of engineered nanomaterials referred to in point (f) of Article 2(2) to technical and scientific progress or to definitions agreed at international level.***

#### ***Article 27b 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.***
- 1a. ***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.***



2. *The power to adopt delegated acts referred to in Article 27a shall be conferred on the Commission for a period of 5 years after [...]¹. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-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 3 months before the end of each period.*
3. *The delegation of power referred to in Article 27a 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.*
4. *As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*
5. *A delegated act adopted pursuant to Article 27a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 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 the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.*

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<sup>1</sup> Publications Office: please insert the date of entry into force of this Regulation.

## Chapter VII Transitional and final provisions

### *Article 28 Repeal*

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 are hereby repealed *from the date of application of this Regulation*.

### *Article 28a Amendments to Regulation (EU) No 1169/2011*

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

- a) *The following point (h) is added to Article 2(1) of Regulation (EU) No 1169/2011 as follows:*

*“(h) the definition of 'engineered nanomaterials' as established by point (f) of Article 2(2) of Regulation of the European Parliament and of the Council on novel foods”.*

- b) *Point (t) of Article 2(2) and Article 18(5) of Regulation (EU) No 1169/2011 are repealed.*

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

### *Article 29 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 ...<sup>1</sup> shall be ***treated*** as an application under this Regulation.

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<sup>1</sup> Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

***The Commission may not apply Article 10, where a risk assessment was already provided by a Member State on the basis of Regulation (EC) No 258/97 and no other Member State 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 at the date of ***application*** of this Regulation and which fall within the ***scope of this Regulation*** may continue to be placed on the market ***until a decision is taken according to Articles 9 to 11 or Articles 13 to 18*** 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 according to Articles 12 or 19 respectively, but no later than 24 month after the date of the application of this Regulation*** at the latest.
3. The Commission may, by means of implementing acts, adopt measures concerning ***the requirements referred to in Articles 12 and 19, necessary*** for the application of paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

*Article 30*  
*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 ...<sup>1</sup>, ***with the following derogations:***

- a) ***Articles 4(3), 7, 12, 19, 22(8), 27 and 29(3) shall apply from the date of entry into force of this Regulation;***
- b) ***Article 4(2) and (2a) shall apply from the date of application of the implementing acts referred to in Article 4(3);***

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<sup>1</sup> Publications Office: please insert date: **24** months after the date of entry into force of this Regulation.

- c) *Article 4a shall apply from the date of entry into force of this Regulation. However, implementing acts adopted under Article 4a shall not apply before....<sup>1</sup>.*
- d) *Articles 27a and 27b shall apply from the date of entry into force of this Regulation. However, delegated acts adopted under those Articles shall not apply before....<sup>2</sup>*

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

For the European Parliament,

For the Council,

The President

The President

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<sup>1</sup> Publications Office: please insert date: **24** months after the date of entry into force of this Regulation.

<sup>2</sup> *Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.*