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From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: Proposal for a Regulation of the European Parliament and of the Council
on novel foods
- Outcome of the European Parliament's first reading
(Strasbourg, 26 to 29 October 2015)

I. INTRODUCTION

The Committee on the Environment, Public Health and Food Safety submitted 90 amendments to the proposal for a Regulation (amendments 1-90). In addition:

- the EUL/NGL political group submitted one amendment (amendment 91);
- the ENF political group submitted four amendments (amendments 92-95);
- the S&D, Greens/EFA, EFDD and EUL/NGL political groups jointly submitted 24 amendments (amendments 96-99, 101-107 and 109-121);
- the S&D, Greens/EFA and EFDD political groups jointly submitted one amendment (amendment 100); and
- the S&D and EFDD political groups jointly submitted one amendment (amendment 108).

II. VOTE

When it voted on 28 October 2015, the plenary adopted 14 amendments (amendments 44, 46, 89 and 101-111).

The Commission's proposal as thus amended constitutes the Parliament's first-reading position, which is contained in its legislative resolution as set out in the Annex hereto ¹.

¹ The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics***. The symbol "■" indicates deleted text.

Novel foods *I**

European Parliament legislative resolution of 28 October 2015 on the proposal for a regulation of the European Parliament and of the Council on novel foods (COM(2013)0894 – C7-0487/2013 – 2013/0435(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0894),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0487/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the positions of both Council and European Parliament on 29 March 2011, when the conciliation on novel foods failed,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French National Assembly and the French Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 30 April 2014²,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on International Trade and the Committee on Agriculture and Rural Development (A8-0046/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

² OJ C 311, 12.9.2014, p. 73.

Position of the European Parliament adopted at first reading on 28 October 2015 with a view to the adoption of Regulation (EU) 2015/... of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

(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 Committee³,

Acting in accordance with the ordinary legislative procedure⁴,

³ OJ C 311, 12.9.2014, p.73.

⁴ Position of the European Parliament of 28 October 2015.

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.
- (2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market needs to 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 are among the objectives of the Union as established in the Treaty on European Union (TEU). It is important that all relevant Union legislation, including this Regulation, take those objectives into account.***
- (3) ***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.***

- (4) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council⁵ and by Commission Regulation (EC) No 1852/2001⁶. 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.
- (5) *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 Council⁷, *food* enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council⁸, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁹, *food* flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council¹⁰ and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council¹¹ should be excluded from the scope of this Regulation.

⁵ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁶ Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).

⁷ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

⁸ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

⁹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

¹⁰ Regulation (EC) No 1334 /2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

¹¹ Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3).

- (6) 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 Council¹².
- (7) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, *one of the criteria for food to be considered a novel food should continue to be* the absence of 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 dates of their accession.

¹² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (8) *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 that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. Those 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 for food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae, for food from microorganisms, fungi or algae and for 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.*

- (9) 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.*

- (10) *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. The term 'engineered nanomaterial' is currently defined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council¹³. 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.*

¹³ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (11) Vitamins, minerals and other substances intended to be used in food supplements *in accordance with Directive 2002/46/EC of the European Parliament and of the Council¹⁴ and Regulation (EC) No 1925/2006 of the European Parliament and of the Council¹⁵ 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 in accordance with Regulation (EU) No 609/2013 of the European Parliament and of the Council¹⁶*, should also be assessed in accordance with the rules laid down in this Regulation *when they fall within the definition of novel food set out therein.*

¹⁴ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

¹⁵ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

¹⁶ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

- (12) Where *vitamins, minerals or other substances* used in accordance *with* Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 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 where those vitamins, minerals or other substances 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.
- (13) **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 as, or in, a food supplement should be subject to this Regulation.

- (14) *Food from animal clones has been regulated under Regulation (EC) No 258/97. It is crucial that no legal ambiguity should emerge as regards the placing on the market of food from animal clones during the transitional period after 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.*
- (15) The placing on the market within the Union of traditional foods from third countries should be facilitated where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in at least one third country for at least 25 years as a part of the customary diet *of a significant number of people*. The history of safe food use should not include non-food uses or uses not related to normal diets.

- (16) **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.
- (17) 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 to a food ingredient that has not **yet** been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.

- (18) Directive 2001/83/EC of the European Parliament and of the Council¹⁷ 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.

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¹⁷ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(19) 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 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 on human consumption before 15 May 1997 or **the** information available **is insufficient**, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information.



(20) 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.

(21) 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, the Union list by including *in that list* the novel foods already authorised or notified in accordance with ■ Regulation (EC) No 258/97 ■ , including any existing authorisation conditions. *That list* should be *transparent and easily accessible*.

(22) 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 food 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.

(23) 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 give its opinion if the update is liable to have an effect on 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.*

(24) *The Commission and 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 the right to extend those deadlines.*

(25) 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, as required, 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.

(26) As regards the possible use of nanomaterials for food use, *the Authority* considered in its opinion of 6 April 2011 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 Organisation for Economic Co-operation and Development Council Recommendation of 19 September 2013 on the Safety Testing and Assessment of Manufactured Nanomaterials 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*.

(27) 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 those materials.

*(28) 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 risk 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 the food they have placed on the market.***

*(29) **New technologies and innovations in food production should be encouraged as they 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.***

(30) 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 *of a novel food* 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.

(31) 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 Council¹⁸, 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.

¹⁸ 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).

(32) *In accordance with Directive 2010/63/EU of the European Parliament and of the Council¹⁹, 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.*

(33) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 ■ 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.*

(34) *Materials and articles intended to come into contact with novel foods are subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council²⁰ and the specific measures adopted thereunder.*

¹⁹ *Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).*

²⁰ *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).*

(35) 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 procedures on traditional foods from third countries.

(36) For those applications which have been submitted under Regulation (EC) No 258/97 ***and for which 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 (EC) No 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.

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

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

(39) In order to achieve the objectives of this Regulation, the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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.

(40) In order to ensure uniform conditions for the implementation of this Regulation with regard to updating the Union list concerning the adding of a traditional food from a third country where no reasoned safety objections have been expressed, implementing powers should be conferred on the Commission.

(41) 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, have been 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.

(42) Since the objectives of this Regulation, *in particular the* laying down *of* 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 TEU. 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 those objectives,

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.
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;

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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.

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 microorganisms, 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
- *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.
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*;
- (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 ...⁺ 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:

⁺ OJ: please insert date: 24 months after the entry into force of this Regulation.

- (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.

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*

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 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), (b) and (e) of paragraph 2 of this Article, publicly available.***

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

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.

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.

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 ...⁺, 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;

⁺ OJ: please insert date: 24 months after the date of entry into force of this Regulation.

(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 a 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*.
2. Within four months from the date on which a 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 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.

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).

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

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.*

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.

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 ...⁺ 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;

⁺ OJ: please insert date: 24 months after the date of entry into force of this Regulation.

- (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.

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.

Article 23

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 period referred to in paragraph 3, **if an applicant has not withdrawn the application and in case of disagreement** the Commission **shall** decide **■** which **parts of the information are to** 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;
- (e) *the results of the studies carried out to demonstrate the safety of the food;*
- (f) where *appropriate*, the analysis method(s);
- (g) *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 as *referred to in paragraph 4* and received by them under this Regulation, 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 30(3).

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. That 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;
 - (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.

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 ...⁺ 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.

⁺ OJ: please insert date: 24 months after the date of entry into force of this Regulation.

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 nanomaterials referred to in point (f) of Article 3(2) to technical and scientific progress or to definitions agreed at international level.

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 ...⁺. 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.*

⁺ *OJ: please insert the date of entry into force of this Regulation.*

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/...⁺ of the European Parliament and of the Council^{*}.

**** Regulation (EU) 2015/ ... of the European Parliament and of the Council of ... 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 ...).⁺⁺***

2) Point (t) of Article 2(2) is 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 3(2) of this Regulation.

3) In Article 18, paragraph 5 is repealed.

⁺ OJ: Please insert the number of this Regulation.

⁺⁺ OJ: Please insert the number, date and publication reference of this Regulation.

Article 34

Repeal

**Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 are hereby repealed from ...⁺.
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 ...⁺⁺ 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.

⁺ OJ: Please insert **the date: 24 months after the date of the entry into force of this Regulation.**

⁺⁺ OJ: please insert date: 24 months after the date of entry into force of this Regulation.

2. Foods *not falling within the scope of Regulation (EC) No 258/97*, which are lawfully placed on the market by...⁺ 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 ...*⁺⁺. █

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).

⁺ OJ: please insert the date of *application* of this Regulation.

⁺⁺ OJ: please insert date: 24 months after the date of application of this Regulation.

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 ...⁺, ***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 ...⁺⁺;***
- (b) Article 4(2) and (3) shall apply from the date of application of the implementing acts referred to in Article 4(4);***
- (c) Article 5 shall apply from ...⁺⁺. However, implementing acts adopted under Article 5 shall not apply before...⁺.***
- (d) Articles 31 and 32 shall apply from ...⁺⁺. However, delegated acts adopted under those Articles shall not apply before...⁺.***

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

■ Done at...

For the European Parliament

For the Council

The President

The President

⁺ OJ: please insert date: 24 months after the date of entry into force of this Regulation.

⁺⁺ OJ: please insert ***the date of entry into force of this Regulation.***