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*Committee on Agriculture and Rural Development*

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**2013/0435(COD)**

14.10.2014

# **AMENDMENTS**

## **31 - 307**

**Draft opinion**  
**Daciana Octavia Sârbu**  
(PE537.498v02-00)

Proposal for a regulation of the European Parliament and of the Council on novel foods

Proposal for a regulation  
(COM(2013)0894 – C7-0487/2013 – 2013/0435(COD))

AM\_Com\_LegOpinion

**Amendment 31**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Recital 1**

**Text proposed by the Commission**

(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, as well as *benefitting* 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 unfair conditions of competition.

**Amendment**

(1) The free movement of safe and wholesome food is an essential aspect and contributes significantly to the health and well-being of citizens, as well as *benefitting* 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 unfair conditions of competition.

Or. es

**Amendment 32**  
**Giulia Moi**

**Proposal for a regulation**  
**Recital 1**

*Text proposed by the Commission*

(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, as well as *benefitting* 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 unfair conditions of competition.

*Amendment*

(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, as well as *benefitting* 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 unfair conditions of competition, *as well as among agri-food business operators and SMEs*.

Or. en

**Amendment 33**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Recital 1 a (new)**

**Text proposed by the Commission**

**Amendment**

*(1a) The right to produce and consume healthy food that is free of pesticides, GMOs, hormones and antibiotics that may pose a risk to human and animal health or to the environment is part of the fight for food sovereignty and a fundamental human right.*

Or. es

**Amendment 34**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

*Amendment*

(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.

(2) A high level of protection of human health and of consumers' interests, ***of the environment and animal welfare***, and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency. ***At all times, moreover, the precautionary principle as laid down in 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<sup>1a</sup>, should be applied.***

*Justification*

*It is appropriate to reintroduce this amendment, which had been included in European Parliament's second reading position from 2010.*

**Amendment 35**

**Pablo Iglesias**

**Proposal for a regulation**

**Recital 2**

**Text proposed by the Commission**

(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***.

**Amendment**

(2) A high level of protection of human health and of consumers' interests should be assured in the pursuit of Union food policies, ***and these should be given priority over the interests of the internal market***.

**Amendment 36**

**Nicola Caputo**

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

(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.

*Amendment*

(2) A high level of protection of human health, ***based on the precautionary principle***, 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.

**Amendment 37**

**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

(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.

*Amendment*

(2) A high level of protection of human health and of consumers' interests and ***of the environment and*** the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency.

Or. en

**Amendment 38**

**Viorica Dăncilă**

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

(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.

*Amendment*

(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 on the European Union.***

Or. en

**Amendment 39**

**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

(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.

*Amendment*

(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. ***Due attention should be given to the protection of the environment.***

Or. en

**Amendment 40**

**Daniel Buda**

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

(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.

*Amendment*

(2) A high level of protection of human health, consumers' interests, ***the environment and animal health*** and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency.

Or. ro

**Amendment 41**

**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**

**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2a) Article 13 of the Treaty on the Functioning of the European Union provides that the Union and the Member States are to pay full regard to the welfare***

*requirements of animals when formulating and implementing, inter alia, the Union's agriculture, fisheries and internal market policies. When implementing this Regulation, therefore, due attention should be given to the welfare of animals and implementation should be fully in line with all relevant provisions of Union law on animal welfare, including Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes and 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.*

Or. en

**Amendment 42**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

*Amendment*

*(5) The existing categories of novel food laid down in Article 1 of Regulation (EC) No 258/97 should be clarified and updated by replacing the existing categories with a reference to the general definition of food provided for in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>15</sup>.*

*deleted*

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<sup>15</sup> *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).*



**Amendment 43**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

*(5a) This Regulation should apply to foods and food ingredients which fall under the following categories: foods and food ingredients with a new or intentionally modified primary molecular structure; foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances. The list should be kept open in order to keep pace with scientific progress and new products development. If new categories are included, these should be well defined, justified from a safety perspective and assessed on impact.*

Or. en

**Amendment 44**  
**Paul Brannen**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

*Amendment*

(6) In order to ensure continuity with the rules laid down in Regulation (EC) No

(6) In order to ensure continuity with the rules laid down in Regulation (EC) No

258/97, 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, should be maintained as a criterion for a food to be considered as a novel food. A 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.

258/97, the absence of a use for human consumption *and placing on the market* within the Union before the date of entry into force of that Regulation, namely 15 May 1997, should be maintained as a criterion for a food to be considered as a novel food. A 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.

Or. en

### *Justification*

*Consequence of changes proposed in Article 2.2(a).*

## **Amendment 45** **Nicola Caputo**

### **Proposal for a regulation** **Recital 6**

#### *Text proposed by the Commission*

(6) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, 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, should be maintained as a criterion for a food to be considered as a novel food. A 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.

#### *Amendment*

(6) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree, *interpreted as available in supermarkets, general food outlets or pharmacies*, within the Union before the date of entry into force of that Regulation, namely 15 May 1997, should be maintained as a criterion for a food to be considered as a novel food. A 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.

Or. en

## Amendment 46

José Bové

on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Recital 7

*Text proposed by the Commission*

(7) Emerging technologies in food production processes *may* have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food *or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council*<sup>16</sup>.

*Amendment*

(7) Emerging technologies in food production processes have an impact on food and thereby on food safety, *consumer health and the environment*. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food.

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<sup>16</sup> *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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).*

Or. fr

## Amendment 47

Viorica Dăncilă

**Proposal for a regulation**

**Recital 7**

*Text proposed by the Commission*

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, ***it should also be clarified*** that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food ***or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council***<sup>16</sup>.

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<sup>16</sup> ***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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).***

*Amendment*

(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 as a novel food where a production process which was not previously used for food production in the Union is applied to that food.

Or. en

**Amendment 48**

**Lidia Senra Rodríguez**

**Proposal for a regulation**

**Recital 7**

### Text proposed by the Commission

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food ***or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council***<sup>16</sup>.

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

### Amendment

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food.

Or. es

### Amendment 49 Diane Dodds

#### Proposal for a regulation Recital 7

#### *Text proposed by the Commission*

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. ***Therefore, it should also be clarified that a food should be considered as a novel food*** where a production process which

#### *Amendment*

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Where a production process which was not previously used for food production in the Union is applied to that food, or when

was not previously used for food production in the Union is applied to that food or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>16</sup>.

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

foods contain or consist of engineered nanomaterials, *relevant testing methods should be carried out before the food is declared a "novel food"* as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>16</sup>.

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Or. en

## **Amendment 50**

**Pablo Iglesias**

### **Proposal for a regulation**

#### **Recital 7**

##### **Text proposed by the Commission**

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t)

##### **Amendment**

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t)

of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>16</sup>.

of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>16</sup>.  
***It must be clear that if a food is changed by a new production process such as nanotechnology or nanoscience (about which not enough is known to carry out a risk assessment), that food must only be placed on the market if it has been assessed as safe by means of a valid risk assessment.***

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Or. es

## **Amendment 51**

**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

### **Proposal for a regulation**

**Recital 7**

*Text proposed by the Commission*

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>16</sup>.

*Amendment*

(7) Emerging technologies in food production processes may have an impact on food and thereby on food safety ***and on the environment***. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food or when foods contain or consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council<sup>16</sup>.

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

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<sup>16</sup> 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 Regulation (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 Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Or. en

## **Amendment 52**

**José Bové**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Recital 8 a (new)**

*Text proposed by the Commission*

*Amendment*

***(8a) Foods with a new or intentionally modified primary molecular structure, foods consisting of, or isolated from, micro-organisms, fungi or algae, new strains of micro-organism with no history of safe use and concentrates of substances that naturally occur in plants should be considered as novel foods as defined in this Regulation.***

Or. en

*Justification*

*It is appropriate to reintroduce this amendment, which had been included in European Parliament's second reading position from 2010.*



## Amendment 53

José Bové

on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Recital 9

*Text proposed by the Commission*

(9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, **or a change in particle size of such a substance, for example through nanotechnology**, it **may have** an impact on food and thereby on food safety. Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.

*Amendment*

(9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, it **has** an impact on food and thereby on food safety, **consumer health and the environment**. Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation. **When there is a change in the particle size of such a substance, for example through nanotechnology, the substance must be prohibited.**

Or. fr

## Amendment 54

Lidia Senra Rodríguez

### Proposal for a regulation

#### Recital 9

**Text proposed by the Commission**

(9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, **or a change in particle size of such a substance, for example through**

**Amendment**

(9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, **that** change may have an impact on food and thereby on food safety.

*nanotechnology*, it may have an impact on food and thereby on food safety. Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.

Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.

Or. es

**Amendment 55**  
**Paul Brannen**

**Proposal for a regulation**  
**Recital 9**

*Text proposed by the Commission*

(9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, or a change in particle size of such a substance, for example through nanotechnology, it may have an impact on food and thereby on food safety. Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.

*Amendment*

(9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, or a change in particle size of such a substance, for example through nanotechnology, it may have an impact on food and thereby on food safety. Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation, **after full risk assessment**, and subsequently in accordance with the relevant specific legislation.

Or. en

*Justification*

*Consequence of changes proposed in Article 2.2(a)(i).*

**Amendment 56**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(10) If, prior to 15 May 1997, a food was used exclusively as, or in, a food supplement, as defined in point (a) of Article 2 of Directive 2002/46/EC, it should be allowed to be placed on the market within the Union after that date for the same use without being considered 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.

*Amendment*

(10) If, prior to 15 May 1997, a food was used exclusively as, or in, a food supplement, as defined in point (a) of Article 2 of Directive 2002/46/EC, it should be allowed to be placed on the market within the Union after that date for the same use without being considered 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, ***interpreted as available in supermarkets, general food outlets or pharmacies***, 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.

Or. en

**Amendment 57**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

(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 within a large part of***

*Amendment*

(11) Traditional foods from third countries should ***automatically go through a full risk assessment by EFSA at the beginning of the procedure, even if no reasoned safety objections are presented.***

*the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.*

Or. en

**Amendment 58**  
**Giulia Moi**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

(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 within a large part of the population of the country. *The* history of safe food use *should not include non-food uses or* uses not related to normal diets.

*Amendment*

(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 *normal daily* diet within a large part of the population of the country. *Their safety assessment and management must take into account their* history of safe food use *in the third country, excluding non - food uses,* uses not related to normal diets *and uses for medical purposes.*

Or. en

**Amendment 59**  
**Marc Tarabella**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

(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

*Amendment*

(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 within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

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 within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets. ***Account should also be taken of the fact that the structure and properties of foods from third countries can vary according to climatic conditions.***

Or. fr

#### **Amendment 60**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

#### **Proposal for a regulation**

#### **Recital 11**

##### *Text proposed by the Commission*

(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 within a **large** part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

##### *Amendment*

(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 within a **significant** part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. fr

##### *Justification*

*The word 'significant' is more appropriate here.*

#### **Amendment 61**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Recital 11 a (new)**

*Text proposed by the Commission*

*Amendment*

***(11a) The determination of whether or not consumption of a food by the population of a third country is significant should be based on information supplied by food business operators and, where appropriate, backed up by other information available in the third country. When there is insufficient information on human consumption of a food, a simple and transparent procedure involving the Commission, the EFSA and food business operators should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps in such a consultation process.***

Or. fr

*Justification*

*To clarify how 'significant' consumption is determined.*

**Amendment 62**  
**Lidia Senra Rodríguez**

**Proposal for a regulation**  
**Recital 12**

**Text proposed by the Commission**

**Amendment**

(12) It should be clarified that 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 Article 3 of Regulation (EC) No 178/2002, regardless of whether or not they are processed or unprocessed foods. Therefore,

(12) It should be clarified that 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 Article 3 of Regulation (EC) No 178/2002, regardless of whether or not they are processed or unprocessed foods. Therefore,

where a new production process has been applied to this food *or where the food contains or consists of ‘engineered nanomaterials’* as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011, the food should not be considered to be traditional.

where a new production process has been applied to this food as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011, the food should not be considered to be traditional.

Or. es

**Amendment 63**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 13**

*Text proposed by the Commission*

(13) Food products produced from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food, their composition or amount, should not be considered as novel foods. However, modifications of a food ingredient, such as selective extracts or the use of other parts of a plant, that have so far not been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.

*Amendment*

(13) Food products produced from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food, their composition or amount, should not be considered as novel foods. However, modifications of a food ingredient, such as selective extracts or the use of other parts of a plant, that have so far not been used for human consumption to a significant degree, *interpreted as available in supermarkets, general food outlets or pharmacies*, within the Union, should fall within the scope of this Regulation.

Or. en

**Amendment 64**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Recital 15**

**Text proposed by the Commission**

*(15) Implementing powers should be*

**Amendment**

*deleted*

*conferred to the Commission to decide whether a particular food falls within the definition of a novel food and is thereby subject to rules on novel food laid down in this Regulation.*

Or. es

**Amendment 65**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 15**

*Text proposed by the Commission*

*Amendment*

*(15) Implementing powers should be conferred to the Commission to decide whether a particular food falls within the definition of a novel food and is thereby subject to rules on novel food laid down in this Regulation.*

*deleted*

Or. en

*Justification*

*A decision on the scope is essential for the Regulation and should therefore not be taken by implementing acts.*

**Amendment 66**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 16**

*Text proposed by the Commission*

*Amendment*

(16) The determination of whether a food was used for human consumption to a significant degree within the Union before

(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 they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, *involving the Commission, the Member States and food business operators*, should be established for collecting such information. *Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.*

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 they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure should be established for collecting such information.

Or. en

#### *Justification*

*Simplification, avoiding implementing acts.*

#### **Amendment 67** **Pablo Iglesias**

#### **Proposal for a regulation** **Recital 16**

##### **Text proposed by the Commission**

(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 they intend to place on the market. When

##### **Amendment**

(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 *about* the status of the food they intend to place on the market. When there is no

there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.

information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.

Or. es

**Amendment 68**  
**Michel Dantin**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(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 they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.

*Amendment*

*(Does not affect English version.)*

Or. fr

## *Justification*

*(Does not affect English version.)*

### **Amendment 69**

**Nicola Caputo**

#### **Proposal for a regulation**

##### **Recital 16**

###### *Text proposed by the Commission*

(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 they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.

###### *Amendment*

(16) The determination of whether a food was used for human consumption to a significant degree, ***interpreted as available in supermarkets, general food outlets or pharmacies***, 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 they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.

Or. en

### **Amendment 70**

**Pablo Iglesias**

#### **Proposal for a regulation**

##### **Recital 16 a (new)**

**Text proposed by the Commission**

**Amendment**

*(16a) Ethical and environmental aspects must be considered as part of the risk assessment during the authorisation procedure. Those aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively.*

Or. es

**Amendment 71**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 17**

*Text proposed by the Commission*

(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 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.

*Amendment*

(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 their use should not mislead the consumer, ***which implies clear and precise labelling***. 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, ***or have negative effects on their health. The assessment of the safety of a novel food should be based on the precautionary principle as laid down in Article 7 of Regulation (EC) No 178/2002.***

Or. en

**Amendment 72**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

## Proposal for a regulation

### Recital 17

#### *Text proposed by the Commission*

(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 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.

#### *Amendment*

(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 their use should not mislead the consumer. ***Product labelling requirements are therefore of the utmost importance, particularly if the novel food has been created using new rearing or farming methods, new materials or new production processes.*** 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.

Or. pl

## Amendment 73

Daniel Buda

## Proposal for a regulation

### Recital 17

#### *Text proposed by the Commission*

(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 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.

#### *Amendment*

(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 their use should not mislead the consumer. Therefore ***consumers should be informed about the content of novel foods, the ingredients and the technologies used in the manufacture thereof. Similarly,*** 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.

Or. ro

**Amendment 74**  
**Diane Dodds**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

(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 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.

*Amendment*

(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 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 ***or inferior quality*** for the consumer.

Or. en

**Amendment 75**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(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 novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. ***As those novel foods have already been evaluated for their safety, have been legally***

*Amendment*

(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 a Union list of novel foods by entering novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. ***The initial Union list of authorised novel foods, which constitutes a key element, should be annexed to this***

*produced and marketed in the Union and have not given rise to health concerns in the past, the advisory procedure should be used for the initial establishment of the Union list.*

*Regulation and the list should be updated by means of delegated acts.*

Or. en

#### **Amendment 76**

**José Bové**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 18**

###### *Text proposed by the Commission*

(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 novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. ***As those novel foods have already been evaluated for their safety, have been legally produced and marketed in the Union and have not given rise to health concerns in the past, the advisory procedure should be used for the initial establishment of the Union list.***

###### *Amendment*

(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 a Union list of novel foods by entering novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions.

Or. en

###### *Justification*

*The list of novel foods should be annexed to this Regulation, and updated by means of delegated acts.*

**Amendment 77**  
**Jan Huitema, Ivan Jakovčić, Ulrike Müller**

**Proposal for a regulation**  
**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) New technologies and innovations like biotechnology and nanotechnology in food production should be fostered as this could reduce the environmental impact of food production, enhance food security and bring benefits to consumers. Developments in food production should therefore always be judged according to the latest available scientific evidence in order to ensure sound scientific confirmation of European food safety.***

Or. en

**Amendment 78**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

*Amendment*

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the 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 it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. ***As the updating of the Union***

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the 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 it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. ***The power to adopt acts in***



*list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.*

*accordance with Article 290 TFEU should therefore be delegated to the Commission, in order to update the list.*

Or. en

#### *Justification*

*Since those measures are of general application and are designed to supplement or amend certain non-essential elements of this Regulation, the Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to update the list.*

#### **Amendment 79** **Nicola Caputo**

#### **Proposal for a regulation** **Recital 19**

##### *Text proposed by the Commission*

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the 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 it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. ***As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.***

##### *Amendment*

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the 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 it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. ***Delegated powers, in accordance with Article 290 TFEU, should therefore be conferred on the Commission in order to update the Union list.***

Or. en

#### **Amendment 80** **Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

## Proposal for a regulation

### Recital 19

*Text proposed by the Commission*

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the 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 it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.

*Amendment*

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the 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 it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect. ***The Union list should be easily accessible and fully transparent.***

Or. pl

## Amendment 81

Nicola Caputo

## Proposal for a regulation

### Recital 20

*Text proposed by the Commission*

(20) Criteria for the evaluation of the safety risks arising from novel foods should also be 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 ('EFSA').

*Amendment*

(20) Criteria for the evaluation 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 ('EFSA'). ***EFSA, whose assessments should be undertaken in a transparent manner, should set up a network with Member States and the Advisory Committee on Novel Foods and Processes***

*(ACNFP). Any novel characteristic that may have an impact on health should be assessed on an individual basis.*

Or. en

**Amendment 82**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 21**

*Text proposed by the Commission*

*Amendment*

*(21) As regards the possible use of nanomaterials for food use, EFSA 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<sup>21</sup> 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. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.*

*deleted*

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<sup>21</sup> «Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain», *EFSA Journal* 2011; 9(5):2140.

Or. fr

**Amendment 83**

**Diane Dodds**

**Proposal for a regulation**  
**Recital 21**

*Text proposed by the Commission*

(21) As regards the possible use of nanomaterials for food use, EFSA 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. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.

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<sup>21</sup> EFSA Journal 2011;9(5):2140.

*Amendment*

(21) As regards the possible use of nanomaterials for food use, EFSA 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 **insufficient** information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.

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<sup>21</sup> EFSA Journal 2011;9(5):2140.

Or. en

**Amendment 84**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 21**

*Text proposed by the Commission*

(21) As regards the possible use of nanomaterials for food use, EFSA 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

*Amendment*

(21) As regards the possible use of nanomaterials for food use, EFSA 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. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.

testing methods may need methodological modifications. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials. *The assessment of nanomaterials in food or food ingredient should include details of the composition, nutritional value, metabolism, intended use, the level of microbiological and chemical contaminants, studies into the potential for toxic, nutritional and allergenic effects and details of the manufacturing process used to process the food or food ingredient. When carrying out the scientific safety assessment, consumer concerns and ethical issues should also be considered.*

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<sup>21</sup> EFSA Journal 2011;9(5):2140.

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<sup>21</sup> EFSA Journal 2011;9(5):2140.

Or. en

**Amendment 85**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Recital 21 a (new)**

**Text proposed by the Commission**

**Amendment**

*(21a) Foods produced with engineered nanomaterials or nanomaterials for use in food subject to testing methods by the Commission should not be included in the Union list until they have been assessed and certified as food that is healthy and safe to eat.*

Or. es

**Amendment 86**  
**Giulia Moi**

**Proposal for a regulation**  
**Recital 21 a (new)**

*Text proposed by the Commission*

*Amendment*

***(21a) The safety assessment and post market monitoring shall consider whether the compositional parameters of novel foods are subjected to significant changing due to lower hygienic controls and poor agriculture practices.***

Or. en

**Amendment 87**  
**Daciana Octavia Sârbu**

**Proposal for a regulation**  
**Recital 21 a (new)**

*Text proposed by the Commission*

*Amendment*

***(21a) Food from cloned animals has been regulated under Regulation (EC) No 258/1997 and is due to be prohibited under the forthcoming regulation on the placing of the market of food from animal clones. In accordance with this forthcoming regulation, food from cloned animals should be excluded from the scope of this Novel Food Regulation and should not be placed on the market in the Union.***

Or. en

**Amendment 88**  
**José Bové**  
on behalf of the Verts/ALE Group

## Proposal for a regulation

### Recital 22

*Text proposed by the Commission*

(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 EFSA.

*Amendment*

(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 EFSA. ***In any event, food business operators should inform the Commission of any relevant information regarding the food they have placed on the market.***

Or. en

## Amendment 89

**José Bové**

on behalf of the Verts/ALE Group

## Proposal for a regulation

### Recital 23

*Text proposed by the Commission*

***(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 innovators 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 prior applicant. The protection of scientific data provided by***

*Amendment*

*deleted*

*one 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 prior applicant. However, the overall five year period of data protection which has been granted to the prior applicant should not be extended due to the granting of data protection to subsequent applicants.*

Or. fr

**Amendment 90**  
**Daniel Buda**

**Proposal for a regulation**  
**Recital 23**

*Text proposed by the Commission*

(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 innovators 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 prior applicant. The protection of scientific data provided by one 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 prior applicant. However, the overall five year period of data protection which has been granted to the prior applicant

*Amendment*

(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 innovators 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. ***However, the protection of scientific data should not allow concealment of the content of novel foods or the technological process used.*** 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 prior applicant. The protection of scientific data provided by one 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



should not be extended due to the granting of data protection to subsequent applicants.

protected data with the agreement of the prior applicant. However, the overall five year period of data protection which has been granted to the prior applicant should not be extended due to the granting of data protection to subsequent applicants.

Or. ro

## **Amendment 91**

**Giulia Moi**

### **Proposal for a regulation**

#### **Recital 24**

##### *Text proposed by the Commission*

(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 on the provision of food information to consumers 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 or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

##### *Amendment*

(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 on the provision of food information to consumers and other relevant labelling requirements in Union food law. ***It is*** necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food, ***especially for those coming from third countries.***

Or. en

## **Amendment 92**

**José Bové**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Recital 24**

##### *Text proposed by the Commission*

(24) Novel foods are subject to the general

##### *Amendment*

(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 on the provision of food information to consumers 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 or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. ***There is a need for*** additional labelling information, in particular regarding the description of the food, its source or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

Or. fr

**Amendment 93**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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 on the provision of food information to consumers 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 or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

*Amendment*

(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 on the provision of food information to consumers 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 or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food. ***Materials that give rise to ethical concerns, as in current Regulation (EC) No 258/97, should also be indicated on the label in order to allow the consumers to make informed choices.***

Or. en

**Amendment 94**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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 on the provision of food information to consumers 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 or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

*Amendment*

(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 on the provision of food information to consumers 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 or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

***Therefore, when a novel food is included in the Union list or in the list of traditional foods from third countries, specific conditions of use or labelling obligations may be imposed, which might, inter alia, relate to any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population. It is appropriate to lay down in this Regulation specific labelling obligations in respect of food ingredients present in the form of engineered nanomaterials which fall within the scope of this Regulation.***

Or. en

**Amendment 95**  
**Viorica Dăncilă**

**Proposal for a regulation**  
**Recital 25 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 96**  
**Giulia Moi**

**Proposal for a regulation**  
**Recital 26**

*Text proposed by the Commission*

*Amendment*

(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.

(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 ***shall be harmonised,*** effective, proportionate and dissuasive.

Or. en

**Amendment 97**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

*Amendment*

(27) ***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

(27) 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, ***the power to adopt delegated acts in***

no reasoned safety objections have been expressed, **implementing powers** should be conferred on the Commission.

**accordance with Article 290 TFEU** should be conferred on the Commission.

Or. en

#### *Justification*

*Since those measures are of general application and are designed to supplement or amend certain non-essential elements of this Regulation, the Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to update the list.*

### **Amendment 98**

**Nicola Caputo**

#### **Proposal for a regulation**

##### **Recital 27**

###### *Text proposed by the Commission*

(27) ***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.***

###### *Amendment*

(27) ***The initial*** Union list ***of*** traditional food from a third country ***should be annexed to this Regulation and the list should be updated by means of delegated acts.***

Or. en

### **Amendment 99**

**José Bové**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 28**

###### *Text proposed by the Commission*

(28) The implementing powers relating to the ***definition of 'novel food', the consultation process for determination of***

###### *Amendment*

(28) The implementing powers relating to the drafting and presentation of applications or notifications for the

*novel food status, other updates of the Union list, the drafting and presentation of applications or notifications for the inclusion of foods in the Union list, the arrangements for checking the validity of applications or notifications, confidentiality treatment and transitional provisions*, should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>22</sup>.

inclusion of foods in the Union list *and* the arrangements for checking the validity of applications or notifications should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>22</sup>. *The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the authorisation of novel foods and of traditional foods from a third country, the updating of the Union list, and the consultation process for determination of a novel food status. 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.*

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<sup>22</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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<sup>22</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

**Amendment 100**  
**Nicola Caputo**

**Proposal for a regulation**  
**Recital 28**

*Text proposed by the Commission*

(28) The implementing powers relating to the *definition of 'novel food', the*

*Amendment*

(28) The implementing powers relating to the consultation process for determination

consultation process for determination of novel food status, *other updates of the Union list*, the drafting and presentation of applications or notifications for the inclusion of foods in the Union list, the arrangements for checking the validity of applications or notifications, confidentiality treatment *and transitional provisions*, should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>22</sup> .

of novel food status, the drafting and presentation of applications or notifications for the inclusion of foods in the Union list, the arrangements for checking the validity of applications or notifications *and* confidentiality treatment should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>22</sup> .

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<sup>22</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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<sup>22</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

#### **Amendment 101**

**José Bové**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Recital 28 a (new)**

*Text proposed by the Commission*

*Amendment*

***(28a) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>1 a</sup> lays down general rules for the performance of official controls to verify compliance with food law. Therefore, the Member States are to carry out official controls in accordance with Regulation (EC) No 882/2004, in order to enforce***

*compliance with the present Regulation.*

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*<sup>1a</sup> OJ L 165, 30.4.2004, p. 1. Corrected version (OJ L 191, 28.5.2004, p. 1). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).*

Or. en

#### *Justification*

*A specific reference to the Regulation on official controls had been included in the Commission proposal from 2008, and it is appropriate to keep this reference.*

#### **Amendment 102**

**Pablo Iglesias**

#### **Proposal for a regulation**

#### **Article 1 – paragraph 1**

##### **Text proposed by the Commission**

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure *the effective functioning of the internal market while providing* a high level of *protection of* human health and *consumer* interests.

##### **Amendment**

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure a high level of human *and animal* health *protection, and also protects the social and economic* interests *of consumers. At the same time, national differences relating to assessment of the safety of novel foods and their authorisation may not only constitute an obstacle to the free movement of these products, thus giving rise to unfair competition, but also pose a risk to human and animal health.*

Or. es

#### **Amendment 103**

**Anja Hazekamp**



**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure ***the effective functioning of the internal market while providing*** a high level of protection of human health ***and*** consumer interests.

*Amendment*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure a high level of protection of human health, ***animal health and welfare***, consumer interests ***and the environment, whilst ensuring transparency***.

Or. en

**Amendment 104**  
**Stefan Eck**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market ***while providing a high level of*** protection of ***human*** health and ***consumer interests***.

*Amendment*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure ***a high level of protection of human health and consumers' interests and*** the effective functioning of the internal market, ***whilst ensuring transparency and, where relevant, the*** protection of ***the environment and animal*** health and ***welfare***.

Or. en

**Amendment 105**  
**Marc Tarabella**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health **and** consumer interests.

*Amendment*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health **and well-being**, consumer interests **and food quality**.

Or. fr

**Amendment 106**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 1 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests.

*Amendment*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests **and prohibiting the placing on the market of foods in which nanomaterials are used**,

Or. fr

*Justification*

*There are currently no reliable, scientifically recognised methods for assessing the short-, medium- and long-term impact that nanotechnologies have on health and the environment.*

**Amendment 107**

**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

**Proposal for a regulation**

**Article 1 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests.

*Amendment*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health, **the environment** and consumer interests.

Or. en

**Amendment 108**

**Giulia Moi**

**Proposal for a regulation**

**Article 1 – paragraph 2 – point a**

*Text proposed by the Commission*

(a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;

*Amendment*

(a) genetically modified foods **and their derivatives** falling within the scope of Regulation (EC) No 1829/2003;

Or. en

**Amendment 109**

**Daciana Octavia Sârbu**

**Proposal for a regulation**

**Article 1 – paragraph 2 – point c**

*Text proposed by the Commission*

**(c) food falling within the scope of Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones].**

*Amendment*

**deleted**

Or. ro

**Amendment 110**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Article 1 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) food falling within the scope of Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones].

*Amendment*

(c) food falling within the scope of Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones].  
***Until Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones] enters into force, foods derived from cloned animals and their descendants shall not be authorised and/or placed on the Union list of novel foods authorised to be placed on the market within the Union.***

Or. en

**Amendment 111**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 1 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) food falling within the scope of Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones].

*Amendment*

(c) food falling within the scope of Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones].  
***Until the date of application of that Directive, no food from cloned animals and/or their descendants shall be placed on the market.***

Or. en

**Amendment 112**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 1 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. The purpose of this Regulation is to provide a high level of protection of consumers' interests, and of animal welfare and the environment, while ensuring the effective functioning of the internal market.**

Or. en

*Justification*

*This amendment combines amendment 28 of the draft report with European Parliament's 2010 second reading amendment.*

**Amendment 113**  
**Daciana Octavia Sârbu**

**Proposal for a regulation**  
**Article 1 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. Food derived from cloned animals shall not be placed on the Union list of novel foods or be placed on the market.**

Or. en

**Amendment 114**  
**Paul Brannen**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

(a) 'novel food' means all food that was not used for human consumption **to a**

(a) 'novel food' means all food that was not used for human consumption **and**

*significant degree* within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular:

*marketed* within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular:

Or. en

*Justification*

*The proposed wording is too vague. Since the rationale of the regulation is to address authorisation procedure of novel foods on the EU market, it seems sensible to take the fact of marketing of foodstuffs as a threshold factor.*

**Amendment 115**  
**Daciana Octavia Sârbu**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – introductory part**

*Text proposed by the Commission*

(a) ‘novel food’ means all 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 *includes in particular*:

*Amendment*

(a) ‘novel food’ means all 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*:

Or. en

**Amendment 116**  
**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – introductory part**

*Text proposed by the Commission*

(a) "novel food" means all food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the date of

*Amendment*

(a) "novel food" means all 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 ***includes in particular:***

accession of the various Member States to the Union and ***that falls into at least one of the following categories:***

Or. fr

*Justification*

*To enhance legal certainty.*

**Amendment 117**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – introductory part**

*Text proposed by the Commission*

(a) ‘novel food’ means all 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 includes in particular:

*Amendment*

(a) ‘novel food’ means all food that was not used for human consumption to a significant degree, ***interpreted as available in supermarkets, general food outlets or pharmacies,*** within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular:

Or. en

**Amendment 118**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i a (new)**

*Text proposed by the Commission*

*Amendment*

***(ia) foods and food ingredients with a new or intentionally modified primary molecular structure;***

Or. en

**Amendment 119**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i b (new)**

*Text proposed by the Commission*

*Amendment*

***(ib) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;***

Or. en

**Amendment 120**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i c (new)**

*Text proposed by the Commission*

*Amendment*

***(ic) foods and food ingredients to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances;***

Or. en

**Amendment 121**  
**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point -i (new)**

*Text proposed by the Commission*

*Amendment*

***(-i) food with a new or intentionally***



*modified molecular structure;*

Or. fr

*Justification*

*To allow the regulation to be adapted to take account of new technologies and novel foods brought onto the Union market.*

**Amendment 122**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point -i a (new)**

*Text proposed by the Commission*

*Amendment*

***(-ia) food containing, consisting of or produced from micro-organisms, fungi, algae and other materials of biological or mineral origin;***

Or. fr

*Justification*

*To allow the regulation to be adapted to take account of new technologies and novel foods brought onto the Union market.*

**Amendment 123**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point -i b (new)**

*Text proposed by the Commission*

*Amendment*

***(-ib) food containing, consisting of or produced from plants or parts of plants, with the exception of plants that have been produced using conventional growing methods and have a proven history of safe food use on the Union***

**market;**

Or. fr

*Justification*

*To allow the regulation to be adapted to take account of new technologies and novel foods brought onto the Union market.*

**Amendment 124**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point -i c (new)**

*Text proposed by the Commission*

*Amendment*

***(-ic) food containing, consisting of or produced from animals or parts of animals, with the exception of animals that have been reared using traditional rearing methods and have a proven history of safe food use on the Union market;***

Or. fr

*Justification*

*To allow the regulation to be adapted to take account of new technologies and novel foods brought onto the Union market.*

**Amendment 125**

**Daciana Octavia Sârbu**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point i**

*Text proposed by the Commission*

*Amendment*

(i) food ***to which a new*** production process not used for food production within the Union before 15 May 1997 is applied,

(i) food ***resulted from a*** production process not used for food production within the Union before 15 May 1997 is

*where that production process* gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

applied, *which* gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

Or. en

#### **Amendment 126**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

#### **Proposal for a regulation**

#### **Article 2 – paragraph 2 – point a – point i**

##### *Text proposed by the Commission*

(i) food *to which* a new production process not used for food production within the Union before 15 May 1997 *is* applied, *where that production process* gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

##### *Amendment*

(i) food *resulting from* a new production process not used for food production within the Union before 15 May 1997 *which* gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

Or. fr

##### *Justification*

*Clarification.*

#### **Amendment 127**

**Nicola Caputo**

#### **Proposal for a regulation**

#### **Article 2 – paragraph 2 – point a – point i**

##### *Text proposed by the Commission*

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to

##### *Amendment*

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to

significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

significant changes, ***determined after full risk assessment***, in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

Or. en

**Amendment 128**  
**Paul Brannen**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i**

*Text proposed by the Commission*

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

*Amendment*

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances, ***determined on the basis of full risk assessment***;

Or. en

*Justification*

*Changes described here as an effect of production process can only be determined after full risk assessment.*

**Amendment 129**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i**

*Text proposed by the Commission*

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised *or* the level of undesirable substances;

*Amendment*

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised, the level of undesirable substances, *or where that production process might give rise to ethical concerns*;

Or. en

**Amendment 130**

**Daciana Octavia Sârbu**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point i a (new)**

*Text proposed by the Commission*

*Amendment*

*(ia) - food with a new or intentionally modified primary molecular structure;*

Or. en

**Amendment 131**

**Daciana Octavia Sârbu**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point i b (new)**

*Text proposed by the Commission*

*Amendment*

*(ib) - food containing, consisting of, or produced from microorganisms, fungi or algae;*

Or. en

**Amendment 132**  
**Daciana Octavia Sârbu**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i c (new)**

*Text proposed by the Commission*

*Amendment*

*(ic) food containing, consisting of, or produced from plants, or their parts, except for plants obtained by traditional propagating or breeding practices and having a history of safe food use within the Union, where those practices do not give rise to significant changes in the composition or structure of the food affecting their nutritional value, metabolism or level of undesirable substances;*

Or. en

**Amendment 133**  
**Daciana Octavia Sârbu**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point i d (new)**

*Text proposed by the Commission*

*Amendment*

*(id) food containing, consisting of, or produced from insects or their parts;*

Or. en

**Amendment 134**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point a – point ii**

*Text proposed by the Commission*

*Amendment*

**(ii) food containing or consisting of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;** *deleted*

Or. fr

**Amendment 135**

**Lidia Senra Rodríguez**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point ii**

*Text proposed by the Commission*

**Amendment**

**(ii) food containing or consisting of 'engineered nanomaterials' as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;** *deleted*

Or. es

**Amendment 136**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point iii – indent 1**

*Text proposed by the Commission*

*Amendment*

– a *new* production process has been applied *as referred to in point (i) of this paragraph*; or

– a production process *not used for food production in the Union before 15 May 1997* has been applied; or

Or. fr

*Justification*

*Clarification.*

**Amendment 137**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point iii – indent 2**

*Text proposed by the Commission*

*Amendment*

*– such substances contain or consist of  
"engineered nanomaterials" as defined in  
Article 2(2)t of Regulation (EU) No  
1169/2011;*

*deleted*

Or. fr

**Amendment 138**

**Giulia Moi**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a – point iv a (new)**

*Text proposed by the Commission*

*Amendment*

*(iva) food ingredients as botanical sources  
used or intended to be used for medical  
purposes falling with the scope of  
Directive 2001/83/EC;*

Or. en

**Amendment 139**

**Giulia Moi**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

(b) ‘traditional food from a third country’  
means novel food, other than the  
novel food as referred to in point (a)(i) to

(b) ‘traditional food from a third country’  
means novel food, other than the  
novel food as referred to in point (a)(i) to



(iii), which is derived from primary production, with a history of safe food use in a third country;

(iii), which is derived from primary production **and processed derivatives as defined in Regulation (EC) No 178/2002**, with a history of safe food use **and significant consumption** in a third country;

Or. en

**Amendment 140**  
**Giulia Moi**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point c**

*Text proposed by the Commission*

(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 large part of the population of a third country, prior to a notification referred to in Article 13;

*Amendment*

(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 **and significant consumption** for at least 25 years in the **normal daily** diet of a large part of the population **or geographical region** of a third country, prior to a notification referred to in Article 13;

Or. en

**Amendment 141**  
**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point c**

*Text proposed by the Commission*

(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 **large** part of the population of a third country, prior to a

*Amendment*

(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** part of the population of a third country, prior to a

notification referred to in Article 13;

notification referred to in Article 13;

Or. fr

*Justification*

*The word 'significant' is more appropriate here.*

**Amendment 142**

**Giulia Moi**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

*(ea) "compositional data" means detailed sets of information on the nutritionally important components of food and its chemical compositions which have to remain stable under different climatic and environment conditions in order to confirm the safety of foods, especially those coming from third countries.*

Or. en

**Amendment 143**

**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

*(ea) "cloned animals" means animals produced by means of a method of asexual, artificial reproduction with the aim of producing a genetically identical or nearly identical copy of an individual animal;*

Or. en

**Amendment 144**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point e b (new)**

*Text proposed by the Commission*

*Amendment*

*(eb) "descendants of cloned animals" means animals produced by means of sexual reproduction, in cases in which at least one of the progenitors is a cloned animal;*

Or. en

**Amendment 145**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – subparagraph 2 (new)**

*Text proposed by the Commission*

*Amendment*

*The list of foods and food ingredients shall be kept open in order to keep pace with scientific progress and new products development. If new categories are included, these shall be well defined, justified from a safety perspective and assessed on impact.*

Or. en

**Amendment 146**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 3**

*Text proposed by the Commission*

*Amendment*

**Article 3**

**deleted**

***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, 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).***

Or. en

*Justification*

*A decision on the scope is essential for the Regulation and should therefore not be taken by implementing acts.*

**Amendment 147**

**Nicola Caputo**

**Proposal for a regulation**

**Article 3 – title**

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 148**

**Nicola Caputo**

**Proposal for a regulation**

**Article 3 – paragraph 1**

*Text proposed by the Commission*

In order to ensure the uniform implementation of this Regulation, the Commission may decide, 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).

*Amendment*

In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of **delegated** acts, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).

Or. en

**Amendment 149**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 3 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

Those **delegated** acts shall be adopted in accordance with the procedure referred to in Article 27(**1a new**).

Or. en

**Amendment 150**  
**Giulia Moi**

**Proposal for a regulation**  
**Article 4 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

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

Or. en

**Amendment 151**  
**Michel Dantin**

**Proposal for a regulation**  
**Article 4 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

*(Does not affect English version.)*

Or. fr

*Justification*

*(Does not affect English version.)*

**Amendment 152**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – subparagraph 1 (new)**

*Text proposed by the Commission*

*Amendment*

***Food business operators cannot apply for novel food status and a health claim at the same time in order to avoid overlapping assessments. The novel food product shall be considered safe before EFSA evaluates a health claim.***

Or. en

**Amendment 153**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 4 – paragraph 2**

*Text proposed by the Commission*

2. Food business operators shall consult a Member State 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. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine *in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997*.

*Amendment*

2. Food business operators shall consult a Member State 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. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine *whether or not a food falls within the scope of this Regulation. With a view to determining that, the Member State shall consult the Commission and the other Member States*.

Or. en

**Amendment 154**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 4 – paragraph 2**

*Text proposed by the Commission*

2. Food business operators shall consult a Member State 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. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine *in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997*.

*Amendment*

2. Food business operators shall consult a Member State 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 provide the necessary information to the Member State on request to enable it to determine *whether or not a food comes within the scope of this Regulation*.

Or. fr

*Justification*

*Clarification.*

**Amendment 155**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 4 – paragraph 2**

**Text proposed by the Commission**

2. Food business operators shall consult a Member State *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. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

**Amendment**

2. Food business operators shall *in any event* consult a Member State *to ascertain* whether *the* food which they intend to place on the market within the Union falls within the scope of this Regulation. *Consumer and user organisations shall be informed.* In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

Or. es

**Amendment 156**  
**Michel Dantin**

**Proposal for a regulation**  
**Article 4 – paragraph 2**

*Text proposed by the Commission*

2. Food business operators shall consult a Member State 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. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

*Amendment*

*(Does not affect the English version)*

Or. fr



*Justification*

*(Does not affect the English version)*

**Amendment 157**

**Giulia Moi**

**Proposal for a regulation**

**Article 4 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. Where necessary, agri-food business operators may consult other competent authorities and the Commission which shall communicate the result of the consultation to all Member States.***

Or. en

**Amendment 158**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 4 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

The Commission may, by means of ***implementing acts***, specify the procedural steps of the consultation process provided for in paragraph 2.

The Commission may, by means of ***delegated acts in accordance with Article 26 (a)***, specify the procedural steps of the consultation process provided for in paragraph 2.

Or. en

**Amendment 159**

**Nicola Caputo**

**Proposal for a regulation**

**Article 4 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

The Commission may, by means of **implementing** acts, specify the procedural steps of the consultation process provided for in paragraph 2.

*Amendment*

The Commission may, by means of **delegated** acts, specify the procedural steps of the consultation process provided for in paragraph 2.

Or. en

**Amendment 160**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 4 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

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

*Amendment*

***deleted***

Or. en

**Amendment 161**

**Nicola Caputo**

**Proposal for a regulation**

**Article 4 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

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

*Amendment*

Those **delegated** acts shall be adopted in accordance with the procedure referred to in Article 27(**1a new**).

Or. en

**Amendment 162**

**Marc Tarabella**

**Proposal for a regulation**  
**Article 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 4a**

**Informing the consumer**

**Member States shall be required to inform and reassure consumers that new husbandry or production techniques pose no danger to humans or animals.**

Or. fr

**Amendment 163**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 5 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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').

1. **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') **is annexed to this Regulation.**

Or. en

**Amendment 164**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 5 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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

1. The 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') **is laid down in the**

Articles 6, 7 and 8 ('the Union list').

*Annex.*

Or. en

**Amendment 165**

**Giulia Moi**

**Proposal for a regulation**

**Article 5 – paragraph 1**

*Text proposed by the Commission*

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').

*Amendment*

1. The Commission shall establish and update a Union list of novel foods authorised, ***which shall include a list of traditional food from third countries***, to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ("the Union list").

Or. en

**Amendment 166**

**Giulia Moi**

**Proposal for a regulation**

**Article 5 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. The Union list shall be made public.***

Or. en

**Amendment 167**

**Giulia Moi**

**Proposal for a regulation**

**Article 5 – paragraph 2**

*Text proposed by the Commission*

2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such and used in or on foods under the conditions of use specified therein.

*Amendment*

2. Only novel foods authorised and included in the Union list ***or in the list of traditional foods from third countries*** may be placed on the market within the Union as such and used in or on foods under the conditions of use specified therein.

Or. en

**Amendment 168**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. The Commission shall make the Union list available to the public on its website.***

Or. en

**Amendment 169**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**

**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2 a. The Union list of novel foods should be publicly available from ...\*. The Union list should be published both on the Commission's internet site, and in the Official Journal of the European Union.***

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***\* 24 months following the date of entry into force of this Regulation.***

Or. pl

*Justification*

*The Union list must be publicly available and transparent.*

**Amendment 170**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 5 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

***2b. The Commission shall also make a list of rejected applications publicly available, in order to serve as reference for future applications.***

Or. en

**Amendment 171**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 6 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) it does not, on the basis of the scientific evidence available, pose a safety risk to

(a) it does not, on the basis of the ***independent peer-reviewed*** scientific

human health;

evidence available, pose a safety risk to human *or animal* health *or the environment*;

Or. en

**Amendment 172**  
**Giulia Moi**

**Proposal for a regulation**  
**Article 6 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

(a) it does not, on the basis of the scientific evidence available, pose a safety risk to human health, *under normal consumption conditions and under different climatic and environmental ones*;

Or. en

**Amendment 173**  
**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

**Proposal for a regulation**  
**Article 6 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

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

(a) it does not, on the basis of the scientific evidence available, pose a safety risk to human health *and where applicable the environment*;

Or. en

**Amendment 174**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 6 – paragraph 1 – point a a (new)**

**Text proposed by the Commission**

**Amendment**

*(aa) it is a healthy food that is free of pesticides, GMOs, hormones and antibiotics that may pose a risk to health or the environment;*

Or. es

**Amendment 175**

**Diane Dodds**

**Proposal for a regulation**

**Article 6 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

(b) *its* use does not mislead the consumer;

(b) *it is correctly labelled so that it's* use does not mislead the consumer;

Or. en

**Amendment 176**

**Giulia Moi**

**Proposal for a regulation**

**Article 6 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

(b) its use does not mislead the consumer;

(b) its use does not mislead the consumer, *even to a material degree;*

Or. en

**Amendment 177**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 6 – paragraph 1 – point c**



*Text proposed by the Commission*

(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.

*Amendment*

(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 ***or have a negative impact on his or her health.***

Or. fr

**Amendment 178**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 6 – paragraph 1 – point c a (new)**

**Text proposed by the Commission**

**Amendment**

***(ca) where it is produced in a Member State, it must not have an impact on the environment; the opinion of the European Environment Agency concerning the extent to which the production process and normal consumption have a harmful impact on the environment must always be taken into account in the assessment.***

Or. es

**Amendment 179**

**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**

**Article 6 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

***(ca) where relevant, no significant risk for animal health and welfare or for the environment has been established.***

**Amendment 180**  
**Lidia Senra Rodríguez**

**Proposal for a regulation**  
**Article 6 – paragraph 1 – point c a (new)**

**Text proposed by the Commission**

**Amendment**

*(ca) it does not contain nanomaterials and has not been produced using nanotechnology processes.*

Or. es

**Amendment 181**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 6 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(ca) In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the precautionary principle shall be applied and the food in question shall not be included in the Union list.*

Or. en

*Justification*

*It is appropriate to re-introduce this amendment, which had been included in European Parliament's second reading position from 2010.*

**Amendment 182**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 7 – paragraph 1**

*Text proposed by the Commission*

*No later than ...<sup>23</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) N° 258/97 in the Union list, including any existing authorisation conditions.*

*Amendment*

*The initial Union list of authorised novel foods shall be annexed to this Regulation and that list shall be updated by means of delegated acts.*

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<sup>23</sup> *Publications Office: please insert date: 24 months after the entry into force of this Regulation.*

Or. en

**Amendment 183**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 7 – paragraph 1**

*Text proposed by the Commission*

*No later than ...<sup>23</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) N° 258/97 in the Union list, including any existing authorisation conditions.*

*Amendment*

Novel foods authorised or notified under Articles 4, 5 or 7 of Regulation (EC) N° 258/97 **are listed** in the **Annex to this Regulation**, including any existing authorisation conditions.

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<sup>23</sup> *Publications Office: please insert date: 24 months after the entry into force of this Regulation.*

Or. en

*Justification*

*As the aim is to establish a list of novel foods already authorised under the current provisions, there is no need for an implementing act here. The formulation above was chosen in analogy to Article 30 of Regulation 1333/2008 on food additives.*

**Amendment 184**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 7 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

***That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).***      ***deleted***

Or. en

*Justification*

*As the aim is to establish a list of novel foods already authorised under the current provisions, there is no need for an implementing act here. The formulation above was chosen in analogy to Article 30 of Regulation 1333/2008 on food additives.*

**Amendment 185**

**Nicola Caputo**

**Proposal for a regulation**

**Article 7 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

***That implementing act*** shall be adopted in accordance with the ***advisory*** procedure referred to in Article 27(2).

***The delegated acts*** shall be adopted in accordance with the procedure referred to in Article 27(***1a new***).

Or. en

**Amendment 186**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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

*Amendment*

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

Or. es

**Amendment 187**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point a**

*Text proposed by the Commission*

***(a) Articles 9, 10 and 11 and, where applicable, in accordance with Article 25 or***

*Amendment*

***deleted***

Or. es

**Amendment 188**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point b**

*Text proposed by the Commission*

***(b) Articles 13 to 18.***

*Amendment*

***deleted***

Or. es

**Amendment 189**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**

**Article 8 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) adding, removing or changing the conditions, *specifications or restrictions* associated with the inclusion of a novel food on the Union list.

*Amendment*

(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.

Or. pl

*Justification*

*The Union list of novel foods should clearly indicate what conditions were set when the authorisation was granted.*

**Amendment 190**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 8 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) adding, removing or changing the conditions, specifications or restrictions associated with the inclusion of a novel food on the Union list.

*Amendment*

(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.

Or. fr

*Justification*

*Clarification.*

**Amendment 191**  
**Giulia Moi**

**Proposal for a regulation**  
**Article 8 – paragraph 3 – introductory part**

*Text proposed by the Commission*

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include *where relevant*:

*Amendment*

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include:

Or. en

**Amendment 192**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 8 – paragraph 3 – introductory part**

*Text proposed by the Commission*

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include *where relevant*:

*Amendment*

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include:

Or. en

**Amendment 193**  
**Daniel Buda**

**Proposal for a regulation**  
**Article 8 – paragraph 3 – point a**

*Text proposed by the Commission*

(a) a specification of the novel food;

*Amendment*

(a) a specification of the novel food *and technological process*;

Or. ro

**Amendment 194**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 8 – paragraph 3 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) the date of entry of the novel food in the Union list;***

Or. en

**Amendment 195**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 8 – paragraph 3 – point a b (new)**

*Text proposed by the Commission*

*Amendment*

***(ab) the name and address of the applicant;***

Or. en

**Amendment 196**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 8 – paragraph 3 – point b**

*Text proposed by the Commission*

*Amendment*

(b) the conditions under which the novel food may be used, in order 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) the conditions under which the novel food may be used, in order to avoid, in particular, possible adverse effects on particular groups of the population, ***taking into account the emergence of new allergies in particular***, the exceeding of maximum intake levels and risks in case of



excessive consumption;

Or. fr

*Justification*

*The introduction of novel foods from third countries may trigger food allergies.*

**Amendment 197**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 8 – paragraph 3 – point b**

*Text proposed by the Commission*

(b) the conditions under which the novel food may be used, in order 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;

*Amendment*

(b) **where relevant**, the conditions under which the novel food may be used, in order 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;

Or. en

**Amendment 198**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 8 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) 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

*Amendment*

(c) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, **type of production**, 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

health of specific groups of the population;

the health of specific groups of the population;

Or. es

### **Amendment 199**

**Giulia Moi**

#### **Proposal for a regulation**

#### **Article 8 – paragraph 3 – point c**

##### *Text proposed by the Commission*

(c) 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;

##### *Amendment*

(c) 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, **the** intended use of the food **and its origin**, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;

Or. en

### **Amendment 200**

**José Bové**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 8 – paragraph 3 – point c**

##### *Text proposed by the Commission*

(c) 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;

##### *Amendment*

(c) **where relevant**, 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;

**Amendment 201**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Article 8 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) 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;

*Amendment*

(c) 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; ***if a novel food consists of, or contains ingredients in the form of engineered nanomaterials, this shall be clearly indicated in the list of ingredients, and the names of such ingredients shall be followed by the word 'nano' in brackets;***

Or. en

**Amendment 202**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 8 – paragraph 3 – point d**

*Text proposed by the Commission*

(d) a post-market monitoring requirement in accordance with Article 23.

*Amendment*

(d) ***where relevant***, a post-market monitoring requirement in accordance with Article 23.

Or. en

**Amendment 203**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 8 – paragraph 3 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

*(da) a reference to the source  
country/country of origin.*

Or. es

**Amendment 204**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

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 be empowered to adopt delegated acts, in accordance with Article 27 (1a new), concerning the authorisation of* the placing on the market within the Union of a novel food and *the* updating of the Union list *which shall be annexed to this Regulation.*

Or. en

**Amendment 205**  
**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

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

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.

an application to the Commission by an applicant. ***The Commission should immediately make valid applications available to all Member States.***

Or. pl

*Justification*

*The Member States should be informed from the very beginning of applications that have been deemed complete and valid.*

**Amendment 206**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

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.

*Amendment*

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 forward the application to Member States and make it available to the public on its website.***

Or. en

**Amendment 207**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García**

**Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

The procedure for authorising the placing

*Amendment*

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.

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 should allow Member States to have sight of the application.***

Or. fr

#### **Amendment 208**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

#### **Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 2 – point -a (new)**

*Text proposed by the Commission*

*Amendment*

***-a) the name and address of the applicant;***

Or. fr

*Justification*

*Greater transparency.*

#### **Amendment 209**

**Pablo Iglesias**

#### **Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

(b) the ***composition*** of the ***novel*** food;

(b) the ***designation*** of the food, ***and its specification, including the production process used;***

Or. es

**Amendment 210**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) the production method;***

Or. es

**Amendment 211**  
**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) Production process;***

Or. pl

*Justification*

*The production process can be of great importance in determining whether a given food is novel. See Recital 7.*

**Amendment 212**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

(c) ***independent, peer-reviewed, publically available*** scientific evidence demonstrating that the novel food does not pose a safety risk to human health ***or the environment;***

*Justification*

*There should be no room for pseudo-science or non-transparency: if the food is to be put in the public sphere (in our stomachs / into the environment) then the science should be publically available and unbiased.*

**Amendment 213**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

(c) **conclusive** scientific evidence **produced by independent bodies** demonstrating that the novel food does not pose a safety risk to human health **or the environment**;

Or. es

**Amendment 214**

**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health, **and where relevant, no safety risk for animal health and welfare or for the environment**;

Or. en

**Amendment 215**

**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**



**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;

(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health ***and where applicable the environment;***

Or. en

**Amendment 216**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 2 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

***(ca) an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics;***

Or. es

**Amendment 217**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 9 – paragraph 1 – subparagraph 2 – point d**

*Text proposed by the Commission*

*Amendment*

(d) where ***applicable***, a proposal for ***the conditions of use and a proposal for specific labelling requirements which do not mislead the consumer.***

(d) where ***appropriate***, a proposal for ***post-market monitoring regarding use of the food for human consumption;***

**Amendment 218**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 2 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

*(da) particulars concerning the physical and chemical properties of the novel food or the novel food ingredient.*

Or. es

**Amendment 219**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The Commission *may request EFSA to render its opinion if the update is liable to have an effect on human health.*

2. The Commission *shall forward the valid application to EFSA and request EFSA to render its opinion.*

Or. en

**Amendment 220**

**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**

**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The Commission *may* request EFSA to render its opinion if the update is liable to have an effect on human health.

2. The Commission *shall* request EFSA to render its opinion if the update is liable to have an effect on human health, *animal*

*health and welfare, or the environment.*

Or. en

**Amendment 221**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanislaw Ożóg**

**Proposal for a regulation**

**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The Commission *may* request EFSA to render its opinion if the update is liable to *have an effect on* human health.

2. The Commission *shall* request EFSA to render its opinion if the update is liable to *endanger* human health.

Or. pl

*Justification*

*If there are suspicions that a novel food may endanger human health, the Commission should be obliged to request that the EFSA issue an opinion.*

**Amendment 222**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The Commission *may* request EFSA to render its opinion if the update is liable to have an effect on human health.

2. The Commission *shall* request EFSA to render its opinion if the update is liable to have an effect on human health.

Or. fr

*Justification*

*To enhance food safety.*

**Amendment 223**

**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

**Proposal for a regulation**

**Article 9 – paragraph 2**

*Text proposed by the Commission*

2. The Commission **may** request EFSA to render its opinion if the update is liable to have an effect on human health.

*Amendment*

2. The Commission **shall** request EFSA to render its opinion if the update is liable to have an effect on human health.

Or. en

**Amendment 224**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 9 – paragraph 2**

*Text proposed by the Commission*

2. The Commission **may** request EFSA to render its opinion if the update is liable to have an effect on human health.

*Amendment*

2. The Commission **shall** request EFSA to render its opinion if the update is liable to have an effect on human health.

Or. es

**Amendment 225**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 9 – paragraph 3**

*Text proposed by the Commission*

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.**

*Amendment*

3. The **Commission shall be empowered to adopt delegated acts, in accordance with Article 26 (a) concerning the authorisation of the placing on the market within the Union of novel foods and the updating of the list laid down in the Annex.**

**Amendment 226**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 9 – paragraph 3**

*Text proposed by the Commission*

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.

*Amendment*

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 *delegated acts* in accordance with Article 11.

**Amendment 227**  
**Pablo Iglesias**

**Proposal for a regulation**  
**Article 9 – paragraph 4 – subparagraph 2**

*Text proposed by the Commission*

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

*Amendment*

It shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.

**Amendment 228**  
**Daniel Buda**

**Proposal for a regulation**  
**Article 9 – paragraph 4 – subparagraph 2**

*Text proposed by the Commission*

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

*Amendment*

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

Or. ro

**Amendment 229**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

**Where the Commission requests an opinion from EFSA, it shall forward the valid application to EFSA.** EFSA shall adopt its opinion within nine months from the date of receipt of a valid application.

*Amendment*

EFSA shall adopt its opinion within nine months from the date of receipt of a valid application.

Or. en

**Amendment 230**

**Diane Dodds**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

Where the Commission requests an opinion from EFSA, it shall forward the valid application to EFSA. EFSA shall adopt its opinion within **nine** months from the date of receipt of a valid application.

*Amendment*

Where the Commission requests an opinion from EFSA, it shall forward the valid application to EFSA. EFSA shall adopt its opinion within **six** months from the date of receipt of a valid application.

Or. en

**Amendment 231**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 10 – paragraph 1 – subparagraph 2 – introductory part**

*Text proposed by the Commission*

In assessing the safety of novel foods, EFSA shall, where appropriate, consider the following:

*Amendment*

In assessing the safety of novel foods, EFSA shall, where appropriate **and in accordance with the precautionary principle**, consider the following:

Or. en

**Amendment 232**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Article 10 – paragraph 1 – subparagraph 2 – point b**

*Text proposed by the Commission*

(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.

*Amendment*

(b) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health, **animal health and welfare, or the environment** in the Union.

Or. en

**Amendment 233**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 10 – paragraph 1 – subparagraph 2 – point b**

*Text proposed by the Commission*

(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

*Amendment*

(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.

Union, *taking account of vulnerable consumers or particular groups of consumers.*

Or. en

**Amendment 234**

**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

(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.

(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 *and where applicable to the environment.*

Or. en

**Amendment 235**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

*(ba) whether the composition of the novel food and the conditions of its use do not pose a risk to animal health and welfare and/or the environment.*

Or. en

**Amendment 236**

**José Bové**

on behalf of the Verts/ALE Group



**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 2 – point b b (new)**

*Text proposed by the Commission*

*Amendment*

***(bb) whether cumulative and synergistic effects might arise, and whether particular groups of the population could be adversely affected.***

Or. en

**Amendment 237**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 10 – paragraph 3 – subparagraph 3**

*Text proposed by the Commission*

*Amendment*

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

The period of nine months provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

Or. fr

**Amendment 238**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 10 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

4. Where the additional information referred to in paragraph 3 is not sent to EFSA within the additional period referred

4. Where the additional information referred to in paragraph 3 is not sent to EFSA within the additional period referred

to in that paragraph, it shall *finalise its opinion on the basis of the information already provided to it.*

to in that paragraph, it shall *automatically reject the application made to it, given that it is unable to adopt a position.*

Or. fr

**Amendment 239**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 11 – paragraph 1 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

*Within nine months from the date of publication of EFSA's opinion, the Commission shall submit to the committee referred to in Article 27(1) a draft implementing act updating the Union list taking account of:*

*The Commission shall be empowered to adopt a delegated act in order to update the Union list referred to in Article 5, within nine months from the date of publication of EFSA's opinion referred to in Article 10, taking account of:*

Or. en

**Amendment 240**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 11 – paragraph 1 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

Within nine months from the date of publication of EFSA's opinion, the Commission shall *submit to the committee referred to in Article 27(1) a draft implementing act* updating the Union list taking account of:

Within nine months from the date of publication of EFSA's opinion, the Commission shall *be empowered to present a draft delegated act in accordance with Article 26 (a)* updating the Union list taking account of:

Or. en

**Amendment 241**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 11 – paragraph 1 – subparagraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

**(c) the EFSA's opinion;**

***deleted***

Or. en

**Amendment 242**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 11 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

***That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).***

***deleted***

Or. en

**Amendment 243**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 11 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

That ***implementing*** act shall be adopted in accordance with the ***examination*** procedure referred to in Article 27(3).

That ***delegated*** act shall be adopted in accordance with the procedure referred to in Article 27(***1a new***).

Or. en

**Amendment 244**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 11 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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

**deleted**

Or. fr

**Amendment 245**

**Nicola Caputo**

**Proposal for a regulation**

**Article 12 – title**

*Text proposed by the Commission*

*Amendment*

**Implementing** power concerning administrative and scientific requirements for applications

**Delegated** power concerning administrative and scientific requirements for applications

Or. en

**Amendment 246**

**Nicola Caputo**

**Proposal for a regulation**

**Article 12 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

By ...<sup>24</sup> at the latest, the Commission shall adopt **implementing** acts concerning:

By ...<sup>24</sup> at the latest, the Commission shall adopt **delegated** acts concerning:

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

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

Or. en

**Amendment 247**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 12 – paragraph 1 – point a**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 248**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 12 – paragraph 1 – point c**

*Text proposed by the Commission*

*(c) the type of information required to be  
included in the opinion of EFSA referred  
to in Article 10.*

*Amendment*

*deleted*

Or. en

**Amendment 249**

**Nicola Caputo**

**Proposal for a regulation**

**Article 12 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

Those **delegated** acts shall be adopted in accordance with the procedure referred to in Article 27(**1a new**).

Or. en

**Amendment 250**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**  
**Article 13 – paragraph 1**

*Text proposed by the Commission*

An applicant, who intends to place on the market within the Union a traditional food from a third country, **shall** notify that intention to the Commission.

*Amendment*

An applicant, who intends to place on the market within the Union a traditional food from a third country, **may** notify that intention to the Commission.

Or. pl

*Justification*

*A traditional food from a third country may also undergo the normal authorisation procedure if, for example, the importer is unable to provide documentation attesting to 25 years of safe use in the third country. Therefore, the procedure set out in Articles 13 to 18 should be optional, not obligatory.*

**Amendment 251**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Article 13 – paragraph 2 – point -a (new)**

*Text proposed by the Commission*

*Amendment*

**-a) the name and address of the applicant;**

Or. fr

*Justification*

*Greater transparency.*

**Amendment 252**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point a**

*Text proposed by the Commission*

(a) the name and a description of the traditional food;

*Amendment*

(a) the name and a description of the traditional food; ***the potential for allergenicity of the novel food and metabolism/toxicokinetic studies on the novel food ingredient;***

Or. es

**Amendment 253**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) the production method;***

Or. es

**Amendment 254**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point e**

*Text proposed by the Commission*

*Amendment*

(e) ***where applicable, the conditions of use and specific labelling requirements, which***

(e) ***where appropriate, a proposal for post-market monitoring regarding use of the***

*do not mislead the consumer.*

*food for human consumption;*

Or. es

**Amendment 255**

**Giulia Moi**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point e**

*Text proposed by the Commission*

(e) *where applicable*, the conditions of use and specific labelling requirements, which do not mislead the consumer.

*Amendment*

(e) the conditions of use and specific labelling requirements, which do not mislead the consumer.

Or. en

**Amendment 256**

**Nicola Caputo**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point e**

*Text proposed by the Commission*

(e) where applicable, the conditions of use and specific labelling requirements, which do not mislead the consumer.

*Amendment*

(e) where applicable, the conditions of use and specific labelling requirements, ***including legitimate factors such as ethical concerns***, which do not mislead the consumer.

Or. en

**Amendment 257**

**Pablo Iglesias**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point e a (new)**



*Text proposed by the Commission*

*Amendment*

***(ea) the method of preparation and specifications of a novel food ingredient.***

Or. es

**Amendment 258**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 14 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The Commission shall forward the valid notification provided for in Article 13 ***without delay*** to the Member States and to EFSA.

1. The Commission shall forward the valid notification provided for in Article 13 ***within one month*** to the Member States and to EFSA.

Or. fr

*Justification*

*Clarification.*

**Amendment 259**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 14 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The Commission shall forward the valid notification provided for in Article 13 without delay to the Member States and to EFSA.

1. The Commission shall forward the valid notification provided for in Article 13 without delay to the Member States and to EFSA ***and shall make it available to the public on its website.***

Or. en

## Amendment 260

Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg

### Proposal for a regulation

#### Article 14 – paragraph 2

##### *Text proposed by the Commission*

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 EFSA may submit to the Commission reasoned safety objections, ***based on scientific evidence***, to the placing on the market within the Union of the traditional food concerned.

##### *Amendment*

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 EFSA may submit to the Commission reasoned safety objections, ***with regard to human health***, to the placing on the market within the Union of the traditional food concerned.

Or. pl

##### *Justification*

*The four-month period provided for in this paragraph is not long enough to obtain ‘scientific evidence’. It would therefore be sufficient for the objections as regards safety for human health to be ‘justified’.*

## Amendment 261

José Bové

on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Article 14 – paragraph 2

##### *Text proposed by the Commission*

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 EFSA may submit to the Commission reasoned ***safety*** objections, based on scientific evidence, to the placing on the market within the Union of the traditional food concerned.

##### *Amendment*

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 EFSA may submit to the Commission reasoned objections ***regarding its compliance with Article 6***, based on scientific evidence, to the placing on the market within the Union of the traditional food concerned.

**Amendment 262**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 14 – paragraph 3**

*Text proposed by the Commission*

3. The Commission shall inform the Member States, EFSA and the applicant of the outcome of the procedure referred to in paragraph 2.

*Amendment*

3. The Commission shall inform the Member States, EFSA and the applicant of the outcome of the procedure referred to in paragraph 2. ***Even if no reasoned safety objections are presented, traditional foods from third countries shall automatically go through a full risk assessment by EFSA at the beginning of the procedure.***

Or. en

**Amendment 263**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 14 – paragraph 4**

*Text proposed by the Commission*

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 without delay the Union list.

*Amendment*

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, ***after a convincing full risk assessment by EFSA***, the placing on the market within the Union of the traditional food concerned and update without delay the Union list.

Or. en

**Amendment 264**  
**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 14 – paragraph 4**

*Text proposed by the Commission*

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 without delay the Union list.

*Amendment*

4. Where no reasoned 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 without delay the Union list.

Or. en

**Amendment 265**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Article 14 – paragraph 4**

*Text proposed by the Commission*

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 *without delay* the Union list.

*Amendment*

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 *within one month*.

Or. fr

*Justification*

*Clarification.*

**Amendment 266**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 14 – paragraph 5 – subparagraph 1**

*Text proposed by the Commission*

Where reasoned **safety** objections, based on scientific evidence, are submitted to the Commission in accordance with paragraph 2, the Commission shall not authorise the placing on the market of the traditional food concerned nor update the Union list.

*Amendment*

Where reasoned objections, based on scientific evidence, are submitted to the Commission in accordance with paragraph 2, the Commission shall not authorise the placing on the market of the traditional food concerned nor update the Union list.

Or. en

**Amendment 267**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 16 – paragraph 2 – point a**

*Text proposed by the Commission*

(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;

*Amendment*

(a) whether the history of safe food use in a third country, **assessed on the basis of scientific guidelines and criteria that shall be clarified**, is substantiated by reliable data submitted by the applicant in accordance with Articles 13 and 15;

Or. en

**Amendment 268**  
**Marit Paulsen, Ivan Jakovčić, Fredrick Federley**

**Proposal for a regulation**  
**Article 16 – paragraph 2 – point b**

*Text proposed by the Commission*

(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.

*Amendment*

(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 **and where applicable the environment**.

**Amendment 269**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 16 – paragraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) whether the novel food meant to replace another food does not have different properties that result in nutritional disadvantages for the consumer;***

Or. fr

*Justification*

*Greater safety.*

**Amendment 270**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 16 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

5. Where the additional information referred to in paragraph 4 is not sent to EFSA within the additional period referred to in that paragraph, it shall finalise its opinion on the basis of the ***information already provided to it.***

5. Where the additional information referred to in paragraph 4 is not sent to EFSA within the additional period referred to in that paragraph, it shall ***automatically reject the application made to it, given that it is unable to adopt a position.***

Or. fr

**Amendment 271**

**Nicola Caputo**

**Proposal for a regulation**

**Article 17 – paragraph 1 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

*Within three months of the date of publication of EFSA's opinion, the Commission shall submit to the Committee referred to in Article 27(1) a draft implementing act* to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:

*Amendment*

*The Commission shall be empowered to adopt delegated acts in accordance with Article 27(1a new), within three months of the date of publication of EFSA'S opinion*, to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:

Or. en

**Amendment 272**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 17 – paragraph 1 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

Within three months of the date of publication of EFSA's opinion, the Commission shall *submit to the Committee referred to in Article 27(1) a draft implementing act* to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:

*Amendment*

Within three months of the date of publication of EFSA's opinion, the Commission shall *be empowered to submit a draft delegated act in accordance with Article 26 (a)* to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:

Or. en

**Amendment 273**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 17 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

***That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).***      ***deleted***

Or. en

**Amendment 274**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**  
**Article 18**

*Text proposed by the Commission*

*Amendment*

For removing a traditional food from a third country from the Union list or for adding, removing or changing conditions, ***specifications or restrictions*** associated with the inclusion of a traditional food from a third country on the Union list, 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, Articles 9 to 12 apply.

Or. pl

*Justification*

*See Article 8(2).*

**Amendment 275**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**  
**Article 18**

*Text proposed by the Commission*

*Amendment*

For removing a traditional food from a

***Articles 9 to 12 shall apply*** for removing a



third country from the Union list or for adding, removing or changing conditions, specifications or restrictions associated with the inclusion of a traditional food from a third country on the Union list, **Articles 9 to 12 apply.**

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.

Or. fr

*Justification*

*Clarification.*

**Amendment 276**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 19 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) the **contents**, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5);

*Amendment*

(a) the drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5);

Or. en

**Amendment 277**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 19 – paragraph 1 – point d**

*Text proposed by the Commission*

**(d) the type of information required to be included in the opinion of EFSA referred to in Article 16.**

*Amendment*

**deleted**

**Amendment 278**

**Nicola Caputo**

**Proposal for a regulation**

**Article 19 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

Those **delegated** acts shall be adopted in accordance with the procedure referred to in Article 27(**1a new**).

Or. en

**Amendment 279**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 20 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

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 **must be provided**.

*Amendment*

Where the Commission **or EFSA** requests additional information from an applicant on matters concerning risk management, it shall determine the period **it deems necessary and sufficient for the applicant to be able to provide** that information.

Or. fr

**Amendment 280**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 20 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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 information already provided***.

2. Where the additional information referred to in paragraph 1 is not ***forwarded*** within the ***new*** period ***laid down***, the Commission shall ***not issue an authorisation***.

Or. fr

**Amendment 281**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 22**

*Text proposed by the Commission*

*Amendment*

***[...]***

***deleted***

Or. en

*Justification*

*"Applicants" are applying to put their novel products into the public sphere - that of the stomachs and environments of our fellow citizens. Therefore the science and information about risks should be fully open and transparent. Confidentiality will lead to suppression of data that the public is entitled to know about.*

**Amendment 282**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 22 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

***1. Applicants may request confidential treatment of certain information submitted under this Regulation where***

***deleted***

*disclosure of such information may significantly harm their competitive position.*

Or. fr

**Amendment 283**  
**Daniel Buda**

**Proposal for a regulation**  
**Article 22 – paragraph 1**

*Text proposed by the Commission*

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may significantly harm their competitive position.

*Amendment*

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may significantly harm their competitive position. ***However, applicants may not request confidential treatment of certain information submitted under this Regulation where this might result in unfair competition on the Union market.***

Or. ro

**Amendment 284**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Article 22 – paragraph 4 – subparagraph 2 – point d**

*Text proposed by the Commission*

(d) ***a summary of*** the studies submitted by the applicant;

*Amendment*

(d) the studies submitted by the applicant;

Or. en

**Amendment 285**  
**Daniel Buda**

**Proposal for a regulation**  
**Article 22 – paragraph 5**

*Text proposed by the Commission*

5. The Commission, the Member States and EFSA shall take the 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.

*Amendment*

5. The Commission, the Member States and EFSA shall take the 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, ***the environment and animal health.***

Or. ro

**Amendment 286**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 22 – paragraph 8 – subparagraph 2**

*Text proposed by the Commission*

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

*Amendment*

Those ***delegated*** acts shall be adopted in accordance with the procedure referred to in Article 27(***1a new***).

Or. en

**Amendment 287**  
**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**  
**Article 23 – paragraph 2**

*Text proposed by the Commission*

***2. The food business operators shall***

*Amendment*

***deleted***

*forthwith inform the Commission of:*

*a) any new scientific or technical information which might influence the evaluation of the safety in 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.*

Or. pl

*Justification*

*This paragraph was incorrectly included in an article on the imposition of a monitoring requirement following placing on the market, as this is a separate requirement of a general nature that is independent of the decision on a monitoring requirement following placing on the market. For the sake of the clarity of the text, this should therefore form a separate article in this regulation.*

**Amendment 288**  
**Michel Dantin**

**Proposal for a regulation**  
**Article 23 – paragraph 2 – introductory part**

*Text proposed by the Commission*

*Amendment*

2. The food business operators shall forthwith inform the Commission of:

*(Does not affect the English version)*

Or. fr

*Justification*

*(Does not affect the English version)*

**Amendment 289**  
**Diane Dodds**

**Proposal for a regulation**  
**Article 23 – paragraph 2 – point a**

*Text proposed by the Commission*

*Amendment*

(a) any new scientific or technical **information** which **might** influence the evaluation of the safety in use of the novel food;

(a) any new scientific **evidence** or technical **procedures** which **may** influence the evaluation of the safety in use of the novel food;

Or. en

**Amendment 290**

**Zbigniew Kuźmiuk, Beata Gosiewska, Janusz Wojciechowski, Stanisław Ożóg**

**Proposal for a regulation**

**Article 23 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 23 a**

**Requirements concerning new information**

**The food business operators shall forthwith inform the Commission of:**

**a) any new scientific or technical information which might influence the evaluation of the safety in 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.**

Or. pl

*Justification*

*This paragraph was incorrectly included in an article on the imposition of a monitoring requirement following placing on the market, as this is a separate requirement of a general nature that is independent of the decision on a monitoring requirement following placing on the market. For the sake of the clarity of the text, this should therefore form a separate article in this regulation.*

**Amendment 291**

**Giulia Moi**

**Proposal for a regulation**  
**Article 26**

*Text proposed by the Commission*

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>26</sup> at the latest and shall notify it without delay of any subsequent amendment affecting them.

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<sup>26</sup> Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

*Amendment*

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 **harmonised**, effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ...<sup>26</sup> at the latest and shall notify it without delay of any subsequent amendment affecting them.

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<sup>26</sup> Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Or. en

**Amendment 292**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 26 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 26a**

***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. The power to adopt delegated acts referred to in Articles 4(1), 9 (3), 11(1), and 17 (1) shall be conferred on the Commission for a period of 7 years after entry into force of this Regulation. The Commission shall draw up a report in***



*respect of the delegation of power not later than 9 months before the end of the 7-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 Articles 4(1), 9 (3), 11(1), and 17 (1) 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 Articles 4(1), 9 (3), 11(1), and 17 (1) 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.*

Or. en

#### *Justification*

*Standard text, needed to allow delegated acts - this article 26(a) is referred to throughout the text where we change implementing acts to delegated acts.*

**Amendment 293**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 27 – title**

*Text proposed by the Commission*

*Amendment*

**Committee** procedure

Procedure *for delegated acts*

Or. en

**Amendment 294**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 27 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

**1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be the committee within the meaning of Regulation (EU) No 182/2011.**

**Deleted**

Or. en

**Amendment 295**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 27 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**1a. 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. The delegation of power referred to in Articles 3, 9(3), 11(1), 17(1) and 29(3) shall be conferred on the Commission for a period of seven years from the date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council oppose such extension no later than three months before the end of each period.*

*3. The delegation of power referred to in in Articles 3, 9(3), 11(1), 17(1) and 29(3) 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 at 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 Articles 3, 9(3), 11(1), 17(1) and 29(3) 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 from the 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 two months at the initiative of the European Parliament or of the Council.*

**Amendment 296**

**Nicola Caputo**

**Proposal for a regulation**

**Article 27 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

**Amendment 297**

**Nicola Caputo**

**Proposal for a regulation**

**Article 27 – paragraph 2 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

*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.*

*deleted*

**Amendment 298**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 27 – paragraph 2 – subparagraph 2**

*Text proposed by the Commission*

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.

*Amendment*

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result if, within ***six months***, the chair of the committee so decides or a simple majority of committee members so request.

Or. fr

*Justification*

*Clarification.*

**Amendment 299**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 27 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

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

*Amendment*

***deleted***

Or. en

**Amendment 300**  
**Nicola Caputo**

**Proposal for a regulation**  
**Article 27 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

***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***

*Amendment*

***deleted***

*committee so decides or a simple majority of committee members so request.*

Or. en

**Amendment 301**

**Angélique Delahaye, Pilar Ayuso, Esther Herranz García, Michel Dantin**

**Proposal for a regulation**

**Article 27 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

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.

*Amendment*

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result if, within ***six months***, the chair of the committee so decides or a simple majority of committee members so request.

Or. fr

*Justification*

*Clarification.*

**Amendment 302**

**Giulia Moi**

**Proposal for a regulation**

**Article 27 a (new)**

*Text proposed by the Commission*

*Amendment*

***Article 27a***

***Review***

***No later than 3 years after the date of application of this Regulation and in the light of experience gained, the Commission shall forward to Parliament and Council a report on its implementation and, in particular, of Articles 3 and 8, accompanied, where***

*appropriate, by any proposals. The report shall be made public.*

Or. en

**Amendment 303**

**José Bové**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 29 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

**3. The Commission may, by means of *implementing* acts, adopt transitional measures 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).**

*deleted*

Or. en

**Amendment 304**

**Nicola Caputo**

**Proposal for a regulation**

**Article 29 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

**3. The Commission may, by means of *implementing* acts, adopt transitional measures 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).**

**3. The Commission may, by means of *delegated* acts, adopt transitional measures for the application of paragraphs 1 and 2. Those *delegated* acts shall be adopted in accordance with the procedure referred to in Article 27(*1a new*).**

Or. en

**Amendment 305**  
**Anja Hazekamp, Stefan Eck**

**Proposal for a regulation**  
**Article 29 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3a. Until Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones] enters into force, foods derived from cloned animals and their descendants shall not be authorised and/or placed on the Union list of novel foods authorised to be placed on the market within the Union.***

Or. en

**Amendment 306**  
**José Bové**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 30 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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

***This Regulation shall not enter into force until Council Directive XXX/XX/EU [on the placing on the market of food from animal clones] is in force. This condition being satisfied, this Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.***

Or. en

**Amendment 307**  
**Nicola Caputo**

**Proposal for a regulation**  
**Annex (new)**

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*Text proposed by the Commission*

*Amendment*

***Union List of authorised novel foods and  
list of traditional foods from third  
countries***

Or. en