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Committee on the Environment, Public Health and Food Safety

2013/0435(COD)

20.10.2014

AMENDMENTS
94 - 192

Draft report
James Nicholson
(PE537.480v02-00)

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

Proposal for a regulation
(COM(2013)0894 – C8-0487/2013 – 2013/0435(COD))

AM_Com_LegReport

Amendment 94
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Citation 2 a (new)

Text proposed by the Commission	*Amendment*
	Having regard to the positions of both Council and European Parliament on 29 March 2011, when the conciliation on novel foods failed;

Or. en

Amendment 95
Jean-François Jalkh, Mireille D'Ornano, Sylvie Goddyn

Proposal for a regulation
Recital 1

Text proposed by the Commission	*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.***	(1) The free movement of ***food must not have any a priori legitimacy, and the implementation of the internal market must be subordinate to a public health imperative which each country is free to define.***

Or. fr

Justification

The public interest and subsidiarity, which are among Europe's core values, need to be emphasised with respect to the establishment of an integrated and competitive market.

Amendment 96
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL 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[1], should be applied.***

Or. en

([1] OJ L 31, 1.2.2002, p. 1.)

Justification

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

Amendment 97
Pavel Poc

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	(2) A high level of protection of human health and of consumers' interests***, of the***

effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency.	***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 [1 a], should be applied.***
	[1 a] OJ L 31, 1.2.2002, p. 1.

Or. en

Justification

Reintroduction of amendment included in European Parliament's second reading position from 2010.

Amendment 98
Nicola Caputo

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***, based on the precautionary principle,*** and of consumers' interests and the effective functioning of the internal market ***need to*** be assured in the pursuit of Union food policies, whilst ensuring transparency.

Or. en

Amendment 99
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council[8] and by Commission Regulation (EC) No 1852/2001[9]. Those rules need to be updated to simplify the current authorisation procedures and ***to*** take account of recent developments in Union law. For the sake of clarity of Union legislation, Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and Regulation (EC) No 258/97 should be replaced by this Regulation.	(3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council[8] and by Commission Regulation (EC) No 1852/2001[9]. Those rules need to be updated to simplify the current authorisation procedures***, improve consumer safety*** and take account of recent developments in Union law. For the sake of clarity of Union legislation, Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and Regulation (EC) No 258/97 should be replaced by this Regulation.
[8] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).	[8] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).
[9] Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).	[9] Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).

Or. fr

Amendment 100
Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Foods which are intended to be used for technological purposes and genetically modified food ***should*** not fall within the scope of this Regulation as they are already covered by other Union rules. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[10], enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council[11], food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council[12], flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council[13] and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council[14] should be excluded from the scope of this Regulation.	(4) Foods which are intended to be used for technological purposes and genetically modified food ***must*** not fall within the scope of this Regulation as they are already covered by other Union rules. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[10], enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council[11], food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council[12], flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council[13] and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council[14] should be excluded from the scope of this Regulation.
[10] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).	[10] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
[11] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).	[11] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).
[12] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).	[12] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).
[13] Regulation (EC) No 1334 /2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).	[13] Regulation (EC) No 1334 /2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

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

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

Or. fr

Amendment 101
Eleonora Evi

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Foods which are intended to be used for technological purposes and genetically modified food should not fall within the scope of this Regulation as they are already covered by other Union rules. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[10], enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council[11], food used solely as additives falling within the scope of Regulation (EC) No 1333/2008[12] of the European Parliament and of the Council, flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council[13] and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council[14] should be excluded from the scope of this Regulation.	(4) Foods which are intended to be used for technological purposes and genetically modified food should not fall within the scope of this Regulation as they are already covered by other Union rules. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[10] ***and Directive 2001/18/EC,*** enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council[11], food used solely as additives falling within the scope of Regulation (EC) No 1333/2008[12] of the European Parliament and of the Council, flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council[13] and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council[14] should be excluded from the scope of this Regulation.

[10] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically

[10] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically

modified food and feed (OJ L 268, 18.10.2003, p. 1).

[11]Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).

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

[13] Regulation (EC) No 1334 /2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

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

modified food and feed (OJ L 268, 18.10.2003, p. 1).

[11]Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).

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

[13] Regulation (EC) No 1334 /2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

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

Or. it

Justification

GMOs are covered by both the regulation referred to and Directive 2001/18/EC.

Amendment 102
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	***deleted***

of Regulation (EC) No 178/2002 of the European Parliament and of the Council[15] .

[15] 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).

Or. en

Amendment 103
Françoise Grossetête

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[15].	(5) The existing categories of novel food laid down in Article 1 of Regulation (EC) No 258/97 should be clarified and updated by ***adding relevant new categories to*** the existing categories ***and*** 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[15].
[15] 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).	[15] 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).

Or. fr

Amendment 104
Sirpa Pietikäinen

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[15] .	(5) The categories of novel food laid down in Article 1 of Regulation (EC) No 258/97 should be ***maintained and where appropriate*** updated by ***adding new relevant*** categories ***and*** 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[15] .
[15] 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).	[15] 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).

Or. en

Amendment 105
Pavel Poc

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	(5) The categories of novel food ***listed*** in Article 1 of Regulation (EC) No 258/97 should be ***maintained and where appropriate*** updated by ***adding new relevant*** categories ***and*** a reference to the general definition of food provided for in

(EC) No 178/2002 of the European Parliament and of the Council[15] .

[15] 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).

Regulation (EC) No 178/2002 of the European Parliament and of the Council[15] .

[15] 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).

Or. en

Justification

Amended for consistency reasons.

Amendment 106
Michel Dantin, Angélique Delahaye

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[15].	(5) The existing categories of novel food ***listed*** in Article 1 of Regulation (EC) No 258/97 should be clarified and updated 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[15]. ***Before the date of application of this Regulation, the Commission should adopt guidance, after consulting the stakeholders, on the categories of novel foods which would assist the applicants and Member States in understanding whether a food falls within the scope of this Regulation and into which category of novel food a food falls.***

[15] Regulation (EC) No 178/2002 of the

[15] 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).

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).

Or. fr

Amendment 107
Julie Girling

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[15] .	(5) The existing categories of novel food ***listed*** 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[15] . ***Before the date of application of this Regulation, the Commission should adopt guidance, following a consultation with stakeholders, on the categories of novel foods which would assist the applicants and Member States in understanding whether a food falls within the scope of this Regulation and into which category of novel food a food falls.***
[15] 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).	[15] 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).

Or. en

Amendment 108
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

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[15].	(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[15]. ***The categories to be defined should take into account the possibilities of technological innovation to ensure that such innovations, even disruptive innovations, follow the same authorisation procedures.***
[15] 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).	[15] 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).

Or. fr

Amendment 109
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 110
Nicola Caputo

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 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	(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

Member States to the Union.	a use in the Member States irrespective of the date of accession of the various Member States to the Union.

Or. en

Amendment 111
Michèle Rivasi, José Bové, Younous Omarjee

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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[16]***.	(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.
[16] 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 112
Elisabetta Gardini

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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[16].	(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 ***and which results in differences in the structure, composition and nutritional properties of the finished product*** is applied to that food or when ***products*** 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.
[16] 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).	[16] 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. it

Justification

It needs to be made clear that a food is 'novel' not merely because new production processes or nanomaterials have been used but also because the use of those new processes results in changes to the structure, composition and nutritional properties of the finished product, as is clear from other parts of the proposal for a regulation.

Amendment 113
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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***[16] .	(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.

[16] 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

Justification

As regards the definition of nanomaterials, it is not appropriate to refer to Reg. 1169/2011, as the latter deals with labelling, whereas this Regulation is about risk assessment. EFSA recognizes uncertainties and recommends a 10% threshold for food-related nano-applications. If the 50% threshold was applied even for risk assessment purposes, there would be the serious risk that some nano-ingredients will not be captured by the definition, and would therefore not be subject to risk assessment.

Amendment 114
Nicola Caputo

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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[16]*** .	(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.

[16] 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 115
Pavel Poc, Daciana Octavia Sârbu

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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[16]*** .	(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.

[16] 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

Justification

In view of the current uncertainties over safety for food related applications and given the current lack of validated analytical methods for nanomaterials and detection methods for lower nanoparticles threshold, scientific progress and state-of-the art in terms of availability and validation of analytical technology should be considered for any food regulatory frameworks and when reviewing the definition of nanomaterial.

Amendment 116
Eleonora Evi

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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[16].	(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[16]***, which account for not less than 10% of the food by weight or volume, as calculated by adding together the percentages present in the individual ingredients***.
[16] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of	[16] 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).

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. it

Amendment 117
Sirpa Pietikäinen

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) According to the Commission Recommendation on the definition of nanomaterial (2011/696/EU) in specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%. In view of the current uncertainties over safety, a lower nanoparticle number threshold, e.g. 10%, as proposed by the EFSA scientific Committee, should be considered for food related applications instead of the currently proposed (50%).

Or. en

Amendment 118
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) Vitamins, minerals and other substances intended to be used in food supplements or to be added to food ***including infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes,*** and total diet replacement for weight control are subject to the rules provided for in Directive 2002/46/EC of the European Parliament and of the Council[17], in Regulation (EC) No 1925/2006 of the European Parliament and of the Council[18] and in Regulation (EU) No 609/2013 of the European Parliament and of the Council[19]. Those substances should also be assessed in accordance with the rules laid down in this Regulation when they fall within the definition of novel food laid down in this Regulation.	(8) Vitamins, minerals and other substances intended to be used in food supplements or to be added to food and total diet replacement for weight control are subject to the rules provided for in Directive 2002/46/EC of the European Parliament and of the Council[17], in Regulation (EC) No 1925/2006 of the European Parliament and of the Council[18] and in Regulation (EU) No 609/2013 of the European Parliament and of the Council[19]. Those substances should also be assessed in accordance with the rules laid down in this Regulation when they fall within the definition of novel food laid down in this Regulation. ***Infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children and food for special medical purposes shall be subject to special rules in view of the particular fragility of the consumers concerned.***
[17] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).	[17] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
[18] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).	[18] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).
[19] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and	[19] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and

repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

Or. fr

Amendment 119
Pavel Poc

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Food with a new or intentionally modified primary molecular structure, food containing, consisting of, or produced from micro-organism, fungi or algae, food derived from tissue culture or cell culture, food containing, consisting of, isolated or produced from plants or animals or their parts, except for animals and plants obtained by traditional propagating or breeding practices, and having a history of safe food use within the Union market, should be considered as novel food as defined in this Regulation

Or. en

Justification

Amended for consistency reasons.

Amendment 120
Bart Staes
on behalf of the Verts/ALE Group

Lynn Boylan
on behalf of the GUE/NGL 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 121
Michèle Rivasi, José Bové, Younous Omarjee

Proposal for a regulation
Recital 9

Text proposed by the Commission	*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	(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 this Regulation and subsequently in accordance with the relevant specific legislation.

with the relevant specific legislation. ***Where there is a change in the particle size of such a substance, for example through the use of nanotechnology, the substance shall be prohibited.***

Or. fr

Amendment 122
Nicola Caputo

Proposal for a regulation
Recital 10

Text proposed by the Commission	*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 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.	(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 123
Pavel Poc

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) Food derived from cloned animals has been regulated under Regulation (EC) No 258/1997. It is crucial that no legal ambiguity emergences as regards the placing on the market of food from animal clones and/or their descendants. Until specific legislation on food derived from cloned animals and their descendants enters into force, this food should fall under the scope of this Regulation on the condition that, while placed on the market within the Union, it is appropriately labelled for the final consumer.

Or. en

Justification

Amended for consistency reasons.

Amendment 124
Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh

Proposal for a regulation
Recital 11

Text proposed by the Commission	*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.***	(11) The placing on the market within the Union of traditional foods from third countries should be ***restricted and controls on these foods enhanced***, ***even*** where the history of safe food use in a third country has been demonstrated.

Or. fr

Amendment 125
Sirpa Pietikäinen

Proposal for a regulation
Recital 11

Text proposed by the Commission	*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.	(11) The placing on the market within the Union of traditional foods from third countries***, such as insects,*** 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.

Or. en

Amendment 126
Eleonora Evi

Proposal for a regulation
Recital 11

Text proposed by the Commission	*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.	(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 ***50*** years as a part of the customary diet ***of the majority*** 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. it

Amendment 127
Pavel Poc

Proposal for a regulation
Recital 11

Text proposed by the Commission	*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.	(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 ***set out in the scientific and technical guidance to be given by the European Food Safety Authority ('EFSA')***. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. en

Justification

For the 'history of safe food use' data requirements have to be set up and clearer criteria for what constitutes a 'history of safe use' should be put forward by the EFSA.

Amendment 128
Nicola Caputo

Proposal for a regulation
Recital 11

Text proposed by the Commission	*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	(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.	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. ***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.***

Or. en

Amendment 129
Angélique Delahaye, Françoise Grossetête, Michel Dantin

Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) The determination as to whether or not a food was consumed by the population of a third country to a significant degree should be based on information provided by food business operators and, where appropriate, supported by other information available in the third countries. Where 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 to collect such information. Implementing powers should be conferred on the Commission to set out in detail the procedural stages of that consultation process.

Or. fr

Justification

To clarify the notion of 'significant' consumption.

Amendment 130
Lynn Boylan
on behalf of the GUE/NGL Group
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, 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.	(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 ***and are either unprocessed or have gone through a primary process. However, where a secondary process involving the combination of foods in a particular way to change the properties of the food or involving*** 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.

Or. en

Justification

Almost all food derives from primary production. The purpose of this category is to allow traditional food such as fruits, juices and seeds to enter the EU market following a less burdensome application procedure. Therefore it should be clarified for the industry and for consumers the kind of process which is allowed which doesn't change the properties of this food.

Amendment 131
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

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, 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.	(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 process ***which had not previously*** been ***used for this type of food is*** applied to ***it*** 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.

Or. fr

Amendment 132
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan, Stefan Eck
on behalf of the GUE/NGL Group

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, 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)***	(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, the food should not be

of Regulation (EU) No 1169/2011, the food should not be considered to be traditional.	considered to be traditional.

Or. en

Justification

As regards the definition of nanomaterials, it is not appropriate to refer the Reg. 1169/2011, as the latter deals with labelling, whereas this Regulation is about risk assessment. EFSA recognizes uncertainties and recommends a 10% threshold for food-related nano-applications. If the 50% threshold was applied even for risk assessment purposes, there would be the serious risk that some nano-ingredients will not be captured by the definition, and would therefore not be subject to risk assessment.

Amendment 133
Nicola Caputo

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, 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.	(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', the food should not be considered to be traditional.

Or. en

Amendment 134
Eleonora Evi

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, 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.	(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, ***which account for not less than 10% of the food by weight or volume, as calculated by adding together the percentages present in the individual ingredients,*** the food should not be considered to be traditional.

Or. it

Amendment 135
Nicola Caputo

Proposal for a regulation
Recital 13

Text proposed by the Commission	*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	(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.	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 136
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL 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 137
Pavel Poc

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) Implementing powers should be	***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. en

Justification

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

Amendment 138
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL 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 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***	(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 should be established for collecting such information.

process.

Or. en

Justification

This is an essential decision and should therefore not be taken by implementing acts.

Amendment 139
Eleonora Evi

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 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***.	(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 by 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, ***the food in question must be considered as a novel food***.

Or. it

Amendment 140
Michel Dantin, Angélique Delahaye

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 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.	*(Does not affect English version)*

Or. fr

Justification

Does not affect English version.

Amendment 141
Nicola Caputo

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	(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.	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 142
Elisabetta Gardini

Proposal for a regulation
Recital 17

Text proposed by the Commission	*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 for the consumer.	(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 less advantageous for the consumer.

Or. it

Justification

Given the nature of novel foods, the advantages or disadvantages go well beyond the food's nutritional properties and relate to the food's composition as a whole. Therefore, the word 'nutritionally' should be deleted, as it fails to reflect all of the differences that novel foods can entail.

Amendment 143
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 17

Text proposed by the Commission	*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 for the consumer.	(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe***, beneficial to consumers,*** 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. ***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

Justification

It is appropriate to reintroduce the reference to the precautionary principle, which had been included in European Parliament's second reading position from 2010. The requirement that a novel food should be beneficial for consumers is in analogy to the Food Additives Regulation 1333/2008 (Article 6(2).

Amendment 144
Bart Staes

on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 18

Text proposed by the Commission	*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***, 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.***	(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 145
Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh

Proposal for a regulation
Recital 18

Text proposed by the Commission	*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***, 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.	(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. 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. ***This list must be approved by each Member State and any harmonisation of legislation based on this Regulation should be subject to the provisions of Article 114(4) TFEU. The list must be transparent, easily accessible and regularly updated.***

Or. fr

Amendment 146
Annie Schreijer-Pierik

Proposal for a regulation
Recital 18

Text proposed by the Commission	*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, by means of an	(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.

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.

Following the latest technological innovations and scientific developments, the list should be regularly, and flexibly be updated and expanded if necessary.

Or. en

Amendment 147
Nicola Caputo

Proposal for a regulation
Recital 18

Text proposed by the Commission	*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***, 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	(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 Regulation and the list*** should be ***updated by means of delegated acts***.

used for the initial establishment of the Union list.

Or. en

Amendment 148
Pavel Poc

Proposal for a regulation
Recital 18

Text proposed by the Commission	*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, 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.***	(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 ***a delegated*** 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.

Or. en

Justification

The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to update the Union list.

Amendment 149
Jan Huitema

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 150
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL 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 list implies the application of criteria laid down in this Regulation, implementing***	(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 accordance with Article 290 TFEU should therefore be delegated to the Commission,***

powers should be conferred on the Commission in that respect.	***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 151
Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh

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 list ***implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect***.	(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 ***transparent*** procedure 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 ***more rigorous*** procedure to update the Union list if no reasoned safety objections are expressed. ***Each Member State must issue a favourable opinion on*** the updating of the Union list ***for a food from a third country***. ***In the case of an unfavourable opinion, the Member State may decide whether or not to allow the free movement in its territory of the food from a third country.***

Or. fr

Amendment 152
Nicola Caputo

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 list implies the application of criteria laid down in this Regulation, implementing powers should*** be conferred on the Commission in ***that respect***.	(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, shall therefore*** be conferred on the Commission in ***order to update the Union list***.

Or. en

Amendment 153
Elisabetta Gardini

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 list implies the application of criteria laid down in this Regulation, implementing	(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 ***the applicants should be able to opt for*** a faster and simplified procedure to update the Union list***, so as to ensure that access times are similar to those for similar EU products***. ***That procedure should be authorised in cases where*** no reasoned safety objections

powers should be conferred on the Commission in that respect.	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.
	Or. it

Amendment 154
Eleonora Evi

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 list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.	(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 ***on a case-by-case basis*** 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.
	Or. it

Amendment 155
Pavel Poc

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 list implies the application of criteria laid down in this Regulation, implementing powers*** should ***be conferred on*** the Commission ***in that respect***.	(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 accordance with Article 290 TFEU*** should ***therefore be delegated to*** the Commission***, in order to update the list***.

Or. en

Justification

The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to update the Union list.

Amendment 156
Eleonora Evi

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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').	(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 ***under a transparent and inclusive procedure*** by the European Food Safety Authority ('EFSA')***, in consultation with Member State health authorities, after stakeholder groups have been consulted***.

Or. it

Amendment 157
Nicola Caputo

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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').	(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 158
Michèle Rivasi, Younous Omarjee, José Bové

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[21] 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	***deleted***

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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[21] EFSA Journal 2011; 9(5):2140.

Or. fr

Amendment 159
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL 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[21] 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.	(21) As regards the possible use of nanomaterials for food use, EFSA ***acknowledged*** in its opinion of 6 April 2011[21] on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain that ***the test methods currently available might not be adequate for assessing the risks associated with nanomaterials and considered, more specifically, 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 ***shall therefore develop non-animal*** test methods which take into account specific

	characteristics of engineered nanomaterials ***as a matter of urgency***.
[21] EFSA Journal 2011;9(5):2140.	[21] EFSA Journal 2011;9(5):2140.

Or. en

Justification

This amendment had already been included in European Parliament's 2010 2nd reading position. The EFSA report says: 'There are currently uncertainties related to the identification, characterisation and detection of ENM that are related to the lack of suitable and validated test methods to cover all possible applications, aspects and properties of ENM. Similarly, there are a number of uncertainties related to the applicability of current standard biological and toxicological testing methods to ENM.' (ENM= Engineered Nanomaterials)

Amendment 160
Nicola Caputo

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[21] 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.	(21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011[21] 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. ***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.
[21] EFSA Journal 2011;9(5):2140.	[21] EFSA Journal 2011;9(5):2140.

Or. en

Amendment 161
Eleonora Evi

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[21] 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.	(21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011[21] 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. ***In view of the current gaps in toxicological knowledge and measurement methodologies, the precautionary principle should be applied in order to restrict human exposure to nanomaterials.***

[21] EFSA Journal 2011; 9(5):2140.

[21] EFSA Journal 2011; 9(5):2140.

Or. it

Amendment 162
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) In order to protect human health, the use of nanotechnologies in food production should be prohibited until appropriate nano-specific test methods have been approved for use and adequate safety assessments on the basis of these tests can be carried out.

Or. en

Justification

It is appropriate to reintroduce this amendment, which had been included in European Parliament's second reading position, as there has not been much progress since then, and EFSA acknowledges that there are uncertainties regarding testing methods for nanomaterials.

Amendment 163
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 21 b (new)

Text proposed by the Commission	*Amendment*
	(21b) Differing interpretations of the term 'particle' exist. It should therefore be clarified that foods containing soft nanomaterials, such as micelles or liposomes, are also covered by the definition of 'novel food'.

Or. en

Justification

It has to be specified that the term 'particle' in the context of the definition of nanomaterials in this Regulation does not only cover pieces of matter with defined physical boundaries, as this would imply that according to current interpretation all 'soft' nanomaterials (e.g. micelles) were not covered and would therefore not be subject to pre-market-approval. However, these are exactly the applications which are relevant from a regulatory perspective because their use is being envisaged in applications for food (e.g. as carriers for vitamins and other substances with a nutritional or physiological effect).

Amendment 164
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 21 c (new)

Text proposed by the Commission	*Amendment*
	(21c) When test methods are applied to nanomaterials, an explanation should be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

Or. en

Justification

This wording has already been agreed upon within Regulation 528/2012 concerning the

making available on the market and use of biocidal products (see Annex II point 5).

Amendment 165
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 21 d (new)

Text proposed by the Commission	*Amendment*
	(21d) Only nanomaterials entered in a list of approved substances should be present in food packaging, accompanied by a limit on migration into or onto the food products contained in such packaging.

Or. en

Justification

As this regulation deals with nanomaterials in food, inter alia, it is important to ensure that also nanoparticles that might accidentally migrate into food are taken into account. There is an urgent need for action, as no specific legislation exists so far, and testing requirements are either non-existent or inappropriate test methods are applied. This amendment had already been included in European Parliament's second reading position from 2010.

Amendment 166
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 22

Text proposed by the Commission	*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	(22) When a novel food is authorised and included in the Union list, ***post-market monitoring requirements*** should ***be introduced*** to monitor the use of the authorised novel food to ensure that the use is within safe limits as established in the

limits as established in the safety assessment by EFSA.

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

Justification

Based on amendments 88 and 89 of the draft report.

Amendment 167
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

Proposal for a regulation
Recital 23

Text proposed by the Commission	*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. 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	(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 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 ***those of an initial applicant,*** with the agreement of the ***latter***. 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

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

Or. fr

Amendment 168
Julie Girling

Proposal for a regulation
Recital 23

Text proposed by the Commission	*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. 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 should not be extended due to the granting of data protection to subsequent applicants.	(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 ***ten*** 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. en

Amendment 169
Biljana Borzan

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) While ensuring the confidentiality of the application, an indicative list of applications consisting of basic information should be made available by the Commission to interested parties. That list should prevent identical or duplicate applications from being submitted in succession and therefore reduce the administrative burden for both the potential applicants and the Union.

Or. en

Amendment 170
Nicola Caputo

Proposal for a regulation
Recital 24

Text proposed by the Commission	*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.	(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 171
Dita Charanzová

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) Novel foods are subject to the requirements of Union law on materials and articles intended to come into contact with food, in particular Regulation (EC) No 1935/2004 of the European Parliament and of the Council[1 a] and the specific measures adopted pursuant thereto.
	[1 a] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

Or. en

Justification

This recital is to provide information and to reconfirm that novel foods and third country foods are subject not only to EU labelling requirements, but also EU packaging requirements. The new recital does not create any new legal obligation in this regulation.

Amendment 172
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) In its 2010 second reading on the novel food dossier, the European Parliament, by a very large majority, asked for prohibiting the placing on the market of foods from cloned animals and their descendants. After the conciliation on novel foods failed in March 2011, the Commission committed to come forward with a specific proposal on cloned animals and their descendants, taking into account both the positions of Council and European Parliament. However, the proposals on cloning and clone food presented in December 2013 do not provide for any measures as regards descendants of cloned animals, not even with a view to inform the consumers. Moreover, it does not allow the European Parliament to exercise its rights as Co-legislator. It is therefore appropriate for the Commission to use the opportunity the appointment of the new College offers and to withdraw the 2013 proposals in order to come forward with new proposals, based on the ordinary legislative procedure, in order to take account of the demands by the Parliament.

Or. en

Justification

Against all promises given by the Commission, the 'clone food proposal' does not take into account EP's demands and does not provide for any measures as regards descendants of cloned animals. This is an enormous setback compared to March 2011, when at least labelling of fresh beef was agreed upon by all institutions, and a slap in the face of MEPs, who had, by very large majority, asked for a ban on food from cloned animals and their descendants. Moreover, the legal base of the measure does not allow for codecision, so that the EP would even be deprived from its powers as a co-legislator.

Amendment 173
Renate Sommer

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) In order to allow the Union list to be modified as new novel foods are authorised, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to update the Union list. 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 a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Or. en

Amendment 174
Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh

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

Or. fr

Amendment 175
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL 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 no reasoned safety objections have been expressed, ***implementing powers*** should be conferred on 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, ***the power to adopt delegated acts in 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 176
Eleonora Evi

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

Or. it

Amendment 177
Nicola Caputo

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 no reasoned safety objections have been expressed, implementing powers should be conferred on the Commission***.	(27) ***The initial*** Union list ***of*** traditional food from a third country ***shall be annexed to this Regulation and the list shall be updated by means of delegated acts***.

Or. en

Amendment 178
Pavel Poc

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 no reasoned safety objections have been expressed***, implementing powers should be conferred on the Commission***.	(27) ***The Commission should be empowered to adopt delegated acts, in accordance with Article 26 a*** 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.

Or. en

Justification

The Commission should be empowered to adopt delegated acts in accordance with Article

290 TFEU in order to update the Union list.

Amendment 179
Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The implementing powers relating to the definition of 'novel food', the 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[22].	***deleted***
[22] 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. fr

Amendment 180
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The implementing powers relating to the definition of 'novel food', the ***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[22] .	(28) The implementing powers relating to the definition of 'novel food', 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, should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[22] .
[22] 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).	[22] 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 181
Nicola Caputo

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The implementing powers relating to the ***definition of 'novel food', the*** consultation process for determination of novel food status, ***other updates of the Union list,*** the drafting and presentation of applications or notifications for the	(28) The implementing powers relating to the consultation process for determination 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

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[22] .

[22] 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).

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[22] .

[22] 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 182
Pavel Poc

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The implementing powers relating to the ***definition of 'novel food', the 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[22] .	(28) The implementing powers relating to 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[22] .

[22] Regulation (EU) No 182/2011 of the

[22] 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).	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

Justification

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

Amendment 183
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) 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.

Or. en

Amendment 184
Pavel Poc

Proposal for a regulation
Recital 28 b (new)

Text proposed by the Commission	*Amendment*
	(28b) In order to supplement or amend certain elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the definition of 'novel food', of the authorisation of a novel food and of a traditional food from a third country, of establishing and updating the Union list, and of adopting transitional measures. 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 a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Or. en

Justification

A decision on the scope is essential for the Regulation and should therefore not be taken by implementing acts. The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to update the Union list.

Amendment 185
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group

Proposal for a regulation
Recital 28 c (new)

Text proposed by the Commission	*Amendment*
	(28c) 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[1]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.

Or. en

([1] 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).)

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 186
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*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.	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, animals and consumer

interests. ***The following provisions should apply to products intended for human consumption and for consumption by animals, whether livestock or pets.***

Or. fr

Amendment 187
Marit Paulsen, Fredrick Federley, Ulrike Müller, Catherine Bearder

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*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.	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 188
Michèle Rivasi, José Bové, Younous Omarjee

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*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.	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 189
Renate Sommer

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

Text proposed by the Commission	*Amendment*
	1a. The purpose of this Regulation is to provide a high level of protection of human health and of consumers' interests, while ensuring the effective functioning of the internal market.

Or. en

Amendment 190
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. 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 191
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
(a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;	(a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003 ***and Directive 2001/18/EC***;

Or. it

Amendment 192
Pavel Poc
Proposal for a regulation
Article 1 – paragraph 2 – point c

Text proposed by the Commission	*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].	***Deleted***

Or. en