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***I
REPORT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: James Nicholson

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2013)0894),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0487/2013),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the positions of both Council and European Parliament on 29 March 2011, when the conciliation on novel foods failed;

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Assembly and the French Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 30 April 2014[1],

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on International Trade and the Committee on Agriculture and Rural Development (A8-0046/2014),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C 311, 12.9.2014, p.73

Amendment 1

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

Amendment 2

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***,*** consumers' interests ***and of the environment*** and the effective functioning of the internal market ***need to*** be assured in the pursuit of Union food policies, whilst ensuring transparency. ***Animal health and welfare and the precautionary principle as laid down in Regulation (EC) No 178/2002 are also taken into account.***

Amendment 3

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The standards laid down in Union legislation should be applied to all foods placed on the market within the Union, including foods imported from third countries.

Justification

This amendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate that Union standards should also apply to imported food.

Amendment 4

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 to take account of recent developments in Union law ***and technological progress***. Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and replaced by this Regulation.
[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	[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).

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).

Amendment 5

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) ***Food*** intended to be used for technological purposes and genetically modified food which is already covered by other Union acts should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[10]***and Directive 2001/18/EC of the European Parliament and of the Council[10a], food*** 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], ***food*** 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,	[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).

18.10.2003, p. 1).

[10 a] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, 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).

Amendment 6

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 existing categories of novel food ***listed*** in Article 1 of Regulation (EC) No 258/97 should be clarified and 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.

(EC) No 178/2002 of the European Parliament and of the Council. ***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.***

Amendment 7

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 Member States to the Union.	(6) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, ***one of the criteria for the food to be considered as a novel food should continue to be*** the absence of a use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997. ***Use*** within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union.

Amendment 8

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	(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

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]*** .	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.

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[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).

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 9

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	(8) Vitamins, minerals and other substances intended to be used in food supplements ***in accordance with Directive***

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***.

[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).

[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).

2002/46/EC of the European Parliament and of the Council[17] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council[18] 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 subject to Regulation (EU) No 609/2013 of the European Parliament and of the Council[19]***,*** should also be assessed in accordance with this Regulation when they fall within the definition of novel food ***therein***.

[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).

[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).

Amendment 10

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.

Justification

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

Amendment 11

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

Justification

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

Amendment 12

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) ***A*** food used ***prior to 15 May 1997*** exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC, should be ***permitted*** to be placed on the market within the Union after that date for the same use***, as it should not be*** considered ***to be*** a novel food for the purposes of this Regulation. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than in, or as, a food supplement should be subject to this Regulation.

Amendment 13

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) Food derived from cloned animals has been governed by Regulation (EC) No 258/1997. It is crucial that no legal ambiguity emerges as regards the placing on the market of food from cloned animal 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 condition that, while such food is placed on the market within the Union, it is appropriately labelled for the final consumer.

Justification

Amended for consistency reasons.

Amendment 14

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, ***including 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 of a ***significant number of people in at least one third country as set out in the scientific and technical guidance to be given by the Commission based on advice from 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.

Amendment 15

Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) The determination of whether or not consumption of a food by the population

	of a third country is significant should be based on information supplied by food business operators and, where appropriate, backed up by other information available in the third country. When there is insufficient information on human consumption of a food, a simple and transparent procedure involving the Commission, EFSA and food business operators should be established for collecting such information.

Justification

To clarify how 'significant' consumption is determined.

Amendment 16

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.

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 17

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 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.	(13) Food produced ***exclusively*** from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or ***their*** amount, should not be considered ***to be*** novel foods. However, modifications of a food ingredient that have not ***yet*** been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.

Amendment 18

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Directive 2001/83/EC of the European Parliament and of the Council[20] applies where a product, taking into account all its characteristics, may fall both within the definition of "medicinal product" as laid down in ***Article 1(2) of*** that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the	(14) Directive 2001/83/EC of the European Parliament and of the Council[20] applies ***in cases*** where a product, taking into account all its characteristics, may fall both within the definition of "medicinal product" as laid down in that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the

definition of food as laid down in ***Article 2 of*** Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.	definition of food as laid down in Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.
_____	_____
[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Amendment 19

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***

Justification

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

Amendment 20

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The Commission and EFSA should be subject to specific deadlines to guarantee a smooth processing of applications. However, in difficult cases the Commission and EFSA should have a right to extend those deadlines, if

necessary.

Amendment 21

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, where appropriate, supported by other information available in the Member States. Food business operators should consult Member States ***and the Commission*** if they are unsure of the status of the food ***which*** they intend to place on the market. ***Where*** there is no information or ***the*** information available on human consumption before 15 May 1997 ***is insufficient***, a simple and transparent procedure should be established for collecting such information.

Amendment 22

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	(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 ***safety assessment***

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.	***should be based on the precautionary principle as laid down in Article 7 of Regulation (EC) No 178/2002. In addition, their*** use should not mislead the consumer. Therefore ***consumers should be informed about the content of novel foods, the ingredients and the technologies used in the manufacture thereof. Product labelling requirements are therefore of the utmost importance, particularly if the novel food has been created using new rearing or farming methods, new materials or new production processes. Similarly***, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous ***or of an inferior quality*** for the consumer.

Justification

The first part of thisamendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate here that the precautionary principle should be applied.

Amendment 23

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***	(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 already authorised or notified in accordance with Regulation (EC) No 258/97, including any existing authorisation conditions. ***The list should be transparent, easily accessible and regularly updated.***

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.

Justification

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

Amendment 24

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 a sound scientific confirmation of European food safety.

Amendment 25

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	(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.***	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 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.***

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 26

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 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 of a novel food that may have an impact on health should be assessed on an individual basis.***

Amendment 27

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 , more specifically, considered 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 ***should therefore develop non-animal*** test methods which take into account specific characteristics of engineered nanomaterials ***as a matter of urgency***. ***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.

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 28

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) 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'.

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 29

Proposal for a regulation
Recital 21 b (new)

Text proposed by the Commission	*Amendment*
	(21b) 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 or adjustments that have been made in order to respond to the specific characteristics of these materials.

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 30

Proposal for a regulation
Recital 21 c (new)

Text proposed by the Commission	*Amendment*
	(21c) 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.

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 31

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 limits as established in the safety assessment by EFSA.	(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 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.***

Justification

Based on amendments 88 and 89 of the draft report.

Amendment 32

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 ***the applicants*** in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation. The proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the ***initial*** applicant. The protection of scientific data provided by ***an*** applicant should not prevent other applicants from seeking the inclusion in the Union list on the basis of their own scientific data or ***those of an initial applicant,*** with the agreement of the ***latter***. However, the overall ***seven*** year period of data protection which has been granted to the ***initial*** applicant should not be extended due to the granting of data protection to subsequent applicants.

Amendment 33

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) If an applicant requests data protection on the same food both under this Regulation and Regulation (EC)

1924/2006, the Commission should endeavour to align the timing of both authorisation procedures to let the data protection periods run concurrently. If this necessitates delaying one of the procedures, the applicant should be consulted in advance.

Amendment 34

Proposal for a regulation
Recital 23 b (new)

Text proposed by the Commission	*Amendment*
	(23b) 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.

Amendment 35

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	(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. ***Additional*** labelling information ***should be included***, in particular regarding the description of the food, its ***origin, its composition and*** its conditions of use to ensure that consumers are sufficiently

informed of the nature of the novel food.	informed of the nature of the novel food***, including that coming from third countries***. ***Therefore, when a novel food is included in the Union list or in the list of traditional foods from third countries, specific conditions of use or labelling requirements may be imposed, which might, inter alia, relate to any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population. It is appropriate to lay down in this Regulation specific labelling requirements in respect of food ingredients present in the form of engineered nanomaterials which fall within the scope of this Regulation. Materials that give rise to ethical concerns, as in the current Regulation (EC) No 258/97, should also be indicated on the label in order to allow the consumers to make informed choices.***

Amendment 36

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).

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 37

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, was in favour of a prohibition on 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 informing 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 that the appointment of the new Commission 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 Parliament.

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 38

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) For those applications which have been submitted under Regulation (EC) No 258/97 before the date of application of this Regulation risk assessment and authorisation procedures should be concluded in accordance with this Regulation. Furthermore, due to clarification of the definition of novel food laid down in this Regulation and to enhance legal certainty, a food that was legally placed on the market at the date of application of this Regulation, should in principle be allowed to be placed on the market until the risk assessment and authorisation procedures have been concluded. Therefore, transitional ***rules*** should be laid down to ensure a smooth transition to the rules of this Regulation.	(25) For those applications which have been submitted under Regulation (EC) No 258/97 before the date of application of this Regulation risk assessment and authorisation procedures should be concluded in accordance with this Regulation. Furthermore, due to clarification of the definition of novel food laid down in this Regulation and to enhance legal certainty, a food that was legally placed on the market at the date of application of this Regulation, should in principle be allowed to be placed on the market until the risk assessment and authorisation procedures have been concluded. Therefore, transitional ***provisions*** should be laid down to ensure a smooth transition to the rules of this Regulation.

Amendment 39

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.

Amendment 40

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.

Justification

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

Amendment 41

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 for the inclusion of foods in the Union list, ***the procedural steps for the exchange of information for submitting safety objections, the type of information to be included in the opinion adopted by EFSA 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).	[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).

Justification

The recital should be adapted following the result of the vote of the different amendments on delegated/implementing acts

Amendment 42

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) In order to supplement or amend certain non-essential 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 establishing which forms of food fall within the scope of this Regulation for each of the categories of novel foods, establishing the procedural steps of the consultation procedure, the definition of "significant part of the population of a third country", and updating the Union list of novel foods. 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.

Amendment 43

Proposal for a regulation
Recital 28 b (new)

Text proposed by the Commission	*Amendment*
	(28b) Regulation (EC) No 882/2004 of the European Parliament and of the Council[1a] 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 this Regulation.

[1a] 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 (OJ L 165, 30.4.2004, p. 1. Corrected version OJ L 191, 28.5.2004, 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 44

Proposal for a regulation
Article 1 – paragraph 1 and 2 - point a and b

Text proposed by the Commission	*Amendment*
Subject matter and scope	Subject matter***, purpose*** and scope
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.
	1a. The purpose of this Regulation is to provide a high level of protection of human health and consumers' interests, and of the environment, while ensuring the effective functioning of the internal market.
2. This Regulation shall not apply to:	2. This Regulation shall not apply to:
(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***;
(b) foods when and in so far as they are used as:	(b) foods when and in so far as they are used as:
(i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;	(i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;
(ii) food additives falling within the scope of Regulation (EC) No 1333/2008;	(ii) food additives falling within the scope of Regulation (EC) No 1333/2008;
(iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;	(iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;
(iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the	(iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the

scope of Directive 2009/32/EC;	scope of Directive 2009/32/EC;

Amendment 45

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***

+

Amendment 46

Proposal for a regulation
Article2

Text proposed by the Commission	*Amendment*
Definitions	Definitions
1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.	1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.
2. The following definitions shall also apply:	2. The following definitions shall also apply:
(a) "novel food" means ***all*** food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and ***includes in particular:***	(a) "novel food" means ***any*** food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and ***that falls under at least one of the following categories:***
	(-i) food with a new or intentionally modified primary molecular structure;
	(-ia) food consisting of, isolated from or produced from micro-organisms, fungi or algae;
	(-ib) food consisting of, isolated from or

	produced from plants, except for plants having a history of safe food use within the Union market and obtained by:
	- traditional propagating practices; or
	- non-traditional propagating practices where those practices do not give rise to significant changes in the composition or structure of the food affecting their nutritional value, metabolism or level of undesirable substances;
	(-ic) food derived from cloned animals or their descendants, subject to Article 29 a (new);
	(-id) food containing, consisting of, or obtained from cellular or tissue cultures;
	(-ie) food consisting of, isolated from or produced from animals or their parts, including whole animals, such as insects, except for food from animals obtained by traditional breeding practices and having a history of safe food use within the Union market;
(i) food ***to which*** a new production process not used for food ***production*** within the Union before 15 May 1997 is applied, ***where that production process gives*** rise to significant changes in the composition or structure of the food ***which affect*** its nutritional value, the way it is metabolised or the level of undesirable substances;	(i) food ***resulting from*** a new production process not used for food within the Union before 15 May 1997, ***which may give*** rise to significant changes in the composition or structure of the food ***affecting*** its nutritional value, the way it is metabolised or the level of undesirable substance***, or where that production process might give rise to ethical concerns***;
(ii) food ***containing or consisting of 'engineered nanomaterials' as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;***	(ii) food ***resulting from or affected by intentional changes in the particle size, shape or structure, or in the particle size distribution, through any technology that reduces them to nanoscale. A threshold of 10%, as recommended by EFSA, should be considered for food related applications;***
(iii) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:	(iii) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

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

– such substances contain or consist of ***'engineered nanomaterials' as defined in Article 2(2)t of Regulation (EU) No 1169/2011;***

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

– such substances contain or consist of ***any intentionally manufactured material containing particles, in an unbound state or as an aggregate or agglomerate and where, for 10% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm to 100nm; or***

– a new source or starting material has been used, for a single form or for mixtures of vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013.

(iv) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

(iv) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

(b) "traditional food from a third country" means novel food, other than the novel food as referred to in point (a)***(i) to*** (iii), which is derived from primary production, with a history of safe food use in a third country;

(b) "traditional food from a third country" means novel food, other than the novel food as referred to in point (a) ***(-i), (i), (ii)*** and (iii), which is derived from primary production, with a history of safe food use in a third country;

(c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a ***large part of the population of a*** third country, prior to a notification referred to in Article 13;

(c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a ***significant number of people in at least one*** third country ***as defined in guidelines referred to in Article 4 of this Regulation,*** prior to a notification referred to in Article 13***;***

(d) "the applicant" means the Member State, the third country or the interested party, who may represent several interested parties, who has submitted an application in accordance with Article 9 or 15 or a

(d) "the applicant" means the Member State, the third country or the interested party, who may represent several interested parties, who has submitted an application in accordance with Article 9 or 15 or a

notification in accordance with Article 13 to the Commission;	notification in accordance with Article 13 to the Commission;
(e) "valid application" and “valid notification” mean an application or a notification which falls in the scope of this Regulation and contains the information required for risk assessment and authorisation procedure.	(e) "valid application" and “valid notification” mean an application or a notification which falls in the scope of this Regulation and contains the information required for risk assessment and authorisation procedure***;***
	(ea) "new production process" means a process not used for food production within the Union before 15 May 1997;
	(eb) "traditional propagating practices" or 'traditional breeding practices' mean practices used for food production within the Union before 15 May 1997;
	(ec) "cloned animals"means animals produced by means of a method of asexual, artificial reproduction with the aim of producing a genetically identical or nearly identical copy of an individual animal;
	(ed) "descendants of cloned animals" means animals produced by means of sexual reproduction, in cases in which at least one of the progenitors is a cloned animal.

Amendment 47

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
Article 3	***deleted***
Implementing power concerning the definition of novel food in Article 2(2)(a)	
In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in Article	

2(2)(a).

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

Justification

This Article is more consistent with Article 4 and has accordingly been moved.

Amendment 48

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Procedure for determination of novel food status	Procedure for determination of novel food status
1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.	1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.
2. ***Food business operators shall consult a Member State where*** they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation***. In that case, food*** business operators shall provide the necessary information to the Member State ***on request*** to enable it to determine ***in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997.***	2. ***Where*** they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, ***food business operators shall consult the Member State in which they first intend to place the novel food. Food*** business operators shall provide the necessary information to the Member State to enable it to determine ***whether or not a food falls within the scope of this Regulation. With a view to determining that assessment, the Member State may consult the Commission and other Member States.***
3. ***The*** Commission ***may, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraph 2.***	3. ***The*** Commission ***shall be empowered to adopt delegated acts in accordance with Article 26 a specifying:***
	- which forms of food fall within the scope of this Regulation for each of the

	categories in Article 2(2)(a); ***- the procedural steps of the consultation process; and*** ***- after consultation with EFSA, the definition of "significant part of the population of a third country"***
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	***Those delegated acts shall be adopted by ...[+].***
	_____ [+] ***OJ: please insert date: 12 months after the entry into force of this Regulation.***

Amendment 49

Proposal for a regulation
Article 5

Text proposed by the Commission	*Amendment*
Union list of novel foods	Union list of novel foods
1. The ***Commission shall establish and update a*** Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6***, 7*** and 8 ("the Union list").	1. The Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6 and 8 ("the Union list") ***is set out in the Annex***.
2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such ***and*** used in or on foods ***under*** the conditions of use specified therein.	2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such ***or*** used in or on foods ***according to*** the conditions of use ***and to the labelling requirements*** specified therein.
	2a. The Commission shall also make available on its website a list of rejected applications, in order to serve as reference for future applications. That list shall specify the reasons for rejection.

Amendment 50

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:	The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:
(a) it does not, on the basis of ***the*** scientific evidence ***available***, pose a safety risk to human health;	(a) it does not, on the basis of scientific evidence, ***and after application of the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002,*** pose a safety risk to human health***, nor to animal welfare and where applicable to the environment***;
(b) its ***use does*** not mislead the consumer;	(b) its ***intended use, presentation and labelling do*** not mislead the consumer***, especially when there is a significant change in the nutritional value of a food intended to replace another food***;
c) where it is intended to replace another food, it ***does not differ*** from that food in such a way that its normal consumption would be ***nutritionally disadvantageous*** for the consumer.	c) where it is intended to replace another food, it ***differs*** from that food in such a way that its normal consumption would be ***significantly advantageous*** for the consumer ***in nutritional, health, environmental and social terms***;
	(ca) it is possible to ensure the traceability of the materials used in its manufacture.
	In the case of diverging opinions among scientific studies as referred to in point (a), a conclusion shall be drawn up on the basis of the opinion rendered by EFSA.

Justification

An insignificant difference in nutritional value should not justify a refusal to authorise an application when such difference will not have an impact on human health. If conflict arises between conclusions of scientific studies EFSA must have the power to adjudicate and draw decisive conclusions.

Amendment 51

Proposal for a regulation

Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the precautionary principle shall be applied and the food in question shall not be included in the Union list.

Justification

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

Amendment 52

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

Text proposed by the Commission	*Amendment*
	Foods to which production processes have been applied that require specific risk assessment methods (for example, foods produced using nanotechnologies as referred to in Article 2 (2) (ii)) may not be included in the Union list until such specific methods have been approved by EFSA for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective foods is safe.

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 53

Proposal for a regulation
Article 7

Text proposed by the Commission	*Amendment*
Article 7	***deleted***
No later than …[23] the Commission shall, by means of an implementing act, establish the Union list by entering novel foods authorised or notified under Articles 4, 5 or 7 of Regulation (EC) N° 258/97 in the Union list, including any existing authorisation conditions.	
That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).	
_____	
[23] Publications Office: please insert date: 24 months after the entry into force of this Regulation.	

Amendment 54

Proposal for a regulation
Article 8

Text proposed by the Commission	*Amendment*
Contents of the Union list	Contents ***and updating*** of the Union list
1. The Commission shall authorise a novel food and update the Union list in accordance with the rules laid down in:	1. The Commission shall authorise a novel food and update the Union list in accordance with the rules laid down in:
(a) Articles 9, 10 and 11 and, where applicable, in accordance with Article 25 or	(a) Articles 9, 10 and 11 and, where applicable, in accordance with Article 25 or
(b) Articles 13 to 18.	(b) Articles 13 to 18.
2. The authorisation of a novel food and updating of the Union list provided for in paragraph 1 shall consist of one of the	2. The authorisation of a novel food and updating of the Union list provided for in paragraph 1 shall consist of one of the

following:	following:
(a) adding a novel food to the Union list;	(a) adding a novel food to the Union list;
(b) removing a novel food from the Union list;	(b) removing a novel food from the Union list;
(c) adding, removing or changing the ***conditions***, specifications or ***restrictions*** associated with the inclusion of a novel food on the Union list.	(c) adding, removing or changing the specifications***, conditions of use, additional specific labelling requirements or post-market monitoring requirements*** associated with the inclusion of a novel food on the Union list.
3. The entry for a novel food in the Union list provided for in paragraph 2 shall include where relevant:	3. The entry for a novel food in the Union list provided for in paragraph 2 shall include ***the specification of the novel food, the date of entry of the novel food in the Union list and*** where relevant:
(a) a specification of the novel food;	
(b) the conditions under which the novel food may be used, in order to avoid, in particular, possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;	***(a)*** the conditions under which the novel food may be used, in order to avoid, in particular, possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;
(c) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;	***(b)*** additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;
(d) a post-market monitoring ***requirement*** in accordance with Article 23.	***(c)*** post-market monitoring ***requirements*** in accordance with Article 23.

Amendment 55

Proposal for a regulation
Article 9

Text proposed by the Commission	*Amendment*
The procedure ***for authorising the placing on the market within the Union of a novel food and*** updating the Union list.	The ***procedures*** for updating the Union list.
1. The ***procedure*** for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 8 shall start either on the Commission's initiative or following an application to the Commission by an applicant.	1. The ***procedures*** for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 8 shall start either on the Commission's initiative or following an application to the Commission by an applicant. ***The Commission shall make the application available to the Member States without delay. The Commission shall also publish a summary of the application on its webpage based on the information referred to in point (-a), (a) and a summary of scientific evidence referred to in point (c).***
The application shall include:	The application shall include:
	(-a) the name and address of the applicant;
(a) the name and description of the novel food;	(a) the name and description of the novel food;
	(aa) the description of the production process;
(b) the composition of the novel food;	(b) the ***detailed*** composition of the novel food;
(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;	(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health ***and where applicable to the environment***;
	(ca) where applicable, the analysis method or methods;
(d) where applicable, a proposal for the conditions of use and a proposal for specific labelling requirements which do not mislead the consumer.	(d) where applicable, a proposal for the conditions of ***intended*** use and a proposal for specific labelling requirements which do not mislead the consumer.
2. The Commission ***may*** request EFSA ***to render*** its opinion if the update is liable to have an effect on human health.	2. The Commission ***shall*** request ***that*** EFSA ***renders*** its opinion if the update is liable to have an effect on human health.
	2a. The Commission shall acknowledge

	receipt of the application to the applicant within 15 days of receiving the application. Within one month of receipt of the application, the Commission shall verify the validity of the application. Where the application has not been considered as valid, the Commission shall inform the applicant thereof, specifying the reasons and stop the procedure.
	2b. When test methods are applied to nanomaterials as referred to in Article 2 (2) (ii), an explanation shall be provided of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.
3. The ***procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 8 shall end with the adoption of an implementing act in accordance with Article 11.***	3. The ***Commission shall be empowered to adopt delegated acts, in accordance with Article 26 a, to update the Union list laid down in the Annex.***
4. By way of derogation from paragraph 3, the Commission may ***end the authorisation procedure and*** decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.	4. By way of derogation from paragraph 3, the Commission may decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.
Where applicable, it shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.	Where applicable, it shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.
In such cases, the Commission shall inform the applicant and all Member States directly, indicating the reasons for not considering the update justified.	In such cases, the Commission shall inform the applicant and all Member States directly, indicating the reasons for not considering the update justified.
5. The applicant may withdraw its application ***referred to in paragraph 1*** at any time ***before the adoption of EFSA's opinion referred to in paragraph 2***, thereby terminating the procedure for authorising a novel food and updating the Union list	5. The applicant may withdraw its application at any time, thereby terminating the procedure for authorising a novel food and updating the Union list.

Amendment 56

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
Opinion of EFSA	Opinion of EFSA
1. Where the Commission requests an opinion from EFSA, it shall forward the valid application to EFSA. EFSA shall adopt its opinion within nine months from the date of receipt of a valid application.	1. Where the Commission requests an opinion from EFSA, it shall forward the valid application to EFSA ***within one month***. EFSA shall adopt its opinion within nine months from the date of receipt of a valid application.
In assessing the safety of novel foods, EFSA shall***, where appropriate,*** consider the following:	In assessing the safety of novel foods, EFSA shall consider the following:
(a) whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;	(a) whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
(b) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union.	(b) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union ***and where applicable to the environment;***
	(ba) whether cumulative and synergistic effects could arise, and whether particular groups of the population could be adversely affected;
	(c) whether a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
2. EFSA shall forward its opinion to the Commission, the Member States and***, where applicable,*** to the applicant.	2. EFSA shall forward its opinion to the Commission, the Member States and to the applicant.
3. In duly justified cases, where EFSA requests additional information from the	3. In duly justified cases, where EFSA requests additional information from the

applicant, the period ***of nine months*** provided for in paragraph 1 may be extended.	applicant, the ***nine month*** period provided for in paragraph 1 may be extended.
After consulting the applicant, EFSA shall specify a period within which that additional information ***may*** be provided and shall inform the Commission ***of the additional period required***.	After consulting the applicant, EFSA shall specify a period within which that additional information ***is to*** be provided and shall inform the Commission ***thereof.***
Where the Commission does not object within eight working days of being informed by EFSA, the period ***of nine months*** provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.	Where the Commission does not object within eight working days of being informed by EFSA, the ***nine month*** period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.
4. Where the additional information referred to in paragraph 3 is not ***sent*** to EFSA within the additional period referred to in that paragraph, it shall ***finalise*** its opinion on the basis of the information ***already provided to it***.	4. Where the additional information referred to in paragraph 3 is not ***provided*** to EFSA within the additional period referred to in that paragraph, it shall ***adopt*** its opinion on the basis of the ***available*** information. ***The failure by the applicant to provide the additional information may be a reason for EFSA to adopt a negative opinion.***
5. Where applicants submit additional information on their own initiative, they shall send it to the Commission and to EFSA.	5. Where applicants submit additional information on their own initiative, they shall send it to the Commission and to EFSA.
In such cases, EFSA shall give its opinion within the period of nine months provided for in paragraph 1.	In such cases, EFSA shall give its opinion within the period of nine months provided for in paragraph 1.
6. EFSA shall make the additional information referred to in paragraph 3 available to the Commission and to the Member States.	6. EFSA shall make the additional information referred to in paragraph***s*** 3 ***and 5*** available to the Commission and to the Member States.

Amendment 57

Proposal for a regulation
Article 11

Text proposed by the Commission	*Amendment*
Authorisation of a novel food and updating the Union list	Updating the Union list
1. ***Within nine*** months from the date of publication of EFSA's opinion***, the Commission shall submit to the committee referred to in Article 27(1) a draft implementing act updating the Union list*** taking account of:	1. ***The Commission shall be empowered to adopt a delegated act in accordance with Article 26 a, in order to update the Union list referred to in Article 5, within six*** months from the date of publication of EFSA's opinion ***referred to in Article 10*** taking account of:
(a) the conditions provided for in Article 6 ***where applicable***;	(a) the conditions provided for in Article 6;
(b) any relevant provisions of Union law;	(b) any relevant provisions of Union law;
(c) the EFSA's opinion;	(c) EFSA's opinion;
(d) any other legitimate factors relevant to the application under consideration.	
That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).	
2. Where the Commission has not requested an opinion from EFSA in accordance with Article 9(2), the ***nine***-month period provided for in paragraph 1 shall start from the date on which the Commission received a valid application in accordance with Article 9(1).	2. Where the Commission has not requested an opinion from EFSA in accordance with Article 9(2), the ***six***-month period provided for in paragraph 1 shall start from the date on which the Commission received a valid application in accordance with Article 9(1).

Amendment 58

Proposal for a regulation
Article 12

Text proposed by the Commission	*Amendment*
Implementing ***power concerning*** administrative and scientific requirements for applications	Implementing ***acts laying down*** administrative and scientific requirements for applications
By …[24] at the latest, the Commission shall adopt implementing acts concerning:	By …[24] at the latest, the Commission shall adopt implementing acts concerning:
(a) the contents, drafting and presentation of the application referred to in	(a) the contents, drafting and presentation of the application referred to in

Article 9(1);	Article 9(1);
(b) the arrangements for checking the validity of those applications;	(b) the arrangements for checking the validity of those applications;
(c) the type of information ***required*** to be included in the opinion of EFSA referred to in Article 10.	(c) the type of information to be included in the opinion of EFSA referred to in Article 10.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).
[24] Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.	[24] Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Justification

Alignment with Council objective to correct terminology.

Amendment 59

Proposal for a regulation
Article 13

Text proposed by the Commission	*Amendment*
Notification of traditional foods from third countries	Notification of traditional foods from third countries
An applicant, who intends to place on the market within the Union a traditional food from a third country, ***shall notify*** that intention to the Commission.	***Instead of following the procedure referred to in Article 9, an*** applicant, who intends to place on the market within the Union a traditional food from a third country, ***may opt to submit a notification*** of that intention to the Commission.
The notification shall include the following information:	The notification shall include the following information:
	(-a) the name and address of the applicant;
(a) the name and a description of the traditional food;	(a) the name and a description of the traditional food;
(b) its composition;	(b) its ***detailed*** composition;

(c) its country of origin;	(c) its country ***or countries*** of origin;
(d) documented data demonstrating the history of safe food use in a third country;	(d) documented data demonstrating the history of safe food use in a third country ***as set out in the guidelines referred to in Article 4 of this Regulation***;
(e) where applicable, the conditions of use and specific labelling requirements, which do not mislead the consumer.	(e) where applicable, the conditions of ***intended*** use and specific labelling requirements, which do not mislead the consumer.

Amendment 60

Proposal for a regulation
Article 14

Text proposed by the Commission	*Amendment*
Procedure for traditional foods from third countries	Procedure for ***notifying the placing on the market of*** traditional foods from third countries
1. The Commission shall forward the valid notification provided for in Article 13 ***without delay*** to the Member States and to EFSA.	1. The Commission shall forward the valid notification provided for in Article 13 ***within one month*** to the Member States and to EFSA.
2. Within four months from the date on which the valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or EFSA may submit to the Commission reasoned safety objections, based on scientific evidence, to the placing on the market within the Union of the traditional food concerned.	2. Within four months from the date on which the valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or EFSA may submit to the Commission reasoned safety objections, based on scientific evidence, to the placing on the market within the Union of the traditional food concerned.
3. The Commission shall inform the ***Member States, EFSA and*** the applicant of the outcome of the procedure referred to in paragraph 2.	3. The Commission shall inform the applicant ***of any reasoned objection as soon as it is submitted. The Member States, EFSA and the applicant shall be informed of the outcome*** of the procedure referred to in paragraph 2.
4. Where no reasoned ***safety*** objections are made in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall ***authorise the placing on the market within the***	4. Where no reasoned objections are made in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission, ***by means of delegated act in accordance with Article 26 a*** shall update

Union of the traditional food concerned and update ***without delay*** the Union list.	the Union list ***within one month***. ***The entry in the Union list shall specify that it concerns a traditional food from a third country. Where applicable, certain conditions for use, specific labelling requirements, or post-market monitoring requirements shall be specified.***
5. Where reasoned safety objections, based on scientific evidence, are submitted to the Commission in accordance with paragraph 2, the Commission shall ***not authorise the placing on the market of the traditional food concerned nor*** update the Union list.	5. Where reasoned safety objections, based on scientific evidence, are submitted to the Commission in accordance with paragraph 2, the Commission shall not update the Union list.
In that case, the applicant may submit an application to the Commission in accordance with Article 15.	In that case, the applicant may submit an application to the Commission in accordance with Article 15.

Amendment 61

Proposal for a regulation
Article 15 – paragraph 1

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

Justification

Alignment with Council objective to provide clarity.

Amendment 62

Proposal for a regulation
Article 16

Text proposed by the Commission	*Amendment*
Opinion of EFSA on a traditional food from a third country	Opinion of EFSA on a traditional food from a third country
1. EFSA shall adopt its opinion within six months from the date of receipt of a valid application.	1. EFSA shall adopt its opinion within six months from the date of receipt of a valid application.
2. In assessing the safety of a traditional food from a third country, EFSA shall consider the following matters:	2. In assessing the safety of a traditional food from a third country, EFSA shall consider the following matters:
(a) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant in accordance with Articles 13 and 15;	(a) whether the history of safe food use in a third country***, as set out in the guidelines referred to in Article 4 of this Regulation,*** is substantiated by reliable data submitted by the applicant in accordance with Articles 13 and 15;
(b) whether the composition of the food and the conditions of its use, do not pose a safety risk to human health in the Union.	(b) whether the composition of the food and the conditions of its use, do not pose a safety risk to human health in the Union ***and where applicable to the environment***.
3. EFSA shall forward its opinion to the Commission, the Member States and the applicant.	3. EFSA shall forward its opinion to the Commission, the Member States and the applicant.
4. In duly justified cases, where EFSA requests additional information from the applicant, the period ***of six months*** provided for in paragraph 1 may be extended.	4. In duly justified cases, where EFSA requests additional information from the applicant, the ***six-month*** period provided for in paragraph 1 may be extended.
After consulting the applicant, EFSA shall specify a period within which that additional information ***may*** be provided and shall inform the Commission ***of the additional period needed.***	After consulting the applicant, EFSA shall specify a period within which that additional information ***is to*** be provided and shall inform the Commission ***thereof.***
Where the Commission does not object within eight working days of being informed by EFSA, the period ***of six months*** provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.	Where the Commission does not object within eight working days of being informed by EFSA, the ***six-month*** period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.
5. Where the additional information referred to in paragraph 4 is not ***sent*** to	5. Where the additional information referred to in paragraph 4 is not ***provided***

EFSA within the additional period referred to in that paragraph, it shall finalise its opinion on the basis of the information ***already provided to it***.	to EFSA within the additional period referred to in that paragraph, it shall finalise its opinion on the basis of the ***available*** information. ***The failure to provide the additional information may be a reason for EFSA to adopt a negative opinion.***
6. Where applicants submit additional information on their own initiative, they shall send it to the Commission and to EFSA.	6. Where applicants submit additional information on their own initiative, they shall send it to the Commission and to EFSA.
In such cases, EFSA shall give its opinion within the period ***of six months*** provided for in paragraph 1.	In such cases, EFSA shall give its opinion within the ***six-month*** period provided for in paragraph 1.
7. EFSA shall make the additional information available to the Commission and to the Member States.	7. EFSA shall make the additional information available to the Commission and to the Member States.

Amendment 63

Proposal for a regulation
Article 17 – title

Text proposed by the Commission	*Amendment*
Authorisation of a traditional food from a third country and ***update*** of the Union list	Authorisation of a traditional food from a third country and ***updates*** of the Union list

Justification

Alignment with Council objective to provide clarity.

Amendment 64

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1.Within three months of the date of publication of EFSA's opinion, ***the Commission shall submit to the***	1.Within three months of the date of publication of EFSA's opinion, ***the Commission shall adopt a delegated act in***

Committee referred to in Article 27(1) a draft implementing act to authorise the placing on the market within the Union of the traditional food from a third country and ***to*** update the Union list, taking into account the following:	***accordance with Article 26 a authorising*** the placing on the market within the Union of the traditional food from a third country and ***shall*** update the Union list, taking into account the following:
(a) the conditions provided for in Article 6 ***where applicable;***	(a) the conditions provided for in Article 6;
(b) any relevant provisions of Union law;	(b) any relevant provisions of Union law;
(c) the EFSA's opinion;	(c) the EFSA's opinion;
(d) any other legitimate factors relevant to the application under consideration.	(d) any other legitimate factors relevant to the application under consideration.
That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).	

Justification

Alignment with Council objective to provide clarity. It is clear from Article 6 that not all conditions always apply so the words "where applicable" here are redundant and could be misleading.

Amendment 65

Proposal for a regulation
Article 17 – paragraph 2 – subparagraphs 1 and 2

Text proposed by the Commission	*Amendment*
By way of derogation from paragraph 1, the Commission may ***end*** the authorisation procedure and decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.	By way of derogation from paragraph 1, the Commission may ***terminate*** the authorisation procedure and decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.
Where applicable, ***it*** shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.	Where applicable, ***the Commission*** shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.

Justification

Alignment with Council objective to provide clarity.

Amendment 66

Proposal for a regulation
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The applicant may withdraw its application referred to in Article 15 at any time before the adoption of EFSA's opinion referred to in Article 16, thereby terminating the procedure for authorising a traditional food from a third country and updating the Union list.	3. The applicant may withdraw its application referred to in Article 15 at any time before the adoption of EFSA's opinion referred to in Article 16, thereby terminating the procedure for authorising a traditional food from a third country and updating the Union list. ***In such cases, the applicant shall bear the costs incurred by EFSA in processing the application.***

Amendment 67

Proposal for a regulation
Article 18

Text proposed by the Commission	*Amendment*
For removing a traditional food from a third country from the Union list or for adding, removing or changing ***conditions,*** specifications or ***restrictions*** associated with the inclusion of a traditional food from a third country on the Union list***, Articles 9 to 12 apply.***	***Articles 9 to 12 apply for*** removing a traditional food from a third country from the Union list or for adding, removing or changing specifications, ***conditions of use, additional specific labelling requirements*** or ***post-market monitoring requirements*** associated with the inclusion of a traditional food from a third country on the Union list.

Justification

Alignment with Council objective to provide clarity.

Amendment 68

Proposal for a regulation
Article 19

Text proposed by the Commission	*Amendment*
Implementing power concerning administrative and scientific requirements concerning traditional foods from third countries	Implementing power concerning administrative and scientific requirements concerning traditional foods from third countries
By ...[25] the Commission shall adopt implementing acts concerning:	By ...[25]the Commission shall adopt implementing acts concerning:
(a) the contents, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5);	(a) the contents, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5)***, based on EFSA guidelines***, ***including a precise and exhaustive list of documents required for a notification or an application to be valid***;
(b) the arrangements for checking the validity of those notifications and applications;	(b) the arrangements for checking the validity of those notifications and applications;
(c) the procedural steps for the exchange of information with the Member States and with EFSA for submitting reasoned safety objections as referred to in Article 14(2), (4) and (5);	(c) the procedural steps for the exchange of information with the Member States and with EFSA for submitting reasoned safety objections as referred to in Article 14(2), (4) and (5);
(d) the type of information ***required*** to be included in the opinion of EFSA referred to in Article 16.	(d) the type of information to be included in the opinion of EFSA referred to in Article 16.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).
[25] Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.	[25] Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Justification

Alignment with Council objective to correct terminology.

Amendment 69

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the additional information referred to in paragraph 1 is not received within the extended period referred to in that paragraph, the Commission shall ***act on the basis of the information already provided***.	2. Where the additional information referred to in paragraph 1 is not received within the extended period referred to in that paragraph, the Commission shall ***suspend the authorisation process***.

Amendment 70

Proposal for a regulation
Article 21

Text proposed by the Commission	*Amendment*
Extension of time periods	***Ad hoc extension*** of time periods
In exceptional circumstances, the Commission may extend the time periods provided for in Articles 10(1), 11(1) or (2), 16(1) and 17(1) on its own initiative or, where applicable, at EFSA's request, where the nature of the matter in question ***so*** justifies.	In exceptional circumstances, the Commission may extend the time periods provided for in Articles 10(1), 11(1) or (2), 16(1) and 17(1) on its own initiative or, where applicable, at EFSA's request, where the nature of the matter in question justifies ***an appropriate extension***.
In such cases the Commission shall inform the Member States ***and the applicant*** of the extension and the reasons for it.	In such cases the Commission shall inform ***the applicant and*** the Member States of the extension and the reasons for it.

Justification

In general, the extensions should be exceptional and appropriate. The applicant is to be the first informed about the extension.

Amendment 71

Proposal for a regulation

Article 21 a (new)

Text proposed by the Commission	*Amendment*
	Article 21a
	Alignment of time periods with Regulation (EC) 1924/2006
	If the applicant requests data protection in accordance with Article 24 of this Regulation and Article 21 of Regulation (EC) 1924/2006, the Commission may adjust the time periods provided for in Articles 10(1), 11(1) or (2), 16(1) and 17(1) in order to align them with those in Regulation (EC) 1924/2006 so that the two periods of data protection run concurrently. In such cases the applicant shall be consulted before the Commission takes a decision on the alignment.
	In addition to this alignment of intellectual property protection periods, health claim and novel food evaluation and authorisation procedures shall, where possible, also be synchronised, with a view to ensuring that the market in such products operates smoothly and applicants are afforded proper protection.

Amendment 72

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
Confidentiality of ***the*** application for ***updating of*** the Union list	Confidentiality of application for ***updates to*** the Union list
1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may ***significantly*** harm their competitive position.	1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may harm their competitive position.
2. For the purposes of paragraph 1,	2. For the purposes of paragraph 1,

applicants shall indicate which of the information provided they wish to be treated as confidential and provide all the necessary information to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.

applicants shall indicate which ***parts*** of the information provided they wish to be treated as confidential and provide all the necessary information to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.

3. After ***being informed of*** the Commission's position on the request, ***applicants may withdraw their application within three weeks so as to preserve the confidentiality of the information provided.***

Confidentiality shall be preserved until that period expires.

3. After the Commission's position on the request ***has been communicated***, ***confidentiality shall be preserved for a period of three weeks in case the applicant decides to withdraw the application.***

4. After expiry of the time period referred to in paragraph 3, the Commission ***may*** decide ***after consulting with the applicants*** which information ***may*** remain confidential and, in ***the*** case a decision has been taken, ***shall*** notify the Member States and the ***applicants*** accordingly.

4. After expiry of the time period referred to in paragraph 3, ***if the applicant has not withdrawn the application, the Commission shall decide, giving serious consideration to the applicant's request,*** which ***parts of the*** information ***shall*** remain confidential and, in case a decision has been taken, notify the Member States and the ***applicant*** accordingly.

However, confidentiality shall not apply to the following information:

However, confidentiality shall not apply to the following information:

(a) the name and address of the applicant;

(a) the name and address of the applicant;

(b) the name and description of the novel food;

(b) the name and description of the novel food;

(c) the proposed use of the novel food;

(c) the proposed ***conditions of*** use of the novel food;

(d) a summary of the studies submitted by the applicant;

(d) a summary of the studies submitted by the applicant;

(e) ***where applicable, the analysis method(s).***

(e) ***the results of the studies carried out to demonstrate the safety of the food;***

(ea) any prohibition or restriction imposed in respect of the food by a third country.

The Commission shall maintain a list of applications containing, for each application, the information referred to in points (a) to (ea) of the second subparagraph. The Commission shall make that list available upon request.

5. The Commission, the Member States

5. The Commission, the Member States

and EFSA shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation in accordance with paragraph 4, except for information which is required to be made public in order to protect human health.	and EFSA shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation in accordance with paragraph 4, except for information which is required to be made public in order to protect human health ***and the environment***.
6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and EFSA shall not disclose confidential information, including information the ***confidentiality*** of which is the subject of disagreement between the Commission and the applicant.	6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and EFSA shall not disclose confidential information, including the information of which ***confidentiality*** is the subject of disagreement between the Commission and the applicant.
7. The application of paragraphs 1 to 6 shall not affect the ***circulation*** of information concerning the application between the Commission, the Member States and EFSA.	7. The application of paragraphs 1 to 6 shall not affect the ***exchange*** of information concerning the application between the Commission, the Member States and EFSA.
8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.	8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Amendment 73

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission ***may***, for food safety reasons and ***taking into account the opinion of EFSA,*** impose a requirement for post-market monitoring ***of a novel food*** to ensure that the use of the authorised novel food is within safe limits.	1. The Commission ***shall***, for food safety reasons and ***in line with the precautionary principle*** impose a requirement for post-market monitoring ***for all novel food, taking into account the opinion of EFSA for establishing the necessary period, in order*** to ensure that the use of the authorised novel food is within safe limits.

Justification

The consumption of a novel food may reveal risks for human health. Requiring post-market monitoring for all novel food will ensure that the authorised novel food is within safe limits without any adverse effects which will also boost consumers' confidence.

Amendment 74

Proposal for a regulation
Article 23 a (new)

Text proposed by the Commission	*Amendment*
	Article 23a
	Additional information requirements
	Any food business operator who has placed a novel food on the market shall forthwith inform the Commission of any information of which he is aware concerning:
	(a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food;
	(b) any prohibition or restriction imposed by any third country in which the novel food is placed on the market.
	The Commission shall make that information available to the Member States.

Justification

Additional information requirements should be treated separately from post-market monitoring requirements.

Amendment 75

Proposal for a regulation
Article 23 b (new)

Text proposed by the Commission	*Amendment*
	Article 23b
	Migration limits for constituents of food contact materials
	The packaging of novel foods shall comply with the requirements laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. When limits on the migration of certain constituents or groups of constituents into or on to food are set in accordance with Article 5 of this Regulation, specific attention shall be paid to food contact materials made from or containing nanomaterials. Not later than (12 months after entry into force of this Regulation), the Commission shall present a report to the European Parliament and the Council on how to address the issue of nanomaterials in food contact materials. This report shall elaborate, inter alia, on what test methods are needed to ascertain the safety of nanomaterials in food contact materials, whether or not it is appropriate to authorise them, or, if appropriate, what migration limits should be set.

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.

Amendment 76

Proposal for a regulation
Article 23 c (new)

Text proposed by the Commission	*Amendment*
	Article 23c

Privileges of Member States

1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of that food or food ingredient in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.

2. The Commission, in close cooperation with EFSA, shall examine the grounds referred to in paragraph 1 as soon as possible and shall take the appropriate measures. The Member State which took the decision referred to in paragraph 1 may maintain that decision until the measures have entered into force.

Justification

This provision has been taken over from the current legislation (Reg. 258/1997), and was also included in European Parliament's 2nd reading position of 2010.

Amendment 77

Proposal for a regulation
Article 24

Text proposed by the Commission	*Amendment*
Authorisation procedure in case of data protection	Authorisation procedure in case of data protection
1. On request by the applicant, supported by appropriate and verifiable information included in the application provided for in Article 9(1), newly developed scientific evidence or scientific data supporting the application may not be used for the benefit of a subsequent application during a period	1. On request by the applicant, supported by appropriate and verifiable information included in the application provided for in Article 9(1), newly developed scientific evidence or scientific data supporting the application may not be used for the benefit of a subsequent application during a period

of ***five*** years from the date of the authorisation ***and the inclusion*** of the novel food ***in the Union list*** without the agreement of the ***prior*** applicant.	of ***seven*** years from the date of the authorisation of the novel food without the agreement of the ***initial*** applicant.
2. That data protection shall be granted where the following conditions are met:	2. That data protection shall be granted ***by the Commission*** where the following conditions are met:
(a) the newly developed scientific evidence or scientific data was designated as proprietary by the ***prior*** applicant at the time the first application was made;	(a) the newly developed scientific evidence or scientific data was designated as proprietary by the ***initial*** applicant at the time the first application was made***;***
(b) the ***prior*** applicant ***had exclusive right of reference to*** the proprietary scientific evidence or scientific data at the time the first application was made and	(b) the ***initial*** applicant ***can demonstrate ownership of*** the proprietary scientific evidence or scientific data***, by means of verifiable proof*** at the time the first application was made and
(c) the novel food could not have been authorised without the submission of the proprietary scientific evidence or scientific data by the ***prior*** applicant.	(c) the novel food could not have been authorised without the submission of the proprietary scientific evidence or scientific data by the ***initial*** applicant.
However, the ***prior*** applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.	However, the ***initial*** applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.
3. Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.	3. Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.
	3a. In order to avoid the repetition of studies involving vertebrates, reference by a subsequent applicant to studies on vertebrates and other studies that may prevent animal testing shall be allowed. The owner of the data may claim adequate compensation for the use of the data.

Amendment 78

Proposal for a regulation
Article 25 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the fact that the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) during the period of data protection, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data designated as such by the prior applicant or with the agreement of the ***prior*** applicant;	(d) the fact that the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) during the period of data protection, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data designated as such by the prior applicant or with the agreement of the ***initial*** applicant;

Justification

Alignment with Council objective to provide clarity.

Amendment 79

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Scientific evidence or scientific data protected in accordance with Article 24 or for which the protection period under that Article has expired shall not be ***protected again***.	2. Scientific evidence or scientific data protected in accordance with Article 24 or for which the protection period under that Article has expired shall not be ***granted renewed protection***.

Justification

Alignment with Council objective to provide clarity.

Amendment 80

Proposal for a regulation
Chapter 6 – title

Text proposed by the Commission	*Amendment*
Penalties and ***committee procedure***	Penalties and ***general provisions***

Amendment 90

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Exercise of the delegation
	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
	2. The delegation of power referred to in Articles 4(3), 9(3), 11(1), 14(4) and 17(1) shall be conferred on the Commission for a period of seven years from ...*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.
	3. The delegation of power referred to in Articles 4(3), 9(3), 11(1), 14(4) and 17(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

	5. A delegated act adopted pursuant to Articles 4(3), 9(3), 11(1), 14(4) and 17(1)shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months from the notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
	_____
	****OJ: please insert the date of entry into force of this Regulation.***

Amendment 81

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	***deleted***
Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.	

Amendment 82

Proposal for a regulation
Article 27 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*

	The committee shall deliver its opinion within six months after adoption of the proposal referred to in Articles 11(1) and 17(1).

Justification

The time limit proposed does not permit to obtain the objective of reaching a decision within a reasonable time period (18 months). This amendment introduces a time limit for the Committee to deliver its opinion. As a comparison: for the centralized authorisation of medicinal products initial comments needs to be submitted in writing within 22 days.

Amendment 83

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before …[27] shall be considered as an application under this Regulation.	1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before …[27] shall be considered as an application under this Regulation.
[27] Publications Office: please insert date: ***24*** months after the date of entry into force of this Regulation.	[27] Publications Office: please insert date: ***12*** months after the date of entry into force of this Regulation.

Amendment 84

Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission may, by means of ***implementing*** acts, adopt transitional measures for the application of paragraphs 1 and 2. Those ***implementing*** acts shall be adopted in accordance with ***the***	3. The Commission may, by means of ***delegated*** acts, adopt transitional measures for the application of paragraphs 1 and 2. Those ***delegated*** acts shall be adopted in accordance with ***Article 26 a***.

examination procedure referred to in Article 27(3).

Justification

Amended for consistency reasons.

Amendment 85

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29a
	Until specific legislation on food derived from cloned animals and their descendants enters into force, this food, while it is placed on the market within the Union, shall be accompanied by the following information for the final consumer: "Food derived from cloned animals/ descendants of cloned animals." In the case of pre-packed food, this food information shall be provided by means of a label. In all other cases, this food information shall be provided by other accompanying material.

Justification

Appropriate measures have to be introduced in order to avoid any regulatory gap.

Amendment 86

Proposal for a regulation
Article 29 b (new)

Text proposed by the Commission	*Amendment*
	Article 29b
	Reporting
	No later than ...*, the Commission shall

	report to the European Parliament and to the Council about the implementation of this Regulation, addressing in particular the impact of the new simplified procedure on traditional foods from third countries.
	**** OJ: Please insert the date of five years following the date of entry into force of this Directive.***

Amendment 87

Proposal for a regulation
Article 30 – paragraph 2

Text proposed by the Commission	*Amendment*
It shall apply from …[28] .	It shall apply from …[28] .
[28] Publications Office: please insert date: ***24*** months after the date of entry into force of this Regulation.	[28] Publications Office: please insert date: ***12*** months after the date of entry into force of this Regulation.

Amendment 88

Proposal for a regulation
Annex (new)

Text proposed by the Commission	*Amendment*
	Annex
	Union List of authorised novel foods and of traditional foods from third countries and conditions of use

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

EXPLANATORY STATEMENT

Background

The Union's rules on novel foods were established on 15 May 1997 upon entering into force by Regulation (EC) No 258/97 of the European Parliament and of the Council and by Commission Regulation (EC) No 1852/2001. Food business operators, industry stakeholders and policymakers in the Union's institutions acknowledged that any new food or food ingredient required pre-market authorisation in order to maintain the high levels of protection of human health and of consumers' interests European citizens have come to expect. Nevertheless, no one could have foreseen the substantive scientific and technological developments in the food sector during the intervening period that has called the suitability of the existing definition of novel foods defined in Regulation (EC) No 258/97 into question. A vast array of new foods and food ingredients have been developed since the regulation came into force, including food containing, consisting of, or produced from microorganisms, fungi and algae, or food with an intentionally modified primary molecular structure. The existing definition of novel foods does not cover these types of food and food ingredients.

A revision of the definition contained in the Regulation is clearly necessary. Attempts were made to revise the regulation in a Commission proposal in 2008. Despite considerable agreement at the conciliation committee stage, the inclusion of placing on the market of food from cloned animals ultimately proved too controversial to reach political agreement. In December 2013, the Commission returned with a new proposal to revise the existing Regulation, incorporating areas of agreement reached at the conciliation committee stage previously but excluding the cloning issue, on which the Commission has instead opted to publish two separate proposals.

Clarifying the scope and definition of what constituted a novel food therefore remains an outstanding issue. However, it is not the only issue worthy of further scrutiny. In addition to the scope and definition, the other areas of chief concern are whether streamlining of the authorisation process can be achieved through the Commission's proposals, and also whether data protection provisions are sufficient in order to stimulate innovation and competitiveness in the European food industry.

The three key areas of definition, streamlining the authorisation process, and robust data protection provisions are not an exhaustive list but the main areas of concern I have with the Commission's proposal, and therefore the focus of my amendments.

Subject matter, purpose and scope

The intention of Regulation (EC) No 258/97 was to introduce a pre-marketing safety assessment for certain well-defined product categories, so that any novel food placed on the market would not have a detrimental impact on human health, consumers' interests, or the functioning of the internal market. It also meant that new formulations of food products using existing ingredients coming onto the market after 15 May 1997 would not be unnecessarily burdened by the Novel Foods Regulation.

The Commission's new proposal retains the provision that a novel food is a food or food ingredient placed on the market, which has not been used for human consumption to a significant before the entrance into force of Regulation (EC) No 258/97. The important difference in the new proposal is the removal of clearly defined categories of what constitutes a novel food. The categories that are listed are used only as examples, rather than an

exhaustive list of novel foods.
After extensive consultation with local producers, industry experts and food business operators, it is clear that the proposed definition is wholly unsatisfactory, lacking in legal certainty, and ultimately failing to clarify the scope and definition of a 'novel food' – a key objective of the Commission's new proposals. While the Commission's intention to expand the concept of a novel food to cover all types of food innovation is a laudable one, the removal of categories has created considerable unease, with many stakeholders questioning whether the definition would apply retroactively to all individual foods that have been placed on the market since 15 May 1997, and whether such products may be subject to legal challenge by Member States or their commercial competitors.
While all interested parties in the food sector were in agreement that the new definition would be unworkable, there were more divergent views on what should take its place. Given the need to acknowledge scientific and technological developments in the food sector, and to improve legal certainty, I consider the most sensible course of action to be the reintroduction of categories of novel foods in an updated form in an effort to "future-proof" the Novel Foods Regulation from unanticipated industry developments.
I have therefore tabled amendments to reintroduce food categories and introduce new categories for food with a new or intentionally modified primary molecular structure; food containing, consisting of, or produced from microorganisms, fungi and algae; and new foods containing, consisting of, or produced from plants or animals, to adapt the regulation to technological progress and new kinds of food entering the Union marketplace.

Streamlining the authorisation process

One of the Commission's stated objectives in the new proposal is to simplify and streamline the regulatory process, thus reducing the administrative burden on applicants, Member State authorities and the Commission itself.
The current pre-market authorisation process has been criticised for being too expensive and too lengthy, with research demonstrating an average of three years for a successful novel food application. The need for applications to go through both the relevant Member State authority and then the Commission is an unnecessary duplication of the time and resources spent on each application.
The Commission have rightly acknowledged that lengthy delays in the process, as well as the costs involved of submitting an application, have created an impediment to innovation and the participation of SMEs. The move to centralise and streamline the authorisation process is welcome, however I have concerns that the Commission's proposals do not go far enough in reducing the time applicants may face.
I have introduced amendments where I believe the application process could be made more efficient if deadlines for various stages of the application process are either stated or reduced. For instance, where the Commission requests an opinion from the European Food Safety Authority ("EFSA"), it should forward a valid novel food application to EFSA within one month, rather than an unspecified period of time. Similarly, I believe a reduction in the number of months the Commission has to submit a draft implementing act to the Standing Committee on the Food Chain and Animal Health, should be in place to make the process more time-efficient.
The introduction of these deadlines will not only enhance the efficacy of the authorisation process, they will provide an additional element of certainty for applicants, Member States and the Commission alike. The proposals as amended also retain a degree of flexibility for both the Commission and EFSA, allowing for appropriate extension of time periods when

necessary in the application process. Such extensions should be the exception, rather than the norm.

Data Protection

Although a streamlined authorisation process will undoubtedly reduce the costs borne by applicants, it is an unavoidably an endeavour which can incur considerable costs, particularly if the applicant has developed new production techniques, new scientific methodologies, or moreover, has had to gather the relevant data to comply with the "history of safe use" provision that applies to traditional food from third countries.

An applicant's investment should therefore receive adequate protection, if food business operators are to be encouraged to improve the competitiveness and innovation of the industry. Under the Commission's proposals an applicant can secure a five year period of data protection for innovative products. A robust data protection regime is necessary to counterbalance the Commission's creation of the generic authorisation procedure, in which a successful novel food authorisation will allow a competitor to place similar food and food ingredients on the market.

The move from 'substantial equivalence' in the current Regulation to generic authorisations in the new proposal have the potential to incentivise innovation. Nevertheless, the proposal as it stands threatens the often invaluable contribution that collaboration between scientists in research institutes or universities and applicants can achieve. Data protection should be granted in cases of publication of studies in a scientific journal, similar to data protection regimes in the United States of America, to encourage, rather than stifle, positive working relationships.

In addition, the review of the Commission's 2008 Impact Assessment presented to the Committee on the Environment, Public Health and Food Safety identified an issue regarding potential conflict between Regulation (EC) No 258/97 and Regulation (EC) No 1924/2006, in which an applicant may seek authorisation of a novel food and of a health claim or claims to be made on that food, and where data protection is justified under the provisions of both Regulations. Although it is not within the scope of this proposal to amend Regulation (EC) No 1924/2006, I believe the Commission should endeavour to do the utmost possible to run applications concurrently in these situations, such that successful applicants under one regulation do not face undue delays in another.

The need for a robust data protection regime should not however come at the expense of increased transparency of the authorisation process, and I have thus tabled amendments that require the Commission to publish detailed guidelines for potential applicants, as well as keeping applicants and Member State authorities informed of the progress of an application at every stage of the process.

Conclusion

A revision of the Regulation on novel foods is eminently sensible and indeed necessary given the scientific and technological strides made in the food industry since 15 May 1997. The food sector is one of the most competitive and innovative on the Union's internal market, thus it is only appropriate for legislation to reflect new realities.

After extensive consultation with local producers, industry experts and food business operators, it is clear the three main areas of concern are the definition of a novel food, streamlining the authorisation process, and robust data protection provisions. In the complex and technical domain of novel foods, what stakeholders need most is a process that is efficient, offers certainty and adequate protection for their products. I consider the

amendments tabled in this report to be both sensible and workable changes to the Commission's proposals, whilst also recognising the Council's drive for greater clarity in any future Novel Foods Regulation.

17.11.2014

OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Jude Kirton-Darling

SHORT JUSTIFICATION

Background

The proposed EU Regulation is the Commission's second attempt at reforming the novel foods regime in the EU, dating from 1997. The existing regulatory framework has been criticised for being particularly burdensome, lengthy and costly to get a novel food authorisation. This is more problematic for those companies whose main market is Europe, compared to the quicker pre-market authorisation process in other third countries such as the United States and Canada. As a consequence, many EU food businesses, SMEs in particular, are not keen to develop and put on the market new foods or food ingredients which would fall under the novel food scope.

At international level, the EU has been repeatedly targeted at the World Trade Organisation by third countries which consider that the novel food authorisation is a barrier to trade and prevents EU market access to foods which have a long history of safe food use in their country of origin.

Considerations

Apart from the overall objective of ensuring food safety, the new Regulation aims at streamlining and simplifying the authorisation procedure for novel food by establishing a Union list of authorised novel foods. The proposals to reduce the administrative burden on both the Member States and their businesses and the length and cost of the authorisation process, as well as to increase competitiveness of the European food industry and in particular for SMEs, including by incentivising innovation, are most welcome.

Further, the proposal introduces a faster and more proportionate safety assessment for traditional foods from third countries. By facilitating market access, these special provisions

for food which has not been marketed in the EU but which has a history of safe use in non-EU countries aim at creating a more balanced system and a positive environment for trade, and thus responding to concerns raised at WTO level about arbitrary and unjustified restrictions on access to the EU market.

Moreover, the proposal's stated objective is to clarify the definition of novel food under the Regulation and thus to enhance legal certainty. Yet concerns have been raised that in particular the removal of categories and the widening of the definitions could result in the opposite, and thus create legislative loopholes that could impact on food safety.

The new definition and the exact notification requirements set for traditional foods from third countries are of particular concern to your rapporteur. The notion of 'history of safe food use' remains rather loosely defined in the proposal, and will need to be accompanied by clear guidance and standards for the collection of data and evidence to be provided by applicants. This is a prerequisite for the new centralised system to be effective, that is, not to run the risk of frequent unreasoned safety objections by the Member States. Moreover, these requirements must be in line with the EU's international commitments so as not to create unjustified restrictions on operators from third countries.
Your rapporteur is aware of the on-going work by the European Food Safety Authority to update existing 1997 guidelines on the scientific aspects and the information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97. Overall, the new centralised system will put a heavier workload on the EFSA which will, needless to say, have to be matched with corresponding resources.

Further to the above-mentioned guidance, your rapporteur finds it essential that sufficient and timely technical assistance be made available to operators in third countries seeking to place traditional foods on the EU market.

Last but not least, your rapporteur deems it important that appropriate monitoring on the implementation and the impact of the new rules be done, in particular as concerns the new simplified procedure on traditional foods from third countries. The results of this monitoring should be reported to the Parliament five years after entry into force of the new Regulation.

These are some of the considerations that underlie the proposals your rapporteur for the Committee on International Trade will put forward. In terms of concrete amendments, the proposals will focus on the provisions concerning traditional goods from third countries and the necessary delegation of power in this respect.

AMENDMENTS

The Committee on International Trade calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

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, ***of the environment*** 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 ***and stimulating innovation and creativity within agri-food SMEs. The precautionary principle, as defined in Regulation (EC) No 178/2002, should apply.***

Amendment 2

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) ***A distinction should be made between traditional food from third countries and novel foods.*** 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 ***as set out in the scientific and technical guidance to be given by the European Food Safety Authority ("EFSA")***. Those foods should have been consumed in a third country for at least 25 years as part of a customary diet within a ***significant*** part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Amendment 3

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain[21] 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 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain[21] 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, ***bearing in mind the precautionary principle,*** the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.
[21] EFSA Journal 2011; 9(5):2140.	[21] EFSA Journal 2011; 9(5):2140.

Amendment 4

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***	(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.

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.	***Additional*** labelling information ***should be included***, in particular regarding the description of the food, its ***origin, its composition and*** its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food***, including those coming from third countries***. ***Therefore, when a novel food is included in the Union list or in the list of traditional foods from third countries, specific conditions of use or labelling requirements may be imposed, which might, inter alia, relate to any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population. It is appropriate to lay down in this Regulation specific labelling requirements in respect of food ingredients present in the form of engineered nanomaterials which fall within the scope of this Regulation.***

Amendment 5

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.	(26) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive ***and should help to ensure a level playing field***.

Amendment 6

Proposal for a regulation
Article 2 − paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) "traditional food from a third country" means novel food, other than the novel food as referred to in point (a)(i) to (iii), which is derived from primary production, with a history of safe food use in a third country;	(b) "traditional food from a third country" means novel food, other than the novel food as referred to in point (a)(i) to (iii), which is derived from primary production ***and processed derivatives, as defined in Regulation (EC) No 178/2002***, with a history of safe food use in a third country;

Amendment 7

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

Text proposed by the Commission	*Amendment*
(c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a ***large*** part of the population of a third country, prior to a notification referred to in Article 13;	(c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a ***significant*** part of the population of a third country, prior to a notification referred to in Article 13;

Amendment 8

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

Text proposed by the Commission	*Amendment*
	The Commission shall be empowered to adopt delegated acts in accordance with

Article 27a concerning the definition of the concept of "significant part of the population of a third country".

Amendment 9

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

Text proposed by the Commission	*Amendment*
(d) **'**the applicant**'** means the Member State, the third country or the interested party, who may represent several interested parties, who has submitted an application in accordance with Article 9 or 15 or a notification in accordance with Article 13 to the Commission;	(d) 'the applicant' means the Member State, the third country**,** or the interested party, who may represent several interested parties, ***or an SME,*** who has submitted an application in accordance with Article 9 or 15 or a notification in accordance with Article 13 to the Commission;

Amendment 10

Proposal for a regulation
Article 3 − title

Text proposed by the Commission	*Amendment*
Implementing power concerning the definition of novel food in Article 2(2)(a)	***Delegation of power***

Amendment 11

Proposal for a regulation
Article 3 − paragraph 1

Text proposed by the Commission	*Amendment*
In order to ensure the uniform implementation of this Regulation, the	***The Commission shall be empowered to adopt delegated acts in accordance with***

Commission may decide, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).	***Article 27a concerning the decision whether or not a particular food falls within the definition of "novel food" as laid down in point (a) of Article 2(2) as well as the authorisation of a traditional food from a third country and updating of the Union list as referred to in Article 17.***

Justification

The rapporteur deems it appropriate to have recourse to the regime of delegated acts to supplement or amend the Regulation in these regards. Should this amendment be adopted a Recital detailing the delegation of power would need to be introduced.

Amendment 12

Proposal for a regulation
Article 3 − paragraph 2

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	***deleted***

Amendment 13

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 (**'**the Union list**'**).	1. The Commission shall establish, update ***and publish*** a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ('the Union list'), ***as set out in the annex of this Regulation. The Union list shall include traditional foods from third countries.***

Amendment 14

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

Text proposed by the Commission	*Amendment*
	(ca) where it is possible to ensure the traceability of the materials used in its manufacture.

Amendment 15

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

Text proposed by the Commission	*Amendment*
(c) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;	(c) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property ***and ensure its traceability***, such as the composition, ***provenance,*** nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;

Justification

The labelling of novel foods must enable the final consumer to determine their origin.

Amendment 16

Proposal for a regulation
Article 13 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) its country of origin;	(c) its country of origin ***and the countries of origin of the materials used in its manufacture***;

Amendment 17

Proposal for a regulation
Article 13 − paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) documented data demonstrating the history of safe food use in a third country;	(d) documented data demonstrating the history of safe food use in a third country***, as set out in the European guidelines under the control of the European Food Safety Authority (EFSA);***

Amendment 18

Proposal for a regulation
Article 13 − paragraph 2 – point e

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

Amendment 19

Proposal for a regulation
Article 17 − paragraph 1 − subparagraph 1

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

Justification

The rapporteur deems it appropriate to have recourse to the regime of delegated acts to supplement the Regulation in these regards. Should this amendment be adopted a Recital detailing the delegation of power would need to be introduced.

Amendment 20

Proposal for a regulation
Article 17 − paragraph 1 − subparagraph 2

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

Amendment 21

Proposal for a regulation
Article 19 − point a

Text proposed by the Commission	*Amendment*
(a) the contents, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5);	(a) the contents, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5), ***based on EFSA guidelines***;

Justification

Apart from updating existing scientific guidelines, the EFSA should develop technical guidance and tools to assist food business operators in 3rd countries for submitting an application or a notification.

Amendment 22

Proposal for a regulation
Article 22 – paragraph 4 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the name ***and*** description of the novel food;	(b) the name***,*** description ***and composition*** of the novel food;

Amendment 23

Proposal for a regulation
Article 23 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The food business operators shall forthwith inform the Commission of:	2. The food business operators ***and the health authorities of the Member States*** shall forthwith inform the Commission of

Amendment 24

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by …[26] at the latest and shall notify it without delay of any subsequent amendment affecting them.	Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive ***and shall ensure a level playing field***. Member States shall notify those provisions to the Commission by …[26] at the latest and shall notify it without delay of any subsequent amendment affecting them.
[26] Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.	[26] Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Amendment 25

Proposal for a regulation
Article 27a new

Text proposed by the Commission	*Amendment*
	Exercise of the delegation
	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
	2. The delegation of power referred to in Article 3 and Article 17 shall be conferred on the Commission for a period of 5 years from ...*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5 year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
	3. The delegation of power referred to in Article 3 and Article 17 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
	5. A delegated act adopted pursuant to Article 3 and Article 17 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period

of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

Justification

The rapporteur deems it appropriate to limit in time the conferral of powers on the Commission. Such limitation brings about more parliamentary control, obliging the Commission to draw up a report in respect of the delegation of power not later than nine months before the end of the established period. On the other hand, tacit extension of the delegation for a period of identical duration prevents overburdening of the legislators and facilitates the implementation of the Regulation.

Amendment 26

Proposal for a regulation
Article 29a new

Text proposed by the Commission	*Amendment*
	Reporting
	Five years after the date of application, the Commission shall report to the European Parliament and to the Council on the implementation of this Regulation, addressing in particular the impact of the new simplified procedure on novel foods and traditional foods from third countries. This report shall be made public.

PROCEDURE

Title	Novel foods
References	COM(2013)0894 – C7-0487/2013 – 2013/0435(COD)
Committee responsible Date announced in plenary	ENVI 16.1.2014
Opinion by Date announced in plenary	INTA 16.1.2014
Rapporteur Date appointed	Jude Kirton-Darling 22.7.2014
Discussed in committee	7.10.2014
Date adopted	6.11.2014
Result of final vote	+: 25 –: 11 0: 2
Members present for the final vote	William (The Earl of) Dartmouth, Tiziana Beghin, David Campbell Bannerman, Daniel Caspary, Salvatore Cicu, Santiago Fisas Ayxelà, Ska Keller, Jude Kirton-Darling, Gabrielius Landsbergis, Bernd Lange, Jörg Leichtfried, Marine Le Pen, David Martin, Anne-Marie Mineur, Alessia Maria Mosca, Franz Obermayr, Franck Proust, Viviane Reding, Olli Rehn, Inmaculada Rodríguez-Piñero Fernández, Matteo Salvini, Marietje Schaake, Helmut Scholz, Adam Szejnfeld, Iuliu Winkler
Substitutes present for the final vote	Bendt Bendtsen, Klaus Buchner, Nicola Danti, Agnes Jongerius, Sajjad Karim, Seán Kelly, Sander Loones, Fernando Ruas, Lola Sánchez Caldentey, Jarosław Wałęsa
Substitutes under Rule 200(2) present for the final vote	Laura Agea, Andi Cristea, Helga Stevens

10.11.2014

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Daciana Octavia Sârbu

SHORT JUSTIFICATION

In January 2008, the Commission proposed a revision of EU legislation on novel foods (2008/0002 (COD)). However, the legislative procedure failed at the conciliation phase mainly because of disagreements over the inclusion of food from cloned animals within the scope of the regulation. In December 2013, the Commission adopted a revised package of measures on animal cloning and novel food.

The proposed novel food regulation no longer covers food from cloned animals, as this is covered by a separate proposal in the package. The rapporteur welcomes the exclusion of food from animal clones from the scope of this regulation and its inclusion in a specific proposal, as this had been requested by the Committee on Agriculture and Rural Affairs previously. The proposal does also not apply to genetically modified foods falling within the scope of Regulation (EC) No 1829/2003[1].

The novel food proposal aims to revise the current novel food legislation (Regulation (EC) No 258/97 [2] and Regulation (EC) No 1852/2001[3]) in order to update and simplify the current authorisation procedures and to take account of recent developments in Union law. With the

[1] 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).

[2] 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).

[3] 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).

proposed Regulation, the Commission intends to create a centralised authorisation system, which should create more certainty for applicants seeking authorisation for a novel food and should simplify and speed up the authorisation process. The rapporteur agrees with the need to simplify the current authorisation procedure, but maintains that priority should be given to safeguarding food safety and the health of consumers, at all stages of the authorisation procedure for novel foods. In addition, in accordance with the precautionary principle, the Union should provide its citizens with a full range of safeguards concerning the safety of foods placed on the market in the Union.

In the case of traditional foods from third countries, in order to remove any barriers to trade caused by the current lengthy authorisation process, the proposal also introduces a simplified authorisation process. If a history of safe use in the third country can be demonstrated and if there are no safety objections from the Member States or EFSA, then the food will be allowed to be placed on the EU market. The rapporteur considers that foods from third countries should also be required to meet equivalent standards to those required from EU foods.

The rapporteur also believes that Member States should have the possibility to consult the Commission and other Member States when they have difficulties establishing whether a food falls within the scope of this Regulation, after considering all the necessary information provided by the food business operators.

At the same time, when assessing the safety of a novel food which is intended to replace a similar food, EFSA needs to ensure that the novel food does not result in a nutritional disadvantage for the consumer when compared to the food it is intended to replace.

The Commission proposes drawing up the initial Union list of authorised novel foods and traditional food from a third country by means of an implementing act. However, the list of novel foods is an essential element which should be incorporated into the basic act (in an annex). Furthermore, the possibility should be provided to update the list of novel foods, without the procedure being as lengthy as for a basic legal act, hence the use of delegated acts.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

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 ***and of the environment*** and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency ***and the protection of animal health***. ***Moreover, the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council [1a], should be applied.***
	_____
	[1a] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1).

Amendment 2

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The standards laid down in Union legislation should be applied to all foods placed on the market within the Union, including foods imported from third countries.

Justification

This amendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate that Union standards should also apply to imported food.

Amendment 3

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.

[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).

Amendment 4

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Foods and food ingredients which fall under the following categories should be considered as novel foods as defined in this Regulation: 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 and other materials of biological or mineral origin; food containing, consisting of, or produced from plants, or their parts, except for plants obtained by traditional propagating or breeding

practices and having a history of safe food use within the Union market, where those practices do not give rise to significant changes in the composition or structure of the food affecting their nutritional value, metabolism or level of undesirable substances; and food containing, consisting of, or produced from insects or their parts;

Amendment 5

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 Member States to the Union.	(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 ***or of placing on the market*** within the Union before the date of entry into force of that Regulation, namely 15 May 1997, should be maintained as a criterion for a food to be considered as a novel food. A use within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union.

Justification

Consequence of changes proposed in Article 2.2(a).

Amendment 6

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Emerging technologies in food production processes may have an impact	(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] .

[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).

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

[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).

Amendment 7

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

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

Justification

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

Amendment 8

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 a part of the ***normal daily*** diet within a ***significant*** part of the population of the country. ***Their safety assessment and management should take into account their*** history of safe food use ***in the third country, excluding*** non-food uses***,*** uses not related to normal diets ***and uses for medical purposes***. ***Account should also be taken of the fact that the structure and properties of foods from third countries can vary according to climatic conditions.***

Amendment 9

Proposal for a regulation
Recital 11 a (new)

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

Justification

To clarify how 'significant' consumption is determined.

Amendment 10

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***

Amendment 11

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.)*

Justification

Linguistic amendment – does not affect the English version – concerns the French version.

Amendment 12

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 ***safety assessment should be based on the precautionary principle as laid down in Article 7 of Regulation (EC) No 178/2002. In addition, their*** use should not mislead the consumer. Therefore ***consumers should be informed about the content of novel foods,***

the ingredients and the technologies used in the manufacture thereof. Product labelling requirements are therefore of the utmost importance, particularly if the novel food has been created using new rearing or farming methods, new materials or new production processes. Similarly, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous ***or inferior quality*** for the consumer.

Justification

The first part of thisamendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate here that the precautionary principle should be applied.

Amendment 13

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.

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 14

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. ***That list should be easily accessible and fully transparent. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of the updating ofthe Union list***

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 15

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Criteria for the evaluation of the safety	(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***’)***.	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 EFSA. ***The 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.***

Amendment 16

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Food from cloned animals has been regulated under Regulation (EC) No 258/1997 and is due to be dealt with in the forthcoming Directive on the placing on the market of food from animal clones. In this context, food from cloned animals should be excluded from the scope of this Regulation.

Amendment 17

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	***deleted***

should be conferred on the Commission.

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 18

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 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 of applications or notifications, ***and*** confidentiality treatment 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).	[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).

Justification

Amendment is consistent with the changes made in the Articles concerning the use of implementing or delegated powers.

Amendment 19

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28 a) In order to supplement or amend certain non-essential 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 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.

Justification

Amendment is consistent with the changes made in the Articles concerning the use of implementing or delegated powers.

Amendment 20

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	1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ***provide a high level of protection of human health,***

while providing a high level of protection of ***human*** health and ***consumers' interests.***	***consumers' interests and the environment, while ensuring*** the effective functioning of the internal market***, transparency, stimulation of innovation within the agri-food industry, and, where relevant, the*** protection of ***animal*** health.

Amendment 21

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***

Amendment 22

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

Text proposed by the Commission	*Amendment*
	2a. Food derived from cloned animals shall not be placed on the Union list of novel foods .

Amendment 23

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

Text proposed by the Commission	*Amendment*
(a) "novel food" means all food that was not used for human consumption to a significant degree within the Union before	(a) " novel food " means all food that was not used for human consumption to a significant degree ***or marketed*** within the

15 May 1997 irrespective of the date of accession of the various Member States to the Union and ***includes in particular***:	Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and ***that falls under at least one of the following categories***:

Justification

To enhance legal certainty.

Amendment 24

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

Text proposed by the Commission	*Amendment*
	(-ia) foods and food ingredients with a new or intentionally modified primary molecular structure;

Amendment 25

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

Text proposed by the Commission	*Amendment*
	(-ib) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae and other materials of biological or mineral origin;

Justification

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

Amendment 26

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

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

Amendment 27

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

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

Amendment 28

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

Text proposed by the Commission	*Amendment*
	(ia) food containing, consisting of, or produced from insects or their parts;

Amendment 29

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

Text proposed by the Commission	*Amendment*
– a ***new*** production process has been applied ***as referred to in point (i) of this paragraph***; or	– a production process ***not used for food production in the Union before 15 May 1997*** has been applied; or

Justification

Clarification.

Amendment 30

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

Text proposed by the Commission	*Amendment*
(c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a ***large*** part of the population of a third country, prior to a notification referred to in Article 13;	(c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a ***significant*** part of the population of a third country, prior to a notification referred to in Article 13;

Justification

The word 'significant' is more appropriate here.

Amendment 31

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

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

Amendment 32

Proposal for a regulation
Article 3 – title

Text proposed by the Commission	*Amendment*
Implementing power concerning the definition of novel food in Article 2(2)(a)	***Delegating*** power concerning the definition of novel food in Article 2(2)(a)

Amendment 33

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission	*Amendment*
In order to ensure the uniform implementation of this Regulation, the Commission ***may*** decide***, by means of implementing acts***, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).	The Commission ***shall be empowered to adopt delegated acts, in accordance with Article 26 a***, ***to*** decide whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).

Justification

It is more appropriate to use delegated powers for a decision of such general application as the definition of novel food, which also determines the scope of this regulation.

Amendment 34

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	***deleted***

Amendment 35

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.	*(Does not affect English version.)*

Justification

Linguistic amendment – does not affect the English version – concerns the French version.

Amendment 36

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation. In that case, food business operators shall provide the necessary information to the Member State ***on request*** to enable it to determine ***in particular the extent to which the food in question was used for human consumption*** within the ***Union before 15 May 1997***.	2. Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation. In that case, food business operators shall provide ***all*** the necessary information to the Member State to enable it to determine ***whether or not a food falls*** within the ***scope of this Regulation***.

Justification

Food business operators need to make available all relevant information related to the new product that they intend to place on a market in order to establish whether it is a novel food.

Amendment 37

Proposal for a regulation
Article 4 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. In order to establish whether a food falls within the scope of this Regulation, Member States may consult the Commission and the other Member States.

Justification

In cases where the Member States have doubts related to inclusion of a food in the scope of this Regulation, they shall have the possibility to consult the Commission and/or the Member States

Amendment 38

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***The Commission shall establish and update a*** Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6***, 7*** and 8 (‘the Union list’).	1. ***A*** Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6 and 8 (‘the Union list’) ***is set out in the Annex***.

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 39

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such and used ***in or on foods under*** the conditions of use specified therein.	2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such and used ***according to*** the conditions of use ***and the labelling requirements*** specified therein.

Justification

Novel foods are subject to labelling requirements under Regulation (EU) No 1169/2011.

Amendment 40

Proposal for a regulation
Article 5 – paragraph 2 a (new)

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

Amendment 41

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

Text proposed by the Commission	*Amendment*
(a) it does not, on the basis of the scientific evidence available, pose a safety risk to human health;	(a) it does not, on the basis of the scientific evidence available, ***and after application of the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002,*** pose a safety risk to human health ***and where applicable to the environment***;

Justification

The first part of this amendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate here that the precautionary principle should be applied.

Amendment 42

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

Text proposed by the Commission	*Amendment*
(b) its use does not mislead the consumer;	(b) its use does not mislead the consumer***, even to a material degree***;

Amendment 43

Proposal for a regulation
Article 7

Text proposed by the Commission	*Amendment*
Article 7	***deleted***
Initial establishment of the Union list	
No later than …[23] the Commission shall, by means of an implementing act, establish the Union list by entering novel foods authorised or notified under Articles 4, 5 or 7 of Regulation (EC) N° 258/97 in the Union list, including any existing authorisation conditions.	
That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).	
[23] Publications Office: please insert date: 24 months after the entry into force of this Regulation.	

Justification

The initial Union list of authorised novel foods and traditional food from a third country

should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 44

Proposal for a regulation
Article 8 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) adding, removing or changing the conditions, ***specifications or restrictions*** associated with the inclusion of a novel food on the Union list.	(c) adding, removing or changing the ***specifications,*** conditions ***of use, additional specific labelling requirements or post-market monitoring requirements*** associated with the inclusion of a novel food on the Union list.

Justification

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

Amendment 45

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

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

Amendment 46

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

Text proposed by the Commission	*Amendment*
(a) a specification of the novel food;	(a) a specification of the novel food ***and technological process***;

Amendment 47

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

Text proposed by the Commission	*Amendment*
	(ab) the name and address of the applicant;

Amendment 48

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

Text proposed by the Commission	*Amendment*
(b) the conditions under which the novel food may be used, in order to avoid, in particular, possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;	(b) ***where relevant,*** the conditions under which the novel food may be used, in order to avoid, in particular, possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;

Amendment 49

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

Text proposed by the Commission	*Amendment*
(c) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the	(c) ***where relevant,*** additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the

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

Amendment 50

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

Text proposed by the Commission	*Amendment*
(d) a post-market monitoring requirement in accordance with Article 23.	(d) ***where relevant,*** a post-market monitoring requirement in accordance with Article 23.

Amendment 51

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

Text proposed by the Commission	*Amendment*
The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 8 shall start either on the Commission's initiative or following an application to the Commission by an applicant.	The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 8 shall start either on the Commission's initiative or following an application to the Commission by an applicant. ***The Commission shall forward the application to Member States and make it available to the public on its website.***

Amendment 52

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

Text proposed by the Commission	*Amendment*
	-a) the name and address of the applicant;

Justification

Greater transparency.

Amendment 53

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

Text proposed by the Commission	*Amendment*
	(b a) the production process;

Justification

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

Amendment 54

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

Text proposed by the Commission	*Amendment*
(c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;	(c) ***independent, peer-reviewed,*** scientific evidence demonstrating that the novel food does not pose a safety risk to human health, ***animal health or environment***;

Amendment 55

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission ***may request*** EFSA ***to render its opinion if the update is liable to have an effect on human health***.	2. The Commission ***shall forward the valid application to the*** EFSA ***and request it to render its opinion***.

Amendment 56

Proposal for a regulation
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 8 shall end with the adoption of an implementing act in accordance with Article 11***.	3. The ***Commission shall be empowered to adopt delegated acts, in accordance with Article 26 a, concerning the authorisation of the placing on the market within the Union of a novel food and the updating of the Union list laid down in the Annex***.

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 57

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

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

Amendment 58

Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1

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

Amendment 59

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

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

Amendment 60

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

Text proposed by the Commission	*Amendment*
(b) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union.	(b) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union ***and where applicable to the environment***.

Amendment 61

Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) whether the novel food meant to replace another food does not have different properties that result in nutritional disadvantages for the consumer.

Justification

When assessing the safety of novel foods, EFSA needs to make sure that a novel food that replaces another similar food does not have different properties to the food it replaces which could result in a nutritional disadvantage for the consumer.

Amendment 62

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

Text proposed by the Commission	*Amendment*
Within nine months from the date of publication of EFSA's opinion, the Commission shall submit to the committee referred to in Article ***27(1) a draft implementing act updating the Union list*** taking account of:	***The Commission shall be empowered to adopt a delegated act in accordance with Article 26 a, in order to update the Union list*** referred to in Article ***5, within nine months from the date of publication of the EFSA's opinion referred to in Article 10,*** taking account of:

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 63

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

Text proposed by the Commission	*Amendment*
(c) the EFSA's opinion;	***deleted***

Justification

The reference to EFSA in point (c) should be removed as there is already a reference to EFSA in the introductory part of the paragraph.

Amendment 64

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

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

Amendment 65

Proposal for a regulation
Article 11 – paragraph 2

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

Amendment 66

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

Text proposed by the Commission	*Amendment*
	-a) the name and address of the applicant;

Justification

Greater transparency.

Amendment 67

Proposal for a regulation
Article 14 – title

Text proposed by the Commission	*Amendment*
Procedure for traditional foods from third countries	***Notification*** procedure for traditional foods from third countries

Justification

It should be specified that the following paragraphs refer to the notification procedure for traditional foods from third countries.

Amendment 68

Proposal for a regulation
Article 14 – paragraph 1

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

Amendment 69

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

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

Amendment 70

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

Text proposed by the Commission	*Amendment*
(b) whether the composition of the food and the conditions of its use, do not pose a safety risk to human health in the Union.	(b) whether the composition of the food and the conditions of its use, do not pose a safety risk to human health in the Union ***and where applicable the environment***.

Amendment 71

Proposal for a regulation
Article 16 – paragraph 2 – point b a (new)

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

Justification

Greater safety.

Amendment 72

Proposal for a regulation
Article 17 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Within three months of the date of publication of EFSA's opinion, the Commission shall submit to the Committee referred to in Article 27(1) a draft implementing act to authorise the	***The Commission shall be empowered to adopt delegated acts in accordance with Article 26 a, within three months of the date of publication of EFSA's opinion,*** to authorise the placing on the market within

placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:	the Union of the traditional food from a third country and to update the Union list, taking into account the following:

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 73

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

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

Amendment 74

Proposal for a regulation
Article 18

Text proposed by the Commission	*Amendment*
For removing a traditional food from a third country from the Union list or for adding, removing or changing conditions, ***specifications or restrictions*** associated with the inclusion of a traditional food from a third country on the Union list***, Articles 9 to 12 apply.***	***Articles 9 to 12 shall apply*** for removing a traditional food from a third country from the Union list or for adding, removing or changing ***specifications,*** conditions ***of use, additional specific labelling requirements or post-market monitoring requirements*** associated with the inclusion of a traditional food from a third country on the Union list.

Justification

See Article 8(2). Clarification.

Amendment 75

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the additional information referred to in paragraph 1 is not ***received*** within the ***extended*** period ***referred to in that paragraph***, the Commission shall ***act on the basis of the information already provided***.	2. Where the additional information referred to in paragraph 1 is not ***forwarded*** within the ***new*** period ***laid down***, the Commission shall ***not issue an authorisation***.

Amendment 76

Proposal for a regulation
Article 22 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission, the Member States and EFSA shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation in accordance with paragraph 4, except for information which is required to be made public in order to protect human health.	5. The Commission, the Member States and ***the*** EFSA shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation in accordance with paragraph 4, except for information which is required to be made public in order to protect human health***, the environment and animal health***.

Amendment 77

Proposal for a regulation
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The food business operators shall forthwith inform the Commission of:	***deleted***
a) any new scientific or technical information which might influence the	

evaluation of the safety in use of the novel food;

b) any prohibition or restriction imposed by any third country in which the novel food is placed on the market.

Justification

This paragraph was incorrectly included in an article on the imposition of a monitoring requirement following placing on the market, as this is a separate requirement of a general nature that is independent of the decision on a monitoring requirement following placing on the market. For the sake of the clarity of the text, this should therefore form a separate article in this regulation.

Amendment 78

Proposal for a regulation
Article 23 a (new)

Text proposed by the Commission	*Amendment*
	Article 23 a
	Requirements concerning new information
	The food business operators shall forthwith inform the Commission of:
	a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;
	b) any prohibition or restriction imposed by any third country in which the novel food is placed on the market.

Justification

This paragraph was incorrectly included in an article on the imposition of a monitoring requirement following placing on the market, as this is a separate requirement of a general nature that is independent of the decision on a monitoring requirement following placing on the market. For the sake of the clarity of the text, this should therefore form a separate article in this regulation.

Amendment 79

Proposal for a regulation
Chapter 6 – title

Text proposed by the Commission	*Amendment*
Penalties and ***committee procedure***	Penalties and ***general provisions***

Amendment 80

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26 a
	Exercise of the delegation
	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
	2. The delegation of power referred to in Articles 3, 9(3), 11(1), 17(1) and 29(3) shall be conferred on the Commission for a period of seven years from ...*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council oppose such extension no later than three months before the end of each period.
	3. The delegation of power referred to in in Articles 3, 9(3), 11(1), 17(1) and 29(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein.

It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 3, 9(3), 11(1), 17(1) and 29(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months from the notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

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

Amendment 81

Proposal for a regulation
Article 27 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	***deleted***

Amendment 82

Proposal for a regulation
Article 27 – paragraph 2 – subparagraph 2

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

Amendment 83

Proposal for a regulation
Article 27 – paragraph 3 – subparagraph 2

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

Justification

Clarification.

Amendment 84

Proposal for a regulation
Article 27 b (new)

Text proposed by the Commission	*Amendment*
	Article 27 b
	Review
	By ... *, and in the light of experience gained, the Commission shall submit to the European Parliament and to the Council a report on the implementation of

this Regulation accompanied, where appropriate, by any legislative proposals.

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****OJ: please insert the date 5 years after the entry into force of this Regulation.***

Justification

Five years after entry into force, the Commission should report to the European Parliament and to the Council about the implementation of the new Regulation.

Amendment 85

Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission ***may, by means of implementing*** acts, adopt transitional measures for the application of paragraphs 1 and 2. ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).***	3. The Commission ***shall be empowered to adopt delegated*** acts, ***in accordance with Article 26 a, to*** adopt transitional measures for the application of paragraphs 1 and 2.

Justification

Delegated acts should be used instead of implementing acts in order to adopt transitional measures.

Amendment 86

Proposal for a regulation
Annex (new)

Text proposed by the Commission	*Amendment*
	Annex
	Union List of authorised novel foods and of traditional foods from third countries

Justification

The initial Union list of authorised novel foods and traditional food from a third country

should be annexed to this Regulation and the list should be updated by means of delegated acts.

PROCEDURE

Title	Novel foods
References	COM(2013)0894 – C7-0487/2013 – 2013/0435(COD)
Committee responsible Date announced in plenary	ENVI 16.1.2014
Opinion by Date announced in plenary	AGRI 16.1.2014
Rapporteur Date appointed	Daciana Octavia Sârbu 17.9.2014
Discussed in committee	23.9.2014 7.10.2014
Date adopted	6.11.2014
Result of final vote	+: 26 –: 11 0: 5
Members present for the final vote	Clara Eugenia Aguilera García, Richard Ashworth, José Bové, Paul Brannen, Nicola Caputo, Matt Carthy, Michel Dantin, Paolo De Castro, Albert Deß, Diane Dodds, Norbert Erdős, Beata Gosiewska, Martin Häusling, Anja Hazekamp, Esther Herranz García, Jan Huitema, Peter Jahr, Jarosław Kalinowski, Elisabeth Köstinger, Zbigniew Kuźmiuk, Nuno Melo, Giulia Moi, Ulrike Müller, James Nicholson, Maria Noichl, Marit Paulsen, Marijana Petir, Laurențiu Rebega, Jens Rohde, Bronis Ropė, Jordi Sebastià, Lidia Senra Rodríguez, Czesław Adam Siekierski, Marc Tarabella, Janusz Wojciechowski, Marco Zullo
Substitutes present for the final vote	Rosa D'Amato, Angélique Delahaye, Michela Giuffrida, Norbert Lins, Momchil Nekov, Sofia Ribeiro

PROCEDURE

Title	Novel foods			
References	COM(2013)0894 – C7-0487/2013 – 2013/0435(COD)			
Date submitted to Parliament	18.12.2013			
Committee responsible Date announced in plenary	ENVI 16.1.2014			
Committees asked for opinions Date announced in plenary	INTA 16.1.2014	ITRE 16.1.2014	IMCO 16.1.2014	AGRI 16.1.2014
Not delivering opinions Date of decision	ITRE 22.1.2014	IMCO 24.9.2014		
Rapporteurs Date appointed	James Nicholson 14.7.2014			
Discussed in committee	23.7.2014	13.10.2014	5.11.2014	
Date adopted	24.11.2014			
Result of final vote	+: –: 0:	58 0 6		
Members present for the final vote	Marco Affronte, Margrete Auken, Pilar Ayuso, Zoltán Balczó, Ivo Belet, Simona Bonafè, Biljana Borzan, Lynn Boylan, Nessa Childers, Alberto Cirio, Birgit Collin-Langen, Mireille D'Ornano, Miriam Dalli, Seb Dance, Angélique Delahaye, Jørn Dohrmann, Stefan Eck, Eleonora Evi, José Inácio Faria, Francesc Gambús, Iratxe García Pérez, Elisabetta Gardini, Enrico Gasbarra, Gerben-Jan Gerbrandy, Jens Gieseke, Julie Girling, Sylvie Goddyn, Matthias Groote, Françoise Grossetête, Jytte Guteland, György Hölvényi, Anneli Jäätteenmäki, Jean-François Jalkh, Benedek Jávor, Karin Kadenbach, Kateřina Konečná, Giovanni La Via, Peter Liese, Norbert Lins, Miroslav Mikolášik, Massimo Paolucci, Gilles Pargneaux, Piernicola Pedicini, Bolesław G. Piecha, Pavel Poc, Michèle Rivasi, Teresa Rodriguez-Rubio, Annie Schreijer-Pierik, Davor Škrlec, Jadwiga Wiśniewska			
Substitutes present for the final vote	Soledad Cabezón Ruiz, Nicola Caputo, Caterina Chinnici, Michel Dantin, Mark Demesmaeker, Ismail Ertug, Esther Herranz García, Jan Huitema, Merja Kyllönen, James Nicholson, Marit Paulsen, Christel Schaldemose, Bart Staes			
Substitutes under Rule 200(2) present for the final vote	Fredrick Federley			
Date tabled	2.12.2014			