EUROPEAN PARLIAMENT 2014 - 2019

Committee on the Environment, Public Health and Food Safety

2013/0435(COD)

06.10.2014

***I
DRAFT 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

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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 opinion of the European Economic and Social Committee of 30 April 2014,

– having regard to Rules 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, the Committee on Internal Market and Consumer Protection and the Committee on Agriculture and Rural Development (A8-0000/2014),

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.

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	(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.	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.

Or. en

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***,*** of consumers' interests ***and of the environment***, and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency.

Or. en

Amendment 3

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	(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.

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.

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

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

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

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

Or. en

Amendment 4

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	(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], ***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

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.

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.

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

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

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

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

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

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

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

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

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

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

Or. en

Amendment 5

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) The existing categories of novel food ***laid down*** in Article 1 of Regulation (EC) No 258/97 should be clarified and updated ***by replacing the existing categories*** with a reference to the general definition of food provided for in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[15].	(5) The existing categories of novel food ***listed*** in Article 1 of Regulation (EC) No 258/97 should be clarified and updated with a reference to the general definition of food provided for in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[15]. ***Before the date of application of this Regulation, the Commission should adopt guidance on the categories of novel foods which would assist the applicants and Member States in understanding whether a food falls within the scope of this Regulation and into which category of novel food a food falls.***
[15] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).	[15] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Or. en

Amendment 6

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) In order to ensure continuity with the rules laid down in Regulation (EC) No	(6) In order to ensure continuity with the rules laid down in Regulation (EC) No

258/97, the absence of a use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997***, should be maintained as a criterion for a food to be considered as a novel food***. ***A use*** within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union.

258/97, ***one of the criteria for the food to be considered a novel food should continue to be*** the absence of a use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997. ***Use*** within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union.

Or. en

Amendment 7

Proposal for a regulation
Recital 7

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

Directive 2000/13/EC of the European Parliament and of the Council, Commission Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Or. en

Amendment 8

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) Vitamins, minerals and other substances intended to be used in food supplements or to be added to food including infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control ***are*** subject to ***the rules provided for in Directive 2002/46/EC of the European Parliament and of the Council[17], in Regulation (EC) No 1925/2006 of the European Parliament and of the Council[18] and in*** Regulation (EU) No 609/2013 of the European Parliament and of the Council[19]***. Those substances*** should also be assessed in accordance with ***the rules laid down in*** this Regulation when they fall within the definition of novel food ***laid down in this Regulation***.	(8) Vitamins, minerals and other substances intended to be used in food supplements ***in accordance to Directive 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

[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).

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).

Or. en

Amendment 9

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.	***deleted***

Or. en

Justification

Recital 9 is redundant as its main points are covered by recitals 7 and 8.

Amendment 10

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.

Or. en

Amendment 11

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	(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.

history of safe food use in a third country has been demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a ***significant*** part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. en

Amendment 12

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) ***Foods*** from third countries which are regarded as novel foods in the Union should only be considered as traditional foods from third countries when they are derived from primary production as defined in Regulation (EC) No 178/2002, regardless of whether they are processed or unprocessed foods. Therefore, where a new production process has been applied to this food, the food should not be considered to be traditional.

Or. en

Amendment 13

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.

Or. en

Amendment 14

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 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.	(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 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).

Or. en

Amendment 15

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The Commission and the European Food Safety Authority ("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.

Or. en

Amendment 16

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	(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

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.	***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, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.

Or. en

Amendment 17

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.	(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be ***significantly*** nutritionally less advantageous for the consumer.

Or. en

Amendment 18

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, by means of an implementing act, a Union list of novel foods ***by entering novel foods*** already authorised or notified in accordance with ***Article 4, 5 or 7 of*** Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. As those novel foods have already been evaluated for their safety, have been legally produced and marketed in the Union and have not given rise to health concerns in the past, the advisory procedure should be used for the initial establishment of the Union list.	(18) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, by means of an implementing act, a Union list of novel foods already authorised or notified in accordance with 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. ***The list should be transparent, easily accessible and regularly updated.***

Or. en

Amendment 19

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and ***the*** procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use ***it is appropriate to provide*** for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. As the updating of the Union	(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use ***the applicants should be able to opt*** for a faster and simplified procedure to update the Union list if no 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.

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

Or. en

Amendment 20

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 ***assessment*** 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 ***EFSA whose assessments should prevail in case of diverging opinions on the safety of food***.

Or. en

Amendment 21

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, 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. ***However, this power should only be applied in duly justified***

cases and not as a standing practice.

Or. en

Amendment 22

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

Or. en

Amendment 23

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) The applicants often work with scientists who publish the results of their work in scientific journals. In order to encourage co-operation between applicants and scientists, it is necessary to guarantee that data protection is granted regardless of whether the data is published in a scientific journal.

Or. en

Amendment 24

Proposal for a regulation
Recital 23 b (new)

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

Or. en

Amendment 25

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.

Or. en

Amendment 26

Proposal for a regulation
Article 1 – title

Text proposed by the Commission	*Amendment*
Subject matter and scope	Subject matter***, purpose*** and scope

Or. en

Justification

It is important that the purpose of this Regulation is clearly defined.

Amendment 27

Proposal for a regulation
Article 1 – paragraph 1

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

Or. en

Justification

It is important that the purpose of this Regulation is clearly defined.

Amendment 28

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

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

Or. en

Justification

It is important that the purpose of this Regulation is clearly defined.

Amendment 29

Proposal for a regulation
Article 2 – paragraph 2 – subparagraph 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 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***:

Or. en

Justification

The reintroduction and revitalisation of categories to the Novel Foods definition is essential to ensure that the Regulation will only apply to defined categories of food as opposed to all food and for legal certainty.

Amendment 30

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

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

Or. en

Justification

The Regulation needs to be adapted to technological progress and new kinds of food entering the EU market.

Amendment 31

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

Text proposed by the Commission	*Amendment*
	(-ia) food containing, consisting of, or produced from microorganisms, fungi and algae;

Or. en

Justification

The Regulation needs to be adapted to technological progress and new kinds of food entering the EU market.

Amendment 32

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

Text proposed by the Commission	*Amendment*
	(-ib) food containing, consisting of, or produced from plants or animals, except for plants or animals 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;

Or. en

Justification

The Regulation needs to be adapted to technological progress and new kinds of food entering the EU market.

Amendment 33

Proposal for a regulation
Article 2 – paragraph 2 – subparagraph 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 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. en

Justification

Alignment with Council objective to provide clarity.

Amendment 34

Proposal for a regulation
Article 2 – paragraph 2 – subparagraph a – point i – indent 3 a (new)

Text proposed by the Commission	*Amendment*
	- 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.

Or. en

Justification

The Regulation needs to be adapted to technological progress and new kinds of food entering the EU market.

Amendment 35

Proposal for a regulation
Article 2 – paragraph 2 – subparagraph 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;	"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;

Or. en

Justification

Food with a new or modified molecular structure cannot constitute traditional food from third countries.

Amendment 36

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

Or. en

Justification

The use of the word "significant" makes it clearer that the definition is relative to the population size of any given country not by worldwide comparison.

Amendment 37

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
Implementing power concerning the definition of novel food in Article 2(2)(a)	***deleted***
In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).	
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).	

Or. en

Justification

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

Amendment 38

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

May 1997.

Or. en

Justification

Each Novel Food application is unique and thus food business operators must have flexibility to consult with Member States on the specificities of their individual application. If they do so they need to provide a Member State with all the necessary information.

Amendment 39

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

Text proposed by the Commission	*Amendment*
	2a. If the Member State is unable to determine whether or not a food falls within the scope of this Regulation, it may consult the Commission and other Member States.

Or. en

Justification

Member States must have the right to consult during the determination process but shall not be required to do so if it is not necessary.

Amendment 40

Proposal for a regulation
Article 4 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission ***may***, ***by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraph 2.***	***By ...[+] the*** Commission ***shall adopt an implementing act establishing guidance specifying*** ***which forms of food or food ingredient***

fall within the scope of this Regulation for each of the categories in Article 2(2)(a) and

the procedural steps of the consultation process.

[+] ***Publications Office: please insert date: 12 months after the entry into force of this Regulation.***

Or. en

Justification

This Regulation will introduce new categories which will reflect the scientific developments as compared to 1997. This will however make the process more complicated. It is extremely important that the Commission publishes accessible guidelines in order to assist applicants. Food business operators must also have clear and accessible line of communication with Member States, EFSA and the Commission during the determination process.

Amendment 41

Proposal for a regulation
Article 4 a (new)

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

Or. en

Justification

See justification on the amendment to Article 3.

Amendment 42

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***/or*** used in or on foods ***according to*** the conditions of use ***and to the labelling requirements*** specified therein.

Or. en

Justification

Labelling requirements may also be part of the authorisation process.

Amendment 43

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

Text proposed by the Commission	*Amendment*
	2a. Access to the Union list shall be publically available from...[+]. The Union list shall be published on the Commission website and in the Official Journal of the European Union.
	_____
	[+]Publications Office: please insert date: 24 months after the entry into force of this Regulation.

Or. en

Justification

It is extremely important that the Union list of Novel Foods is transparent. The Commission should take every step to ensure that the list is readily available to the public.

Amendment 44

Proposal for a regulation
Article 6

Text proposed by the Commission	*Amendment*
General conditions for inclusion of novel foods in the Union list	General conditions for inclusion of novel foods in the Union list
The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:	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 the scientific evidence available, pose a safety risk to human health;
(b) its use does not mislead the consumer;	(b) its use does not mislead the consumer;
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 does not differ from that food in such a way that its normal consumption would be ***significantly*** nutritionally disadvantageous for the consumer.
	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.

Or. en

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 45

Proposal for a regulation
Article 7 – subparagraph 1

Text proposed by the Commission	*Amendment*
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	***By*** …[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
[23] Publications Office: please insert date: 24 months after the entry into force of this Regulation.	[23] Publications Office: please insert date: 24 months after the entry into force of this Regulation.

Or. en

Justification

This is a technical amendment

Amendment 46

Proposal for a regulation
Article 8 – title

Text proposed by the Commission	*Amendment*
Contents of the Union list	Contents ***and updating*** of the Union list

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 47

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.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 48

Proposal for a regulation
Article 8 – paragraph 3

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

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 49

Proposal for a regulation
Article 9 – title

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

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 50

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
The ***procedure*** for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 8 shall start either on the Commission's initiative or following	The ***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.	an application to the Commission by an applicant. ***The Commission shall make the application available to the Member States.***
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 production process;
(b) the composition of the novel food;	(b) the 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;
	(ca) where applicable, the analysis method(s);
(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 use and a proposal for specific labelling requirements which do not mislead the consumer.

Or. en

Justification

The application should be available to all Member States. The new the elements of the application are necessary for the authorities to be able to check if a novel food may be authorised.

Amendment 51

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission ***may*** request EFSA ***to render*** its opinion if the update is liable to ***have an effect on*** human health.	2. The Commission ***shall*** request ***that*** EFSA ***renders*** its opinion if the update ***to the Union list*** is liable to ***pose a safety risk to*** human health.

Or. en

Justification

If there is a legitimate expectation that a food may pose a safety risk to human health the Commission should be obliged to request an opinion from EFSA.

Amendment 52

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1

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

Or. en

Justification

Alignment with Council objective to correct terminology.

Amendment 53

Proposal for a regulation
Article 9 – paragraph 5

Text proposed by the Commission	*Amendment*
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.

Or. en

Justification

The applicant should have a possibility to withdraw the application at any point in the procedure.

Amendment 54

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
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, where appropriate, consider the following:
(a) whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;	(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.
	(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 significantly nutritionally disadvantageous for the consumer.

Or. en

Justification

In order to make the application process more efficient the deadlines for various stages of the application process should be reduced. EFSA's role needs to be aligned with the conditions of authorisation specifies in Article 6.

Amendment 55

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
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.

Or. en

Justification

The applicant is always relevant in the procedure and should be informed at all stages of the procedure.

Amendment 56

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. In duly justified cases, where EFSA requests additional information from the 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.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 57

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the additional information referred to in paragraph 3 is not ***sent*** to EFSA within the additional period referred 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 ***draw up*** its opinion on the basis of the ***available*** information.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 58

Proposal for a regulation
Article 10 – paragraph 6

Text proposed by the Commission	*Amendment*
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.

Or. en

Justification

The additional information should be made public to the Commission and the Member States.

Amendment 59

Proposal for a regulation
Article 11 – paragraph 1

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

Or. en

Justification

In order to make the application process more efficient the deadlines for various stages of the application process should be reduced. In normal cases the Commission does not need nine months to prepare a draft implementing act. Six months should be sufficient, given that Article 21 provides for ad hoc extensions in difficult cases. It is clear from Article 6 that not all conditions always apply, thus the words "where applicable" here are redundant and could be misleading.

Amendment 60

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).	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).

Or. en

Justification

In order to make the application process more efficient the deadlines for various stages of the application process should be reduced. In normal cases the Commission does not need nine months to prepare a draft implementing act. Six months should be sufficient, given that Article 21 provides for ad hoc extensions in difficult cases.

Amendment 61

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

Or. en

Justification

Alignment with Council objective to correct terminology.

Amendment 62

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.	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 composition;
(c) its country of origin;	(c) its country 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;
(e) where applicable, the conditions of use and specific labelling requirements, which do not mislead the consumer.	(e) where applicable, the conditions of use and specific labelling requirements, which do not mislead the consumer.

Or. en

Justification

Alignment with Council objective to enable an applicant to undergo a standard application procedure for novel foods if, for example, there may be no sufficient evidence of safe food consumption in a third country.

Amendment 63

Proposal for a regulation
Article 14 – title

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

Or. en

Justification

Alignment with Council objective to correct terminology.

Amendment 64

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall forward the valid notification provided for in Article 13 ***without delay*** to the Member States and to EFSA.	1. The Commission shall forward the valid notification provided for in Article 13 ***within one month*** to the Member States and to EFSA.

Or. en

Justification

In order to make the application process more efficient the deadlines for various stages of the application process should be reduced.

Amendment 65

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Within four months from the date on which the valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or EFSA may submit to the Commission reasoned safety objections, ***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, ***if a food in question is liable to pose a safety risk to human health***, to the placing on the market within the Union of the traditional food concerned.

Or. en

Justification

Valid notifications must not be unduly prevented from reaching the market by unnecessarily burdensome evidence requirements.

Amendment 66

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
The Commission shall inform the Member States**,** EFSA and the applicant of the outcome of the procedure referred to in paragraph 2.	***The Commission shall inform the applicant of any reasoned safety 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.

Or. en

Justification

The applicant should be able to start preparations for the authorisation procedure as soon as it is clear it will be necessary.

Amendment 67

Proposal for a regulation
Article 14 – paragraph 4

Text proposed by the Commission	*Amendment*
Where no reasoned safety objections are made in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update ***without delay*** the Union list.	Where no reasoned safety objections are made in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update the Union list ***within one month***.

Or. en

Justification

In order to make the application process more efficient the deadlines for various stages of the application process should be reduced.

Amendment 68

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

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

Or. en

Justification

These words are redundant in light of the amendment to paragraph 2 of the same Article.

Amendment 69

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 reasoned safety objections submitted in accordance with Article 14(5).

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 70

Proposal for a regulation
Article 16 – paragraph 4

Text proposed by the Commission	*Amendment*
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	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

inform the Member States of that extension.	Member States of that extension.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 71

Proposal for a regulation
Article 16 – paragraph 5

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

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 72

Proposal for a regulation
Article 16 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 73

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

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 74

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 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 submit to the Committee referred to in Article 27(1) a draft implementing act ***authorising*** the placing on the market within the Union of the traditional food from a third country and ***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).	That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Or. en

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 75

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.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 76

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.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 77

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 ***acts laying down*** 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);
(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),	(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);	(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.

Or. en

Justification

Alignment with Council objective to correct terminology.

Amendment 78

Proposal for a regulation
Article 20 – paragraph 2

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

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 79

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.

Or. en

Justification

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

Amendment 80

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 case the applicant shall be consulted before the Commission

takes a decision on the alignment.

Or. en

Justification

Since the authorisation procedure for novel foods will become centralised it will be possible for the Commission to try to endeavour to proceed with both processes concurrently. It is desirable that both data protection periods run concurrently to offer legal certainty to applicants. The Commission should consult the applicant since aligning one process with the other may result in a significant delay in one of the processes, a result that may be undesired by the applicant.

Amendment 81

Proposal for a regulation
Article 22 – title

Text proposed by the Commission	*Amendment*
Confidentiality of ***the*** application for ***updating*** of the Union list	Confidentiality of application for ***updates*** of the Union list

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 82

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1.Applicants may request confidential treatment of certain information submitted under this Regulation where 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.

Or. en

Justification

Applicants should not need to demonstrate "significant" harm to their competitive position to evoke data protection. This is too high a threshold and will act as a disincentive to applicants.

Amendment 83

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. For the purposes of paragraph 1, applicants shall indicate which ***parts*** of the information provided they wish to be treated as confidential and provide all the necessary information to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 84

Proposal for a regulation
Article 22 – paragraph 3

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

Or. en

Justification

It is important that it is clear that applicants have the right to confidentiality for three weeks in whatever circumstances precede the decision to withdraw their application.

Amendment 85

Proposal for a regulation
Article 22 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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.***

Or. en

Justification

The Commission should grant confidentiality to applications except in the clearly defined cases set out in this article. Analysis methods should remain confidential due to the market sensitive nature of the data.

Amendment 86

Proposal for a regulation
Article 22 – paragraph 6

Text proposed by the Commission	*Amendment*
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.

Or. en

Justification

Linguistic amendment.

Amendment 87

Proposal for a regulation
Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
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

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 88

Proposal for a regulation
Article 23

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 may, for food safety reasons and taking into account the opinion of EFSA, impose ***requirements*** for post-market monitoring. ***Such requirements shall be duly justified and may include, on a case-by-case basis, the identification of the relevant food business operators.***
2. The food business operators shall forthwith inform the Commission of:	
(a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;	
(b) any prohibition or restriction imposed by any third country in which the novel food is placed on the market.	

Or. en

Justification

Post-market monitoring and additional information requirements should be treated separately. The text of a new Article 23 reflects the wording proposed in the Council but adds the words "shall be duly justified" to indicate it should only be applied in exceptional circumstances.

Amendment 89

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.

Or. en

Justification

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

Amendment 90

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. On request by the applicant, supported by appropriate and verifiable information included in the application provided for in Article 9(1), newly developed scientific evidence or scientific data supporting the application may not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the ***initial*** applicant.

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 91

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
That data protection shall be granted where the following conditions are met:	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***, regardless of whether the data has been published in a scientific journal;***
(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 had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made and
(c) the novel food could not have been 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 prior applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.

Or. en

Justification

Data protection should be granted in cases of publication of studies in a scientific journal. It is extremely important for innovation that industry works closely with scientists and academics. The provisions on data protection should not be detrimental to their co-operation. Alignment with Council objective to provide clarity.

Amendment 92

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;

Or. en

Justification

Alignment with Council objective to provide clarity.

Amendment 93

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***.

Or. en

Justification

Alignment with Council objective to provide clarity.

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.