



EUROPEAN PARLIAMENT

2014 - 2019

Committee on International Trade

2013/0435(COD)

10.10.2014

AMENDMENTS

13 - 109

Draft opinion
Jude Kirton-Darling
(PE537.403v01-00)

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

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

AM\1036876EN.doc

PE539.697v01-00

EN

United in diversity

EN

AM_Com_LegOpinion

Amendment 13
Anne-Marie Mineur

Proposal for a regulation
Citation 1

Text proposed by the Commission

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 **and 192** thereof,

Or. en

Amendment 14
Tiziana Beghin, David Borrelli

Proposal for a regulation
Recital 1

Text proposed by the Commission

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

Amendment

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as benefitting their social and economic interests. Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating unfair conditions of competition **including for agri-food industry and in particular for SMEs**.

Or. en

Amendment 15
José Bové
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 2

Text proposed by the Commission

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

Amendment

(2) A high level of protection of human health and of consumers' interests, **environmental friendliness**, and effective functioning of the internal market should be **ensured** in the pursuit of Union food policies, whilst ensuring transparency. **Furthermore, and in all instances, the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety must apply.**

Or. fr

Justification

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

Amendment 16
Franz Obermayr

Proposal for a regulation
Recital 2

Text proposed by the Commission

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

Amendment

(2) **In the pursuit of Union food policies priority should be given to transparency and to compliance with the precautionary principle, with a view to guaranteeing** a high level of protection of human health and of consumers' interests and the effective functioning of the internal market.

Amendment 17
Tiziana Beghin, David Borrelli

Proposal for a regulation
Recital 2

Text proposed by the Commission

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

Amendment

(2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency ***and stimulating innovation and creativity within the agri-food SMEs and applying the standards laid down in Union legislation to all food, including those imported from third countries.***

Or. en

Amendment 18
Marielle de Sarnez

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) The Union applies the precautionary principle in the areas of health and food.

Or. fr

Justification

The precautionary principle must apply to all decisions relating to the environment and the health of European citizens so that they enjoy the highest level of protection against environmental, health and food risks.

Amendment 19
Anne-Marie Mineur

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) In its Communication of 2 February 2000 the Commission stressed the importance of the precautionary principle.

Or. en

Amendment 20
Marielle de Sarnez

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 Council¹⁰, enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council¹¹, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹², flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council¹³ **and** extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council¹⁴ should be excluded from the scope of this Regulation.

(4) Foods which are intended to be used for technological purposes and genetically modified food ***or food from cloned animals*** 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 Council¹⁰, enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council¹¹, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹², flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council¹³, extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council¹⁴ ***and food falling within the scope of Council Directive XXX/XX/EU on [the placing on the***

market of food from animal clones
should be excluded from the scope of this
Regulation.

¹⁰Regulation (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).

¹¹Regulation (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).

¹²Regulation (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).

¹³Regulation (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).

¹⁴Directive 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).

¹⁰Regulation (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).

¹¹Regulation (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).

¹²Regulation (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).

¹³Regulation (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).

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

Or. fr

Justification

Foods obtained from cloned animals must not under any circumstances be considered 'novel foods' within the meaning of the definition in this regulation and are thus totally excluded from its scope.

Amendment 21

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 7

Text proposed by the Commission

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

¹⁶*Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulation (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).*

Amendment

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

Or. fr

Amendment 22

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 9

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 23
Marielle de Sarnez

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in a third country has been demonstrated. **Those** foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Amendment

(11) **The status and treatment accorded to traditional foods from third countries should be different from what is accorded to the novel foods referred to in this Regulation.** The placing on the market within the Union of traditional foods from third countries should be facilitated, **in particular by means of an authorisation procedure centralised at Union level, and they should be specifically labelled accordingly**, where the history of safe food use in a third country has been demonstrated. **The foods concerned** should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of

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

Or. fr

Justification

Novel foods corresponding to traditional foods from third countries with a history of safe use must be treated differently from, and more flexibly than, novel foods involving application of nanotechnologies, for instance. It must be more straightforward to place them on the EU market, specifically labelled accordingly, conceivably under a procedure centralised at EU level via the EFSA.

Amendment 24 **Franz Obermayr**

Proposal for a regulation **Recital 11**

Text proposed by the Commission

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in *a* third *country* has been demonstrated. Those foods should have been consumed in *a* third *country* for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Amendment

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in *at least two* third *countries* has been demonstrated. Those foods should have been consumed in *at least two* third *countries* for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. de

Amendment 25 **José Bové** on behalf of the Verts/ALE Group

Proposal for a regulation **Recital 11**

Text proposed by the Commission

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Amendment

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in a third country has been demonstrated, ***in accordance with rules established by the EFSA***. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. fr

Amendment 26
Santiago Fisas Ayxelà

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a ***large*** part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Amendment

(11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a ***significant*** part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. es

Amendment 27
Franck Proust

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) The placing on the market within the Union of traditional foods from third countries should be **facilitated**, where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Amendment

(11) The placing on the market within the Union of traditional foods from third countries should be **authorised** where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

Or. fr

Amendment 28

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 12

Text proposed by the Commission

(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.

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.

Amendment 29
Franz Obermayr

Proposal for a regulation
Recital 12

Text proposed by the Commission

(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.

Amendment

Does not apply to English version.

Amendment 30
Franz Obermayr

Proposal for a regulation
Recital 16

Text proposed by the Commission

(16) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in

Amendment

(16) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in

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

the Member States. Food business operators should consult Member States if they are unsure of the status of the food they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process. ***These provisions notwithstanding, existing national arrangements governing the steps in the process may remain in force in the Member States if they are not fundamentally at odds with the requirements laid down by the Commission.***

Or. de

Amendment 31

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 17

Text proposed by the Commission

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

Amendment

(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their use should not mislead the consumer, ***thus requiring the use of clear and precise labelling.*** Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally, ***and as regards health,*** less advantageous for the consumer. ***The safety of novel foods shall be assessed on the***

basis of the precautionary principle as defined in Article 7 of Regulation (EC) No 178/2002.

Or. fr

Amendment 32
Tiziana Beghin, David Borrelli

Proposal for a regulation
Recital 17

Text proposed by the Commission

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

Amendment

(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer. ***When a novel food comes from third countries, the scope of its use and its composition should not pose a safety risk to human health when exposed to a different climatic conditions and environment.***

Or. en

Amendment 33
Franz Obermayr

Proposal for a regulation
Recital 19

Text proposed by the Commission

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent

Amendment

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent

should be put in place. As regards traditional foods from third countries having a history of safe use it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.

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 **by the EFSA or a Member State. The need to consider scientific evidence notwithstanding, the Commission should be required to initiate an ordinary legislative procedure for the authorisation of a traditional food from a third country if objections are raised by at least one-fifth of the Member States.** As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.

Or. de

Justification

Neben der Einspruchsmöglichkeit durch einen wissenschaftlich begründeten Einspruch durch einen Mitgliedsstaat oder die EFSA, sollte bei Einwänden mehrerer Mitgliedsstaaten - ungeachtet der konkreten Prüfung der wissenschaftlichen Begründung der Einsprüche - die Kommission dazu verpflichtet werden bei der Zulassung von einem Durchführungsrechtsakt abzusehen und das ordentliche Gesetzgebungsverfahren einzuleiten. Dies stellt sicher, dass nicht lediglich die Kommissionsentscheidung hinsichtlich der Validität einer wissenschaftlichen Begründung alleine maßgeblich dafür ist, ob eine Zulassung letztendlich erfolgt und ermöglicht es einer Gruppe von Mitgliedsstaaten hier die Kommission zu einem ordentlichen Gesetzgebungsverfahren zu bewegen. So wird bei umstrittenen neuartigen Lebensmitteln der öffentliche Diskurs durchgeführt, der ganz im Zeichen der geforderten Transparenz steht.

Amendment 34 **Franck Proust**

Proposal for a regulation **Recital 19**

Text proposed by the Commission

(19) It is appropriate to authorise a novel

Amendment

(19) It is appropriate to authorise a novel

food by updating the Union list subject to the criteria and the procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use it is appropriate to provide for a **faster and simplified** procedure to update the Union list if no reasoned safety objections are expressed. As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.

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 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.

Or. fr

Amendment 35

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 21

Text proposed by the Commission

Amendment

(21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain²¹ that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.

deleted

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

Or. fr

Amendment 36
Franck Proust

Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain²¹ that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.

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

Amendment

(21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain²¹ that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. In order to better assess the safety of nanomaterials for food use, ***bearing in mind the precautionary principle***, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.

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

Or. fr

Amendment 37
José Bové

on behalf of the Verts/ALE Group

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.

deleted

Or. fr

Amendment 38
Anne-Marie Mineur

Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

Amendment

(24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food. ***Therefore, when a novel food is included in the Union list or in the list of traditional foods from third countries, specific conditions of use or labelling obligations may be imposed, which might, inter alia, relate to any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population. It is appropriate to lay down in this Regulation specific labelling obligations in respect of food ingredients present in the form of engineered nanomaterials which fall within the scope of this Regulation.***

Or. en

Amendment 39

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Recital 24

Text proposed by the Commission

(24) Novel foods are subject to the general

Amendment

(24) Novel foods are subject to the general

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

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

Or. fr

Amendment 40
Marielle de Sarnez

Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its ***source or*** its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

Amendment

(24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its ***origin, its composition and*** its conditions of use, to ensure that consumers are sufficiently informed of the nature of the novel food.

Or. fr

Justification

Novel foods must be subject to high traceability requirements.

Amendment 41
Tiziana Beghin

Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. ***In certain cases it may be*** necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.

Amendment

(24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. ***It is*** necessary to provide for additional labelling information, in particular regarding the description of the food, its source ***and origin*** or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food, ***including those coming from third countries.***

Or. en

Amendment 42
Tiziana Beghin

Proposal for a regulation
Recital 26

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 43
Franck Proust

Proposal for a regulation
Recital 26

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 44
Franck Proust

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

Amendment

(26a) In the event of an infringement of this Regulation, Member States should be able to share information they possess in the interest of protecting public health.

Or. fr

Amendment 45
José Bové
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

Amendment

1. This Regulation lays down rules for the

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.

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, ensuring transparency **and prohibiting the placing on the market of foods using nanomaterials.**

Or. fr

Amendment 46
Anne-Marie Mineur

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 47
José Bové
on behalf of the Verts/ALE Group

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

Text proposed by the Commission

(ii) food containing or consisting of ‘engineered nanomaterials’ as defined in

Amendment

deleted

Article 2(2)(t) of Regulation (EU) No 1169/2011;

Or. fr

Amendment 48
José Bové
on behalf of the Verts/ALE Group

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

Text proposed by the Commission

Amendment

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

Or. fr

Amendment 49
Tiziana Beghin, David Borrelli

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

Text proposed by the Commission

Amendment

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

(b) ‘traditional food from a third country’ means novel food, other than the novel food as referred to in point (a)(i) to (iii), which is derived from primary production **and processed derivatives as defined in Regulation 178/2002**, with a history of safe food use **and significant consumption** in a third country;

Or. en

Amendment 50
Franz Obermayr

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

Text proposed by the Commission

(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*;

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 *at least two third countries*;

Or. de

Justification

The stipulation that a history of safe use must be provided for only one third country increases the likelihood of authorisation for the traditional food in question being secured through the submission of a set of carefully selected scientific studies. Requiring that such a history must be provided for a second third country makes it less likely that EU decision-makers will be improperly swayed by manipulation and lobbying by the food industry in or from third countries.

Amendment 51
Santiago Fisas Ayxelà

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

Text proposed by the Commission

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

Amendment

(c) ‘history of safe food use in a third country’ means that the safety of the food in question has been confirmed with compositional data and from experience of continued use 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. es

Amendment 52
Tiziana Beghin, David Borrelli

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 53
Daniel Caspary

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

Text proposed by the Commission

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

Amendment

(c) ‘history of safe food use in a third country’ means that the safety of the food in question has been confirmed with compositional data and from experience of continued use 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, ***and with the information referred to in Article 19(1)(a)***;

Or. de

Amendment 54
Tiziana Beghin, David Borrelli

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

Text proposed by the Commission

(d) ‘the applicant’ means the Member State, the third country or the interested party, who may represent several interested parties, who has submitted an application in accordance with Article 9 or 15 or a notification in accordance with Article 13 to the Commission;

Amendment

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

Or. en

Amendment 55
Anne-Marie Mineur

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 56
Anne-Marie Mineur

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

Text proposed by the Commission

Amendment

(eb) ‘descendants of cloned animals’ means animals produced by means of sexual reproduction, in cases in which at least one of the progenitors is a cloned

animal;

Or. en

Amendment 57
Marielle de Sarnez

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

Text proposed by the Commission

Amendment

2a. The items referred to in Article 1(2) of this Regulation shall not be covered by the definition of ‘novel foods’.

Or. fr

Justification

Foods obtained from cloned animals must not under any circumstances be considered ‘novel foods’ within the meaning of the definition in this regulation and are thus totally excluded from its scope.

Amendment 58
Franz Obermayr

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

Text proposed by the Commission

Amendment

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

The Commission may, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraph 2. ***This provision notwithstanding, existing national arrangements governing the consultation process may remain in force in the Member States if they are not fundamentally at odds with the requirements laid down by the Commission.***

Justification

With a view to ensuring that the transition to the new system is not unnecessarily chaotic, established national consultation procedures should not automatically be rendered obsolete by the introduction of the new Commission definition if they are not fundamentally at odds with the requirements laid down by the Commission.

Amendment 59

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ('the Union list').

Amendment

1. The Commission shall establish, **publish** and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ('the Union list').

Or. fr

Amendment 60

Tiziana Beghin, David Borrelli

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ('the Union list').

Amendment

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

Or. en

Amendment 61
Tiziana Beghin, David Borrelli

Proposal for a regulation
Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The Union list shall be made public.

Or. en

Amendment 62
Marine Le Pen

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

Text proposed by the Commission

Amendment

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

(a) *it has been proved scientifically and in accordance with EFSA criteria to pose no risk* to human health;

Or. fr

Amendment 63
Franz Obermayr

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

Text proposed by the Commission

Amendment

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

(a) it does not, *in the light of the Union's precautionary principle and* on the basis of *sufficient* scientific evidence *from independent sources*, pose a safety risk to human health;

Or. de

Amendment 64

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 6 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 65

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 6 – paragraph 1 – point c

Text proposed by the Commission

(c) where it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Amendment

(c) where it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer **or would have an adverse effect on his health.**

Or. fr

Amendment 66

Anne-Marie Mineur

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Amendment 67
Franck Proust

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

Text proposed by the Commission

Amendment

(ca) where it is possible to ensure the traceability of the materials used in its manufacture.

Or. fr

Amendment 68
Marielle de Sarnez

Proposal for a regulation
Article 8 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The European Union shall strive to enhance the influence of its food safety legislation on the international standards established and recognised by the Codex Alimentarius.

Or. fr

Justification

The European Union must work to enhance its influence on the drafting of global food standards and promote the take-up of its food safety legislation in the Codex Alimentarius, which is responsible for drawing up safety and quality standards for the foodstuffs trade.

Amendment 69
Franz Obermayr

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

Text proposed by the Commission

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

Amendment

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

Or. de

Justification

Given the vital role which labelling plays in ensuring that consumers can make informed purchasing decisions, clear reference should be made here to labelling requirements. Cf. Recitals 2 and 24.

Amendment 70

José Bové

on behalf of the Verts/ALE Group

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

Text proposed by the Commission

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

Amendment

(b) 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, **considering in particular the appearance of new allergies**, the exceeding of maximum intake levels and risks in case of excessive consumption;

Or. fr

Amendment 71

Marielle de Sarnez

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

Text proposed by the Commission

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

Amendment

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

Or. fr

Justification

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

Amendment 72
Franz Obermayr

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

Text proposed by the Commission

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

Amendment

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

Or. de

Amendment 73
Marine Le Pen

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

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 74
Franz Obermayr

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

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

Amendment

(2) The Commission **shall** request EFSA to render its opinion **if asked to do so by a Member State or** if the update **could give rise to a breach of the conditions laid down in Article 6**.

Or. de

Amendment 75
Marine Le Pen

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The Commission **shall** request EFSA to render its opinion **in all cases**.

Or. fr

Amendment 76
Anne-Marie Mineur

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 77
José Bové
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. fr

Amendment 78
Franz Obermayr

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

Text proposed by the Commission

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

Amendment

(b) whether the composition of the novel food and the conditions of its use **are consistent with the Union's precautionary principle and thus** do not pose a safety risk to human health in the Union.

Or. de

Amendment 79

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 10 – paragraph 3 – subparagraph 3

Text proposed by the Commission

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.

Amendment

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

Or. fr

Amendment 80

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

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.***

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, ***EFSA, being unable to formulate an opinion, shall automatically reject the application.***

Or. fr

Amendment 81

Franz Obermayr

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

Text proposed by the Commission

Amendment

(a) the conditions provided for in Article 6
where applicable;

(a) the conditions provided for in Article 6;

Or. de

Amendment 82
José Bové
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. fr

Amendment 83
Franck Proust

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

Text proposed by the Commission

Amendment

(c) its country of origin;

(c) its country of origin *and the countries of origin of the materials used in its manufacture*;

Or. fr

Amendment 84
Franz Obermayr

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

Text proposed by the Commission

(d) documented data demonstrating the history of safe food use in **a** third **country**;

Amendment

(d) documented data demonstrating the history of safe food use in **at least two** third **countries**;

Or. de

Amendment 85
Tiziana Beghin, David Borrelli

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

Text proposed by the Commission

(d) documented data demonstrating the history of safe food use in a third country;

Amendment

(d) documented data demonstrating the history of safe food use **and significant consumption** in a third country;

Or. en

Amendment 86
Daniel Caspary

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

Text proposed by the Commission

(d) documented data demonstrating the history of safe food use in a third country;

Amendment

(d) documented data demonstrating the history of safe food use in a third country, **in accordance with Article 19(1)(a)**;

Or. de

Amendment 87
Tiziana Beghin, David Borrelli

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 88
Franz Obermayr

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission

(2) Within *four* months from the date on which the valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or EFSA may submit to the Commission reasoned safety objections, based on scientific evidence, to the placing on the market within the Union of the traditional food concerned.

Amendment

(2) Within *six* 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. ***The need to consider scientific evidence notwithstanding, the Commission shall be required to initiate an ordinary legislative procedure for the authorisation of a traditional food from a third country if objections are raised by at least one-fifth of the Member States.***

Or. de

Justification

Neben der Einspruchsmöglichkeit durch einen wissenschaftlich begründeten Einspruch durch einen Mitgliedsstaat oder die EFSA, sollte bei Einwänden mehrerer Mitgliedsstaaten - ungeachtet der konkreten Prüfung der wissenschaftlichen Begründung der Einsprüche - die

Kommission dazu verpflichtet werden bei der Zulassung von einem Durchführungsrechtsakt abzusehen und das ordentliche Gesetzgebungsverfahren einzuleiten. Dies stellt sicher, dass nicht lediglich die Kommissionsentscheidung hinsichtlich der Validität einer wissenschaftlichen Begründung alleine maßgeblich dafür ist, ob eine Zulassung letztendlich erfolgt und ermöglicht es einer Gruppe von Mitgliedsstaaten hier die Kommission zu einem ordentlichen Gesetzgebungsverfahren zu bewegen. So wird bei umstrittenen neuartigen Lebensmitteln der öffentliche Diskurs durchgeführt, der ganz im Zeichen der geforderten Transparenz steht.

Amendment 89

Tiziana Beghin, David Borrelli

Proposal for a regulation

Article 14 – paragraph 4

Text proposed by the Commission

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

Amendment

4. Where no reasoned safety objections are made in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update without delay ***the list of traditional food from third countries included in*** the Union list.

Or. en

Amendment 90

Franz Obermayr

Proposal for a regulation

Article 16 – paragraph 1

Text proposed by the Commission

(1) EFSA shall adopt its opinion within **six** months from the date of receipt of a valid application.

Amendment

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

Or. de

Justification

Deadline extension in accordance with the extended deadline under Article 14(2).

Amendment 91
Franz Obermayr

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

Text proposed by the Commission

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

Amendment

(b) whether the composition of the novel food and the conditions of its use ***are consistent with the Union's precautionary principle and thus*** do not pose a safety risk to human health in the Union.

Or. de

Amendment 92
Franz Obermayr

Proposal for a regulation
Article 16 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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.

Amendment

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.

Or. de

Amendment 93
Franz Obermayr

Proposal for a regulation
Article 16 – paragraph 4 – subparagraph 3

Text proposed by the Commission

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

Amendment

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

Or. de

Amendment 94

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 16 – paragraph 5

Text proposed by the Commission

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.*

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, *EFSA, being unable to formulate an opinion, shall automatically reject the application.*

Or. fr

Amendment 95

Franz Obermayr

Proposal for a regulation

Article 16 – paragraph 6 – subparagraph 2

Text proposed by the Commission

In such cases, EFSA shall give its opinion within the period of *six* months provided for in paragraph 1.

Amendment

In such cases, EFSA shall give its opinion within the period of *nine* months provided for in paragraph 1.

Amendment 96
Franz Obermayr

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

Text proposed by the Commission

Amendment

(a) the conditions provided for in Article 6
where applicable;

(a) the conditions provided for in Article 6;

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

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

Where the Commission requests additional information from an applicant on matters concerning risk management, it shall determine, *together with the applicant, the period within which that information must be provided.*

Where the Commission *or EFSA* requests additional information from an applicant on matters concerning risk management, it shall determine *the time limits which it deems necessary and sufficient to enable the applicant to provide this information.*

Amendment 98
José Bové
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission

Amendment

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

2. Where the additional information referred to in paragraph 1 is not ***forwarded within the new time limits***, the Commission ***shall not give its approval***.

Or. fr

Amendment 99

José Bové

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

Amendment

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may significantly harm their competitive position.

deleted

Or. fr

Amendment 100

Franck Proust

Proposal for a regulation

Article 22 – paragraph 4 – subparagraph 2 – point b

Text proposed by the Commission

Amendment

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

(b) the name, description ***and composition*** of the novel food;

Or. fr

Amendment 101
Franz Obermayr

Proposal for a regulation
Article 23 – title

Text proposed by the Commission

Amendment

Post-market monitoring

Post-market monitoring **and changes to labelling requirements**

Or. de

Amendment 102
Franz Obermayr

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Amendment

(1) The Commission may, for food safety reasons **and** taking into account the opinion of EFSA, impose a requirement for post-market monitoring of a novel food to ensure that the use of the authorised novel food is within safe limits.

(1) The Commission may, for food safety reasons **and with a view to guaranteeing transparency as regards the use of the novel food, on the basis of a properly substantiated request from a Member State or** taking into account the opinion of EFSA, impose a requirement for post-market monitoring of a novel food **or additional labelling requirements** to ensure that the use of the authorised novel food is within safe limits **and that transparency for consumers is guaranteed.**

Or. de

Justification

In keeping with the thrust of Recitals 2 and 24, on the advice of the EFSA or in response to a request from a Member State the Commission should not only carry out additional monitoring, but also enable concerned consumers to take informed purchasing decisions by imposing an additional labelling requirement. Consumers will thus be able to decide for themselves whether the food in question is safe.

Amendment 103
Franck Proust

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

Text proposed by the Commission

2. The food business operators shall forthwith inform the Commission of:

Amendment

2. The food business operators **and the health authorities of the Member States** shall forthwith inform the Commission of

Or. fr

Amendment 104
Franz Obermayr

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission

(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.

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 **from independent sources** 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.

Or. de

Amendment 105
Tiziana Beghin

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ...²⁶ at the latest and shall notify it without delay of any subsequent amendment affecting them.

²⁶ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Amendment

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive **and shall ensure a level playing field**. Member States shall notify those provisions to the Commission by ...²⁶ at the latest and shall notify it without delay of any subsequent amendment affecting them.

²⁶ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Or. en

Amendment 106
Franck Proust

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ... at the latest²⁶ and shall notify it without delay of any subsequent amendment affecting them.

²⁶ Publications Office: please insert date: 24 months after the date of entry into force of

Amendment

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented **and guarantee fair conditions of competition**. Member States shall notify those provisions to the Commission by ... at the latest²⁶ and shall notify it without delay of any subsequent amendment affecting them.

²⁶ Publications Office: please insert date: 24 months after the date of entry into force of

this Regulation.

this Regulation.

Or. fr

Amendment 107
Anne-Marie Mineur

Proposal for a regulation
Article 29 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Until Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones] enters into force, foods derived from cloned animals and their descendants shall not be authorised and/or placed on the Union list of novel foods authorised to be placed on the market within the Union.

Or. en

Amendment 108
Tiziana Beghin, David Borrelli

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission

Amendment

Article 29a

Reporting

Five years after entry into force and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this regulation and, in particular, of article 3 and 8, accompanied, where appropriate, by any proposal.

Or. en

Amendment 109
Tiziana Beghin, David Borrelli

Proposal for a regulation
Article 29 b (new)

Text proposed by the Commission

Amendment

Article 29b

The report shall be made public.

Or. en