

2.7.2010

A7-0152/ 001-119

AMENDMENTS 001-119

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

Recommendation for second reading

Kartika Tamara Liotard

A7-0152/2010

Novel foods

Council position (11261/3/2009 – C7-0078/2010 – 2008/0002(COD))

Amendment 1

Council position – amending act

Recital 1

Council position

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 to their social and economic interests. Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of novel foods may hinder their free movement, thereby creating unfair competition conditions.

(1) In implementing Union policy and having regard to the Treaty on the Functioning of the European Union, a high level of protection of human health and consumer protection should be guaranteed and also a high level of animal welfare and environmental protection. At all times, moreover, the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹, should be applied.

¹ OJ L 31, 1.2.2002, p. 1.

Justification

EP first reading amendment 1.

Amendment 2

Council position – amending act Recital 2

Council position

(2) A high level of protection of human health should be assured in the pursuit of Union policies. ***Due attention*** should be given, ***where appropriate, to the protection of the environment and to animal welfare.***

Amendment

(2) A high level of human health protection should be assured in the pursuit of Union policies ***and*** should be given ***priority over the functioning of the internal market.***

Justification

EP first reading amendment 2.

Amendment 3

Council position – amending act Recital 2 a (new)

Council position

Amendment

(2a) Article 13 of the Treaty on the Functioning of the European Union clarifies that the Union and the Member States are to pay full regard to the welfare requirements of animals when formulating and implementing policies, since animals are sentient beings.

Justification

EP first reading amendment 3.

Amendment 4

Council position – amending act Recital 2 b (new)

Council position

Amendment

(2b) The standards laid down in Union legislation must be applied to all foods placed on the market within the Union, including foods imported from third countries.

Justification

EP first reading amendment 4.

Amendment 5

**Council position – amending act
Recital 2 c (new)**

Council position

Amendment

(2c) The European Parliament called on the Commission, in its resolution of 3 September 2008 on the cloning of animals for food supply¹, to submit proposals prohibiting for food supply purposes (i) the cloning of animals, (ii) the farming of cloned animals or their offspring, (iii) the placing on the market of meat or dairy products derived from cloned animals or their offspring and (iv) the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring.

¹ OJ C 295 E, 4.12.2009, p. 42.

Justification

EP first reading amendment 5.

Amendment 6

**Council position – amending act
Recital 2 d (new)**

Council position

Amendment

(2d) The Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted on 28-29 September 2005 an opinion which concluded that there were 'major gaps in the knowledge necessary for risk assessment. These include nanoparticle characterisation, the detection and measurement of

nanoparticles, the dose-response, fate, and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles'. Furthermore, the SCENIHR opinion concluded that 'existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles'.

Justification

EP first reading amendment 6.

Amendment 7

**Council position – amending act
Recital 3**

Council position

(3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients and by 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. For the sake of clarity, Regulation (EC) No 258/97 **and Regulation (EC) No 1852/2001** should be repealed and **Regulation (EC) No 258/97** should be replaced by this Regulation. **Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council should therefore become obsolete as regards novel foods.**

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 of 27 January 1997 concerning novel foods and novel food ingredients¹ and by 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 258/97². For the sake of clarity, Regulation (EC) No 258/97 should be repealed and replaced by this Regulation. **This Regulation should include measures currently governed by Regulation (EC) No 1852/2001 and that Regulation should be repealed.**

Justification

Recital 3 from the Commission document.

Amendment 8

**Council position – amending act
Recital 5**

Council position

(5) 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 applies. The existing definition of novel food should be clarified and updated by replacing the existing categories with a reference to the general definition of food in ***that*** Regulation.

Amendment

(5) The existing definition of novel food should be clarified, ***with an explanation of the criteria for novelty***, and updated by replacing the existing categories with a reference to the general definition of food in Regulation ***(EC) No 178/2002***.

Justification

EP first reading amendment 8.

Amendment 9

**Council position – amending act
Recital 5 a (new)**

Council position

(5a) Foods with a new or intentionally modified primary molecular structure, foods consisting of, or isolated from, micro-organisms, fungi or algae, new strains of micro-organism with no history of safe use and concentrates of substances that naturally occur in plants should be considered as novel foods as defined in this Regulation.

Amendment

Justification

EP first reading amendment 9.

Amendment 10

Council position – amending act

Recital 6

Council position

(6) It should also be clarified that a food **is to** be considered as novel when a production technology which was not previously used for **food production in the Union** is applied to that food. In particular, emerging technologies in breeding and food production processes which have an impact on food, and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from animals produced by non-traditional breeding techniques and **from their offspring, foods derived from plants produced by non-traditional breeding techniques**, foods **produced** by new production processes which might have an impact on food, **and foods containing or consisting of engineered nanomaterials**. Foods derived from new plant varieties or animal breeds produced by traditional breeding techniques should not be considered as novel foods. **Furthermore, it should be clarified that foods from third countries which are novel in the Union can be considered as traditional only when they are derived from primary production as defined in Regulation (EC) No 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should neither include foods produced from animals or plants to which a non-traditional breeding technique was applied or foods produced from the offspring of such animals, nor foods to which a new production process is applied.**

Amendment

(6) It should also be clarified that a food **should** be considered as novel when a production technology which was not previously used for **the production of foods to be marketed and consumed** is applied to that food. In particular, emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from **plants and** animals, produced by non-traditional breeding techniques, and foods **modified** by new production processes, **such as nanotechnology and nanoscience**, which might have an impact on food. Foods derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.

Justification

Recital 6 from the Commission document.

Amendment 11

Council position – amending act Recital 6 a (new)

Council position

Amendment

(6a) The cloning of animals is incompatible with Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes¹, point 20 of the Annex of which states that natural or artificial breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned must not be practised. Food from cloned animals or their descendants must therefore not be placed on the Union list.

¹ OJ L 221, 8.8.1998, p. 23.

Justification

EP first reading amendment 11.

Amendment 12

Council position – amending act Recital 7

Council position

Amendment

(7) However, in the light of the opinion of the European Group on Ethics in Science and New Technologies, established by Commission Decision of 16 December 1997, issued on 16 January 2008 and of the opinion of the European Food Safety Authority adopted on 15 July 2008, techniques for the cloning of animals, such as somatic cell nuclear transfer, have specific characteristics such that this Regulation cannot address all the issues of cloning. Therefore, food produced from animals obtained by using a cloning technique and from the offspring thereof should be subject to a report submitted by the Commission to the European Parliament and the Council, followed, if

(7) The European Group on Ethics in Science and New Technologies, established by Commission Decision of 16 December 1997, stated in its Opinion (No. 23) of 16 January 2008 on ethical aspects of animal cloning for food supply that it ‘does not see convincing arguments to justify the production of food from clones and their offspring’. The Scientific Committee of the European Food Safety Authority (EFSA) concluded in its Opinion of 15 July 2008 on animal cloning¹ that ‘the health and welfare of a significant proportion of clones ... have been found to be adversely affected, often severely and with a fatal outcome’.

appropriate, by a legislative proposal. If specific legislation is adopted, the scope of this Regulation should be adapted accordingly.

¹ *The EFSA Journal (2008)767, p.32.*

Justification

EP first reading amendment 12.

Amendment 13

**Council position – amending act
Recital 7 a (new)**

Council position

Amendment

(7a) Only nanomaterials entered in a list of approved substances should be present in food packaging, accompanied by a limit on migration into or onto the food products contained in such packaging.

Justification

EP first reading amendment 13.

Amendment 14

**Council position – amending act
Recital 7 b (new)**

Council position

Amendment

(7b) Foods derived from cloned animals and their descendants should, however, be excluded from the scope of this Regulation. They should be dealt with in a specific regulation, adopted under the ordinary legislative procedure, and should not be subject to the common authorisation procedure. Before the date of application of this Regulation, the Commission should present a corresponding legislative proposal. Pending the entry into force of a regulation on cloned animals, a moratorium should be imposed on the placing on the market of foods

manufactured from cloned animals and their descendants.

Justification

EP first reading amendment 14.

Amendment 15

**Council position – amending act
Recital 8**

Council position

(8) Implementing measures should be adopted to provide for criteria to facilitate the assessment of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997. If, **prior to that date**, a food was used exclusively as, or in, a food supplement, as defined in 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. 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 authorised in accordance with this Regulation.

Amendment

(8) Implementing measures should be adopted to provide for **further** criteria **in order** to facilitate the assessment of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997. If a food was used exclusively as, or in, a food supplement, as defined in 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 supplements¹**, **prior to that date**, it **can** be placed on the market after that date for the same use without being considered as a novel food. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether **it** was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, **other** uses of the food concerned, **namely** other than food supplement **uses, have to** be authorised in accordance with this Regulation.

¹ *OJ L 183, 12.7.2002, p. 51.*

Justification

EP first reading amendment 15.

Amendment 16

Council position – amending act

Recital 9

Council position

(9) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, ***free movement of goods and legal certainty for manufacturers***, it is necessary to develop a uniform definition for engineered ***nanomaterial at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of engineered nanomaterial in this Regulation should be adapted accordingly***

Amendment

(9) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, it is necessary to develop a uniform definition for engineered ***nanomaterials***.

Amendment 17

Council position – amending act

Recital 10

Council position

(10) 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 food. ***However, modifications of a food ingredient, e.g. selective extracts or the use of other parts of a plant, that have so far not been used for human consumption within the Union, should still fall within the scope of this Regulation.***

Amendment

(10) ***Reformulated*** food products produced from ***existing*** food ingredients ***available on the market within the Union***, in particular ***those reformulated*** by changing ***the composition or amounts of those food ingredients***, should not be considered as novel food.

Justification

Recital 8 from Commission document.

Amendment 18

Council position – amending act

Recital 13

Council position

(13) Foods which are intended for technological uses or which are genetically modified should not fall within the scope of this Regulation. Therefore, ***genetically modified food falling within the scope of Regulation (EC) No 1829/2003¹, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008², flavourings falling within the scope of Regulation (EC) No 1334/2008³, enzymes falling within the scope of Regulation (EC) No 1332/2008⁴ and extraction solvents falling within the scope of Directive 2009/32/EC⁵ should not be covered by this Regulation.***

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

² Regulation (EC) No 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).

Amendment

(13) Foods which are intended for technological uses or which are genetically modified should not fall within the scope of this Regulation ***as long as these foods are covered by a safety evaluation and approval according to other Union legislation.*** Therefore, food ***used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, flavourings falling within the scope of 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 foods², extraction solvents falling within the scope of 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)³, enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes⁴ and genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁵ should be excluded from the scope of this Regulation.***

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 34.

³ *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).*

³ *OJ L 141, 6.6.2009, p. 3.*

⁴ *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).*

⁴ *OJ L 354, 31.12.2008, p. 7.*

⁵ *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).*

⁵ *OJ L 268, 18.10.2003, p. 1.*

Justification

EP first reading amendment 17.

Amendment 19

Council position – amending act

Recital 15

Council position

(15) Novel foods, other than vitamins and minerals, intended for particular nutritional uses, for food fortification or as food supplements, should be assessed in conformity with ***this Regulation***. They should also remain subject to the rules provided for in ***Directive 2002/46/EC, in Regulation (EC) No 1925/2006, in Directive 2009/39/EC, and in the specific Directives referred to in Directive 2009/39/EC and in Annex I thereto.***

Amendment

(15) Novel foods, other than vitamins and minerals, intended for particular nutritional uses, for food fortification or as food supplements, should be assessed in conformity with ***the safety criteria and requirements applicable to all novel foods. At the same time*** they should remain subject to the rules provided for in Directive 2009/39/EC and in the specific Directives referred to in ***Article 4(1) thereof and Annex I thereto, in Directive 2002/46/EC and in Regulation (EC) No 1925/2006.***

Justification

Recital 12 from the Commission document..

Amendment 20

Council position – amending act Recital 16

Council position

(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. When there is no or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and any parties concerned, should be established for collecting that information.*

Amendment

(16) *The Commission should establish a simple and transparent procedure for cases in which it does not have information on human consumption before 15 May 1997. The Member States should be involved in this procedure. The procedure should be adopted no later than ... **

**Six months after the entry into force of this Regulation*

Justification

EP first reading amendment 18.

Amendment 21

Council position – amending act Recital 17

Council position

(17) Novel foods should be placed on the market within the Union only if they are safe and do not mislead the consumer. In addition, *where the novel food is intended to replace another food, it* should not differ from *that* food in *a* way that would be nutritionally disadvantageous for the consumer.

Amendment

(17) Novel foods should be placed on the market within the Union only if they are safe and do not mislead the consumer. *The assessment of their safety should be based on the precautionary principle as laid down in Article 7 of Regulation (EC) No 178/2002.* In addition, *they* should not differ from *the* food *that they are to replace* in *any* way that would be nutritionally disadvantageous for the consumer.

Justification

EP first reading amendment 19.

Amendment 22

**Council position – amending act
Recital 19 a (new)**

Council position

Amendment

(19a) Ethical and environmental aspects must be considered as part of the risk management during the authorisation procedure. These aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively.

Justification

This amendment re-establishes partially the EP first reading amendment 23.

Amendment 23

**Council position – amending act
Recital 20**

Council position

Amendment

(20) At present, there is inadequate information on the risks associated with engineered nanomaterials. In order to better assess their safety the Commission, in cooperation with the Authority, should develop test methodologies which take into account specific characteristics of engineered nanomaterials.

(20) Test methods currently available are not adequate for assessing the risks associated with nanomaterials. Non-animal test methods for testing nanomaterials should be developed as a matter of urgency.

Amendment 24

**Council position – amending act
Recital 22**

Council position

Amendment

(22) If traditional foods from third

(22) As regards the safety assessment and

countries are included in the list of traditional foods from third countries, they should be allowed to be placed on the market within the Union, under conditions that correspond to those for which the history of safe food use has been demonstrated. As regards the safety assessment and management of traditional food from third countries, *their history of safe food use in their country of origin* should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets.

management of traditional food from third countries, *the EU rules in force* should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets. *If Member States and/or the Authority have not presented any reasoned safety objections, based on scientific evidence, for example information on adverse health effects, it should be permissible to place the food on the market within the Union after notification of the intention to do so, provided that there are no ethical objections.*

Justification

EP first reading amendment 28.

Amendment 25

**Council position – amending act
Recital 24**

Council position

(24) The inclusion of a novel food in the Union list of novel foods *or in the list of traditional foods from third countries* should be without prejudice to the possibility of evaluating the effects of the overall consumption of a substance which is added to, or used for the manufacture of that food, or of a comparable product in accordance with Regulation (EC) No 1925/2006.

Amendment

(24) The inclusion of a novel food in the Union list of novel foods should be without prejudice to the possibility of evaluating the effects of the overall consumption of a substance which is added to, or used for the manufacture of that food, or of a comparable product in accordance with *Article 8 of Regulation (EC) No 1925/2006.*

Justification

Recital 19 from the Commission document.

Amendment 26

**Council position – amending act
Recital 25**

Council position

(25) Under specific circumstances, in order

Amendment

(25) Under specific circumstances in order

to stimulate research and development within the agri-food industry, and thus innovation, 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. That data and information** should not be used to the benefit of **a subsequent** applicant, during a limited period of time, 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 of novel foods on the basis of their own scientific data.

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 under 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 not be used to the benefit of **another** applicant during a limited period of time, without the agreement of the **first** applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Union list of novel foods on the basis of their own scientific data. **In addition, the protection of scientific data should not prevent transparency and access to information relating to the data used in the safety assessment of novel foods. Intellectual property rights should, nevertheless, be respected.**

Justification

EP first reading amendment 25.

Amendment 27

Council position – amending act

Recital 26

Council position

(26) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC¹ **and, where necessary, to the nutritional labelling requirements laid down in Directive 90/496/EEC²**. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use. Therefore, **when a novel food is included in the Union list or in the list of traditional foods**

Amendment

(26) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC **of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs¹**. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore,

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.

¹ *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29).*

² *Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276, 6.10.1990, p. 40).*

the inclusion of a novel food in the Union list may be subject to specific conditions of use or labelling obligations.

¹ OJ L 109, 6.5.2000, p. 29.

Justification

Recital 21 from the Commission document.

Amendment 28

Council position – amending act Recital 27

Council position

(27) Regulation (EC) No 1924/2006 harmonises the provisions in the Member States which relate to nutrition and health claims. Therefore, claims regarding novel foods should only be made in accordance with that Regulation.

Amendment

(27) Regulation (EC) No 1924/2006 *of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods*¹ harmonises the provisions in the Member States which relate to nutrition and health claims. Therefore, claims regarding novel foods should only be made in accordance with that Regulation. *Where an applicant wishes a novel food to carry a health claim that needs to be authorised in accordance with Article 17 or 18 of Regulation (EC) No 1924/2006 and the novel food and health claim applications both include requests for the protection of proprietary data, the periods of data protection should start together and run concurrently, where the applicant so requests.*

¹ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

¹ OJ L 404, 30.12.2006, p. 9.

Justification

EP first reading amendment 27.

Amendment 29

**Council position – amending act
Recital 28**

Council position

(28) The European Group on Ethics in Science and New Technologies *may* be consulted, *where appropriate*, with a view to obtaining advice on ethical issues regarding the placing on the market *within the Union* of novel foods.

Amendment

(28) The European Group on Ethics in Science and New Technologies (**EGE**) *should* be consulted *in specific cases* with a view to obtaining advice on ethical issues regarding *the use of new technologies and* the placing on the market of novel foods.

Justification

EP first reading amendment 29.

Amendment 30

**Council position – amending act
Recital 29**

Council position

(29) Novel foods placed on the market within the Union under Regulation (EC) No 258/97 should continue to be placed on the market. Novel foods authorised in accordance with Regulation (EC) No 258/97 should be included in the Union list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97 *before the date of application of this Regulation should be transformed into an application under this Regulation where* the initial assessment report provided for under Regulation (EC) No 258/97 has not yet been forwarded to the

Amendment

(29) Novel foods placed on the market within the Union under Regulation (EC) No 258/97 should continue to be placed on the market. Novel foods authorised in accordance with Regulation (EC) No 258/97 should be included in the Union list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97, *in relation to which* the initial assessment report provided for under *Article 6(3) of that* Regulation has not yet been forwarded to the Commission *and in relation to which* an additional assessment report is required in accordance with

Commission, *as well as in all cases where* an additional assessment report is required in accordance with that Regulation. Other *pending* requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation should be processed under the provisions of Regulation (EC) No 258/97.

Article 6(3) or 6(4) of that Regulation before the date of application of this Regulation, should be considered as an application under this Regulation. When required to give an opinion, the Authority and the Member States should take into account the outcome of the initial assessment. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation should be processed under the provisions of Regulation (EC) No 258/97.

Justification

EP first reading amendment 89.

Amendment 31

Council position – amending act Recital 30

Council position

(30) Regulation (EC) No 882/2004¹ lays down general rules for the performance of official controls to verify compliance with food law. *The* Member States *should be requested* to carry out official controls in accordance with *that* Regulation, in order to enforce compliance with this Regulation.

¹ *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules* (OJ L 165, 30.4.2004, p. 1).

Amendment

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

¹ OJ L 165, 30.4.2004, p. 1

Justification

Recital 30 from the Commission document.

Amendment 32

Council position – amending act
Recital 34

Council position

Amendment

(34) The measures necessary for the implementation of this Regulation should be adopted in accordance with Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹.

deleted

¹ OJ L 184, 17.7.1999, p. 23.

Amendment 33

Council position – amending act
Recital 35

Council position

Amendment

(35) In particular, the Commission should be empowered to clarify certain definitions in order to ensure a harmonised implementation of these provisions by the Member States on the basis of relevant criteria, including the definition of "engineered nanomaterial", taking into account the technical and scientific developments, and the non-traditional animal breeding technique that includes techniques used for asexual reproduction of genetically identical animals not used for food production within the Union before 15 May 1997. Furthermore, the Commission should be empowered to adopt any appropriate transitional measures and to update the list of traditional foods from third countries and the Union list.

deleted

Amendment 34

Council position – amending act
Recital 36

Council position

(36) ***In addition***, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997. It is of particular importance that the Commission ***consult experts in the preparatory phase in accordance with the commitment of the Commission undertaken in the Communication of 9 December 2009 on the implementation of Article 290 of the Treaty on the Functioning of the European Union.***

Amendment

(36) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997, ***in respect of the determination of whether a type of food falls within the scope of this Regulation, the adjustment and adaptation of the definition of "engineered nanomaterial" to technical and scientific progress and in line with definitions subsequently agreed at international level, rules on how to proceed in cases in which the Commission has no information about use of a food for human consumption before 15 May 1997, as well as in respect of rules for the application of Article 4(1) and Article 11 and the update of the Union list.*** It is of particular importance that the Commission ***carry out appropriate consultations during its preparatory work, including at expert level.***

Amendment 35

Council position – amending act
Article 1

Council position

This Regulation lays down harmonised rules for the placing of novel foods on the market within the Union with a view to ensuring a high level of protection of human health ***and consumers' interests***, whilst ensuring the effective functioning of the internal market, ***taking into account, where appropriate, the protection of the environment and animal welfare.***

Amendment

This Regulation lays down harmonised rules for the placing of novel foods on the market within the Union with a view to ensuring a high level of protection of human ***life and health, animal health and welfare, the environment and the interests of consumers*** whilst ensuring ***transparency and*** the effective functioning of the internal market ***and stimulating innovation within the agri-food industry.***

Justification

EP first reading amendment 30.

Amendment 36

Council position – amending act

Article 2 - paragraph 2

<i>Council position</i>	<i>Amendment</i>
<p>2. This Regulation shall not apply to:</p> <p>(a) foods when and in so far as they are used as:</p> <p>(i) food additives falling within the scope of Regulation (EC) No 1333/2008;</p> <p>(ii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;</p> <p>(iii) extraction solvents used in the production of foodstuffs and falling within the scope of Directive 2009/32/EC;</p> <p>(iv) food enzymes falling within scope of Regulation (EC) No 1332/2008;</p> <p>(v) vitamins and minerals falling within the respective scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Directive 2009/39/EC, except for vitamin and mineral substances already authorised, which are obtained by production methods or using new sources that were not taken into account when they were authorised under specific legislation, where those production methods or new sources give rise to the significant changes referred to in point (iii) of Article 3(2)(a) of this Regulation.</p> <p>(b) foods falling within the scope of Regulation (EC) No 1829/2003;</p>	<p>2. This Regulation shall, unless otherwise provided for, not apply to:</p> <p>(a) foods when and insofar as they are used as:</p> <p>(i) food additives falling within the scope of Regulation (EC) No 1333/2008;</p> <p>(ii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;</p> <p>(iii) extraction solvents used in the production of foodstuffs and falling within the scope of Directive 2009/32/EC ;</p> <p>(iv) food enzymes falling within scope of Regulation (EC) No 1332/2008;</p> <p>(v) vitamins and minerals falling within the scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Directive 2009/39/EC, except for vitamin and mineral substances already approved which are obtained by production methods or using new sources that were not taken into account when they were authorised under specific legislation, where these production methods or new sources give rise to significant changes referred to in Article 3(2)(a)(iii).</p> <p>(b) foods falling within the scope of Regulation (EC) No 1829/2003;</p>

Justification

EP first reading amendment 91.

Amendment 37

Council position – amending act
Article 2 - paragraph 2 - point b a (new)

Council position

Amendment

(ba) foods derived from cloned animals and their descendants. Before ..., the Commission shall present a legislative proposal to prohibit the placing on the market in the Union of foods derived from cloned animals and their descendants. The proposal shall be forwarded to the European Parliament and the Council.*

** Six months after the date of entry into force of this Regulation.*

Justification

EP first reading amendment 91.

Amendment 38

Council position – amending act
Article 2 - paragraph 2 a (new)

Council position

Amendment

(2a) Notwithstanding paragraph 2, this Regulation shall apply to food additives, food enzymes, flavourings and certain food ingredients with flavouring properties to which a new production process not used before 15 May 1997 is applied that gives rise to significant changes in the composition or structure of the food, such as engineered nanomaterials.

Justification

EP first reading amendment 91.

Amendment 39

Council position – amending act
Article 2 – paragraph 2 b (new)

Council position

Amendment

(2b) Where necessary and taking into account the scope defined in this Article, the Commission may determine, by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23, whether a type of food falls within the scope of this Regulation. Where a novel food is capable of having an effect on the human body comparable to that of a medicinal product, the Commission may seek an opinion of the European Medicines Agency (EMA) on whether it falls under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹, and therefore not under this Regulation.

¹ OJ L 136, 30.4.2004, p. 1.

Justification

EP first reading amendment 91.

Amendment 40

Council position – amending act
Article 3 - paragraph 2 - point a - introductory part and point i

Council position

Amendment

(a) "novel food" means food that was not used for human consumption to a significant degree within the Union before 15 May 1997, including:

(i) food of animal origin, when a non-traditional breeding technique not used for food production within the Union before 15 May 1997 is applied to the animal and food derived from the

(a) "novel food" means:

(i) food that was not used for human consumption to a significant degree within the Union before 15 May 1997;

offspring of these animals;

Justification

EP first reading amendments 92 and 35.

Amendment 41

Council position – amending act

Article 3 - paragraph 2 - point a - point ii

Council position

(ii) food of plant origin, when a non-traditional breeding technique not used **for food production within the Union** before 15 May 1997 **is applied to the plant, if that non-traditional breeding technique applied to a plant gives rise to significant changes in the composition or structure of the food, which affect its nutritional value, how it is metabolised or the level of undesirable substances;**

Amendment

(ii) food of plant **or animal** origin when **to the plant and animal is applied** a non-traditional breeding technique not used before 15 May 1997, **with the exception of foods derived from cloned animals and their descendants;**

Justification

EP first reading amendments 92 and 35.

Amendment 42

Council position – amending act

Article 3 - paragraph 2 - point a - point v

Council position

(v) **traditional food from a third country; and**

Amendment

deleted

Amendment 43

Council position – amending act

Article 3 - paragraph 2 - point a - point vi

Council position

(vi) **food ingredients used exclusively in food supplements within the Union before 15 May 1997, if they are to be used in**

Amendment

deleted

*foods other than food supplements.
However, if a food has been used
exclusively as, or in, a food supplement
prior that date, it may be placed on the
market within the Union after that date
for the same use without being considered
a novel food;*

Amendment 44

**Council position – amending act
Article 3 - paragraph 2 - point b**

Council position

Amendment

*(b) "offspring" means an animal
produced by a traditional breeding
technique, where at least one of its
parents is an animal produced by a non-
traditional breeding technique;*

deleted

Amendment 45

**Council position – amending act
Article 3 - paragraph 2 - point c a (new)**

Council position

Amendment

*(ca) "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;*

Justification

EP first reading amendments 92 and 35.

Amendment 46

**Council position – amending act
Article 3 - paragraph 2 - point c b (new)**

Council position

Amendment

*(cb) "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;

Justification

EP first reading amendments 92 and 35.

Amendment 47

**Council position – amending act
Article 3 - paragraph 2 - point d**

Council position

(d) "traditional food from a third country" means novel food, ***other than the novel food under sub-points (i) to (iv) of point (a), derived from primary production***, with a history of food use in ***any*** third country, ***such*** that the food in question ***has been*** and continues to be part of the ***customary*** diet ***for at least 25 years*** in a large part of the population of the country;

Amendment

(d) "traditional food from a third country" means ***a natural non-engineered*** novel food with a history of food use in ***a*** third country, ***meaning*** that the food in question ***was, for at least 25 years before ...****, and continues to be, part of the ***normal*** diet in a large part of the population of the country;

**** Six months after the date of entry into force of this Regulation.***

Justification

EP first reading amendments 92 and 35.

Amendment 48

**Council position – amending act
Article 3 - paragraph 2 - point e**

Council position

(e) "history of safe food use ***in a third country***" means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use for at least ***25 years*** in the customary diet of a large part of the population of a country.

Amendment

(e) "history of safe food use" means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use for at least ***30 years*** in the customary diet of a large part of the population of a country;

Justification

EP first reading amendments 92 and 35.

Amendment 49

Council position – amending act Article 3 – paragraph 3

Council position

3. The Commission may adopt further criteria to clarify the definitions in sub-points (i) to (iv) of point (a), and in points (c), (d) and (e) of paragraph 2 of this Article in accordance with the regulatory procedure referred to in Article 19(2).

Amendment

3. In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (c) of paragraph 2 of this Article to technical and scientific progress, and in line with definitions subsequently agreed at international level, by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23.

Justification

EP first reading amendment 92 and 35.

Amendment 50

Council position – amending act Article 4 - title

Council position

***Procedure for determination* of novel food status**

Amendment

***Collection of information regarding the classification* of a novel food**

Justification

EP first reading amendment 40.

Amendment 51

Council position – amending act Article 4 - paragraph 1

Council position

1. Food business operators shall verify the status of the food they intend to place on

Amendment

1. The Commission shall collect information from the Member States

the market within the Union with respect to the scope of this Regulation.

and/or from food business operators or any other interested party to determine whether a food falls within the scope of this Regulation. Member States, business operators and other interested parties shall transmit to the Commission information on the extent a food was used for human consumption within the Union before 15 May 1997.

Justification

EP first reading amendment 40.

Amendment 52

**Council position – amending act
Article 4 - paragraph 2**

Council position

2. In case of doubt, food business operators shall consult the relevant competent authority for novel foods as defined in Article 15 of Regulation (EC) No 1331/2008 on the status of the food in question. On request from the relevant competent authority, food business operators shall submit information concerning the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

Amendment

2. The Commission shall publish those data and the conclusions drawn from the data collection and the non-confidential data supporting it.

Justification

EP first reading amendment 40.

Amendment 53

**Council position – amending act
Article 4 – paragraph 3**

Council position

3. Where necessary, the competent authority may consult other competent authorities and the Commission concerning the extent to which a food was

Amendment

3. In order to ensure the completeness of information regarding the classification of novel foods, the Commission shall, not later than..., adopt rules on how to*

used for human consumption within the Union before 15 May 1997. Replies to any such consultation shall also be transmitted to the Commission. The Commission shall summarise the replies received and communicate the result of the consultation to all competent authorities.

proceed in cases in which the Commission has no information about the use of a food for human consumption before 15 May 1997 by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23.

** Six months after the date of entry into force of this regulation.*

Justification

EP first reading amendment 40.

Amendment 54

**Council position – amending act
Article 4 – paragraph 4**

Council position

4. The Commission may adopt implementing measures for paragraph 3 of this Article in accordance with the regulatory procedure referred to in Article 19(2).

Amendment

*4. The Commission may adopt **detailed rules on the application of paragraph 1, in particular as regards the type of information to be collected from Member States and/or from food business operators, by means of delegated acts in accordance with Article 21 and subject to conditions of Articles 22 and 23.***

Justification

Article 4(2) from the Commission document.

Amendment 55

**Council position – amending act
Article 5**

Council position

Article 5

Interpretation decisions

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 19(2) whether a type of food falls within the scope of this

Amendment

deleted

Regulation.

Amendment 56

**Council position – amending act
Article 5 a (new)**

Council position

Amendment

Article 5a

Union list of novel foods

Only novel foods included in the Union list of novel foods ("the Union list") may be placed on the market. The Commission shall keep and publish the Union list on a publicly accessible page intended for that purpose on the website of the Commission.

Justification

EP first reading amendment 41.

Amendment 57

**Council position – amending act
Article 6**

Council position

Amendment

No person shall place on the Union market a novel food if it does not comply with this Regulation.

Novel foods shall not be placed on the market if they do not comply with the provisions of this Regulation.

Justification

EP first reading amendment 42.

Amendment 58

**Council position – amending act
Article 7**

Council position

Amendment

Article 7

Lists of novel foods

- 1. The Commission shall maintain a Union list of authorised novel foods other than traditional foods from third countries (hereinafter "the Union list"), which will be published in accordance with Article 2(1) of Regulation (EC) No 1331/2008.** *deleted*
- 2. The Commission shall establish and maintain a list of traditional foods from third countries authorised pursuant to Article 11(5) of this Regulation, which shall be published in the C series of the Official Journal of the European Union.**
- 3. Only novel foods included in the Union list or in the list of traditional foods from third countries may be placed on the market within the Union.**

Amendment 59

Council position – amending act Article 8 - point a

Council position

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

Amendment

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer ***and of animals, which implies that cumulative and synergistic effects as well as possible adverse effects on particular groups of the population will be taken into account in the risk assessment;***

Justification

EP first reading amendment 43.

Amendment 60

Council position – amending act Article 8 - point c

Council position

(c) **if** 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) **in the case 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.

Justification

EP first reading amendment 45.

Amendment 61

Council position – amending act Article 8 – point c a (new)

Council position

Amendment

(ca) the opinion of the European Environment Agency, which shall be published no later than the day of the publication of the EFSA assessment, concerning the extent to which the production process and normal consumption have a harmful impact on the environment, is taken into account in the risk management;

Justification

This amendment re-establishes partially the EP first reading amendment 47.

Amendment 62

Council position – amending act Article 8 – point c b (new)

Council position

Amendment

(cb) the opinion of the European Group on Ethics in Science and New Technologies, which shall be published no later than the day of the publication of

the EFSA assessment, concerning the extent to which there are ethical objections, is taken into account in the risk management;

Justification

This amendment re-establishes partially the EP first reading amendment 48.

Amendment 63

**Council position – amending act
Article 8 - point c c (new)**

Council position

Amendment

(cc) a novel food that may have any adverse effects on particular groups of the population will be authorised only where specific measures preventing such adverse effects have been implemented;

Justification

EP first reading amendment 49.

Amendment 64

**Council position – amending act
Article 8 – point c d (new)**

Council position

Amendment

(cd) it is not derived from a cloned animal or its descendants.

Justification

Parliament's 1st reading report specifically endorsed future legislation to prohibit these foods being placed on the EU market. This amendment would ensure that these foods are not placed on the market before such legislation is presented.

Amendment 65

Council position – amending act Article 8 - point c e (new)

Council position

Amendment

(ce) maximum intake levels of a novel food as such or as part of another foodstuff or categories of foodstuffs will be laid down, where required in the interests of safe use;

Justification

EP first reading amendment 49.

Amendment 66

Council position – amending act Article 8 - point c f (new)

Council position

Amendment

(cf) cumulative effects of novel foods that are used in different foodstuffs or categories of foodstuffs have been assessed.

Justification

EP first reading amendment 49.

Amendment 67

Council position – amending act Article 8 - paragraph 1 a (new)

Council position

Amendment

1a. Foods to which production processes have been applied that require specific risk assessment methods (for example, foods produced using nanotechnologies) may not be included in the Union list until such specific methods have been approved for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective

foods is safe.

Justification

EP first reading amendment 50.

Amendment 68

**Council position – amending act
Article 8 - paragraph 1 b (new)**

Council position

Amendment

1b. A novel food may be included in the Union list only if the competent authority has submitted an opinion establishing that the food is not harmful to health.

Justification

EP first reading amendment 51.

Amendment 69

**Council position – amending act
Article 8 - paragraph 1 c (new)**

Council position

Amendment

1c. In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the precautionary principle shall be applied and the food in question shall not be included in the Union list.

Justification

EP first reading amendment 52.

Amendment 70

Council position – amending act
Article 9 – paragraph 1

Council position

1. **The Union list shall be updated** in accordance with the procedure laid down in Regulation (EC) No 1331/2008 **and, where applicable, in accordance with Article 16 of this Regulation.**

Amendment

1. **The Commission shall update the Union list, *inter alia in cases of data protection referred to in Article 16*, in accordance with the procedure laid down in Regulation (EC) No 1331/2008. *By way of derogation from paragraphs 4 to 6 of Article 7 of Regulation (EC) No 1331/2008, the Regulation updating the Union list shall be adopted by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23. The Commission shall publish the Union list on a dedicated page of its website.***

Justification

Article 7(4) form the Commission document.

Amendment 71

Council position – amending act
Article 9 - paragraph 2

Council position

2. The entry for a novel food in the Union list shall include a specification of the food, **and, where appropriate, specify the conditions of use, additional specific labelling requirements to inform the final consumer, and/or a post-market monitoring requirement and, where applicable, the information referred to in Article 16(4).**

Amendment

2. The entry of a novel food in the Union list shall include:

- (a) a specification of the food;
- (b) **the intended use of the food;**
- (c) the conditions of use;
- (d) **where appropriate, additional specific labelling requirements to inform the final consumer;**
- (e) **the date of entry of the novel food in**

the Union list and the date of receipt of the application;

(f) the name and address of the applicant;

(g) the date and results of the last inspection according to the monitoring requirements laid down in Article 14;

(h) the fact that the entry is based on newly developed scientific evidence and/or proprietary data protected in accordance with Article 16;

(i) the fact that the novel food may only be placed on the market by the applicant specified in point (e), unless a subsequent applicant obtains authorisation for the food without prejudice to the proprietary data of the original applicant.

Justification

EP first reading amendment 54 and Article 7(3), point (b) from the Commission document.

Amendment 72

**Council position – amending act
Article 9 - paragraph 2 a (new)**

Council position

Amendment

2a. Post-marketing monitoring shall be required for all novel foods. All novel foods which have been allowed onto the market shall be reviewed after five years and whenever more scientific evidence becomes available. In the context of the monitoring, special attention should be paid to the categories of the population with the highest dietary intakes.

Justification

EP first reading amendment 55.

Amendment 73

Council position – amending act Article 9 - paragraph 2 b (new)

Council position

Amendment

2b. In the cases referred to in Article 2 (2a) the procedure shall be employed irrespective of the previous use or authorisation of the substance to which a standard production process was applied.

Justification

EP first reading amendment 56.

Amendment 74

Council position – amending act Article 9 - paragraph 2 c (new)

Council position

Amendment

2c. Where a novel food contains a substance which may pose a risk to human health in the event of excessive consumption, it shall require approval for use within maximum limits in certain foods or food categories.

Justification

EP first reading amendment 57.

Amendment 75

Council position – amending act Article 9 - paragraph 2 d (new)

Council position

Amendment

2d. All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

Justification

EP first reading amendment 90.

Amendment 76

**Council position – amending act
Article 9 - paragraph 2 e (new)**

Council position

Amendment

2e. Products produced from animals fed with genetically modified feeding stuffs must be labelled with the words ‘produced from animal fed with genetically modified feeding stuffs’.

Justification

EP first reading amendment 6.

Amendment 77

**Council position – amending act
Article 9 – paragraph 2 f (new)**

Council position

Amendment

2f. Before the expiry of the period referred to in Article 16(1), the Union list shall be updated in accordance with paragraph 1 of this Article so that, provided that the authorised food still meets the conditions laid down in this Regulation, the specific indications referred to in point (h) of paragraph 2 of this Article, are no longer included.

Justification

Article 7(4) form the Commission document.

Amendment 78

**Council position – amending act
Article 9 – paragraph 2 g (new)**

Council position

Amendment

2g. For the purposes of updating the Union list through inclusion of a novel food, where the novel food does not consist of or contain food subject to data protection according to Article 16 and:

(a) the novel food is equivalent to existing foods, in composition, metabolism and level of undesirable substances,

or

(b) the novel food consists of, or contains, food previously approved for food use in the Union, and the new intended use can be expected not to significantly increase the intake of consumers, including consumers in vulnerable groups,

then the notification procedure referred to in Article 11 of this Regulation shall apply mutatis mutandis, by way of derogation from paragraph 1 of this Article.

Justification

EP first reading amendment 86.

Amendment 79

**Council position – amending act
Article 9 a (new)**

Council position

Amendment

Article 9a

Labelling of novel foods and novel food ingredients

Without prejudice to the provisions and requirements of Directive 2000/13/EC, all specific data on novel foods shall be indicated and labelled as set out below to ensure proper consumer information:

(a) all new foods placed on the market shall be sold with clearly distinctive,

*precise and easily legible labelling
indicating that they are novel foods;*

*(b) all the characteristics or properties of
novel foods such as their composition,
nutritional value and proper use, shall
appear clearly, precisely and in an easily
legible and comprehensible manner on
their packaging;*

*(c) the presence of a novel food or novel
ingredient replacing a material or
ingredient in a food, whether or not the
food is replaced by a novel food, must be
stated clearly, precisely and in an easily
legible and comprehensible manner on
the labelling.*

*Where a novel food contains a substance
which may pose a high risk to human
health in the event of excessive
consumption, the consumer must be
informed of this by means of clear,
precise and easily legible labelling on the
packaging of the food.*

Justification

EP first reading amendment 62.

Amendment 80

**Council position – amending act
Article 10**

Council position

Amendment

Article 10

deleted

***Content of the list of traditional foods
from third countries***

- 1. The list of traditional foods from third countries shall be updated in accordance with the procedure laid down in Article 11.***
- 2. The entry for a traditional food from a third country in the list of traditional foods from third countries shall include a specification of the food, and, where appropriate, specify the conditions of use and/or additional specific labelling requirements to inform the final***

consumer.

Amendment 81

Council position – amending act Article 11

Council position

Procedure for including a traditional food from a third country in the list

1. By way of derogation from the procedure laid down in Article 9(1) of this Regulation, an interested party referred to in Article 3(1) of Regulation (EC) No 1331/2008, who intends to place on the market within the Union a traditional food from a third country, shall submit an application to the Commission.

The application shall include:

- (a) the name and description of the food,***
- (b) its composition,***
- (c) its country of origin,***
- (d) documented data demonstrating the history of safe food use in any third country,***
- (e) where applicable, the conditions of use and specific labelling requirements,***
- (f) a summary of the content of the application.***

The application shall be made in accordance with the implementing rules referred to in paragraph 7 of this Article.

2. The Commission shall forward the valid application referred to in paragraph 1 without delay to the Member States and the Authority.

3. Within six months of receipt of an application, the Authority shall give its opinion. Whenever the Authority seeks supplementary information from the

Amendment

Traditional food from a third country

1. A food business operator intending to place a traditional food from a third country on the market in the Union shall notify this to the Commission, indicating the name of the food, its composition and country of origin.

The notification shall be accompanied by documented data demonstrating the history of safe food use in any third country.

2. The Commission shall forward the notification including the demonstration of history of safe food use referred to in paragraph 1 without delay to the Member States and the Authority and make it publicly available on its website.

3. Within four months from the date on which the notification provided for in paragraph 1 is forwarded by the Commission according to paragraph 2, a

interested party, it shall, after consulting the interested party, lay down a period within which that information shall be provided. The six-month time limit shall be automatically extended by this additional period. The supplementary information shall be made available to the Member States and the Commission by the Authority.

4. In order to prepare its opinion the Authority shall verify that:

(a) the history of safe food use in any third country is substantiated by the quality of data submitted by the interested party; and

(b) the composition of the food and, where applicable, the conditions of its use, do not pose a health risk to consumers in the Union.

The Authority shall forward its opinion to the Commission, the Member States and the interested party.

5. Within three months of the Authority giving its opinion, the Commission shall, in accordance with the regulatory procedure referred to in Article 19(2), update the list of traditional foods from third countries, taking account of the opinion of the Authority, any relevant provisions of Union law and any other legitimate factors relevant to the matter under consideration. The Commission

Member State and the Authority may inform the Commission that they have justified safety objections, based on scientific evidence, to the placing on the market of the traditional food concerned.

In that case, the food shall not be placed on the market in the Union and Articles 5a - 9 shall apply. The notification as referred to in paragraph 1 of this Article shall be considered as an application referred to in Article 3(1) of Regulation (EC) No 1331/2008. Alternatively, the applicant may choose to withdraw the notification.

The Commission shall inform the food business operator concerned accordingly without undue delay and in a demonstrable manner not later than five months from the date of the notification provided for in paragraph 1.

4. If no justified safety objections, based on scientific evidence, have been raised and no information thereof has been communicated to the food business operator concerned in accordance with paragraph 3, the traditional food may be placed on the market in the Union after five months from the date of the notification in accordance with paragraph 1.

5. The Commission shall publish a list of traditional foods from third countries that may be placed on the market in the Union in accordance with paragraph 4 on a dedicated page of the Commission's website. This page shall be accessible from and linked to the page on the Union list of novel foods referred to in Article 5a.

shall inform the interested party accordingly. If the Commission decides not to proceed with an update of the list of traditional foods from third countries, it shall inform the interested party and the Member States accordingly, indicating the reasons for not considering the update justified.

6. At any stage of the procedure the interested party may withdraw its application.

7. By, the Commission shall adopt detailed rules for the implementation of this Article in accordance with the regulatory procedure referred to in Article 19(2).

** OJ: please insert date: 2 years after the entry into force of this Regulation.*

*6. In order to ensure the smooth functioning of the notification procedure provided for in this Article, the Commission shall, before ... *, adopt detailed rules on the application of this Article by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23.*

** Six month after the date of entry into force of this Regulation*

Justification

Article 8 from the Commission document and EP first reading amendments 63-68.

Amendment 82

Council position – amending act Article 12

Council position

Without prejudice to the provisions under **point (a) of Article 9(1)** of Regulation (EC) No 1331/2008 and **by ... ***, the Commission shall, where appropriate, in close cooperation with the Authority **and after consultation with interested parties**, make available technical guidance and tools to assist **interested parties** in preparing and submitting applications under this Regulation; **in particular, food business operators, especially small and medium-sized enterprises.**

Amendment

Without prejudice to the provisions of **Article 9 (1) (a)** of Regulation (EC) No 1331/2008 and **before ... ***, the Commission shall, where appropriate, in close cooperation with the Authority, **the food business operators and small and medium-sized enterprises** make available technical guidance and tools to assist **food business operators and especially small and medium-sized enterprises** in preparing and submitting applications under this Regulation. **Commission Recommendation 97/618/EC of 29 July 1997 concerning the**

scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council²⁶ shall be available for use by applicants until replaced by revised technical guidance issued in accordance with this Article.

*The technical guidance and tools shall be published, not later than ... * , on a publicly accessible page intended for that purpose on the website of the Commission.*

* OJ: Please insert date: **2 years** after the entry into force of this Regulation

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

²⁶ *OJ L 253, 16.9.1997, p. 1.*

Justification

EP first reading amendment 69.

Amendment 83

Council position – amending act Article 13 – introductory part

Council position

In assessing the safety of novel foods, **where appropriate**, the Authority shall, **in particular**:

Amendment

In assessing the safety of novel foods, the Authority shall, **on the basis of the requirements specified in Article 6**:

Justification

EP first reading amendment 70.

Amendment 84

Council position – amending act Article 13 - point a

Council position

(a) consider whether the food **is as safe as food from a comparable food category** already existing on the market **within the**

Amendment

(a) consider whether the **new** food, **irrespective of whether or not it is intended to replace a** food already existing

Union or as safe as the food that the novel food is intended to replace;

on the market, poses any risk of harmful or toxic effects to human health, while also taking into account the implications of any new characteristics;

Justification

EP first reading amendment 71.

Amendment 85

**Council position – amending act
Article 13 - point b**

Council position

Amendment

(b) take into account the history of safe food use.

(b) take into account, **for traditional food from a third country**, the history of safe food use.

Justification

Article 10b from the Commission document.

Amendment 86

**Council position – amending act
Article 13 - paragraph 1a (new)**

Council position

Amendment

In the event of ethical objections, an opinion shall be sought, over and above the safety assessment, from the European Group on Ethics in Science and New Technologies (EGE).

Justification

EP first reading amendment 74.

Amendment 87

Council position – amending act Article 14 - title and paragraph 1

Council position

Special obligations on food business operators

1. The Commission **may**, for food safety reasons and following the opinion of the Authority, **impose** a requirement for post-market monitoring. **The food business operator placing the food on the market within the Union shall be responsible for fulfilling the post marketing requirements specified in the entry of the food concerned in the Community list of novel foods.**

Amendment

Obligations on **the** food business operators

1. The Commission **shall impose**, for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. **This monitoring shall take place five years after the date of inclusion of a novel food in the Union list.**

Justification

EP first reading amendment 75.

Amendment 88

Council position – amending act Article 14 - paragraph 1 a (new)

Council position

Amendment

1a. The monitoring requirements shall also apply to novel foods already on the market, including those approved under the simplified procedure ('notification') laid down in Article 5 of Regulation (EC) No 258/97.

Justification

EP first reading amendment 75.

Amendment 89

Council position – amending act Article 14 - paragraph 1 b (new)

Council position

Amendment

1b. Member States shall appoint competent authorities that will be responsible for the post-marketing monitoring.

Justification

EP first reading amendment 75.

Amendment 90

Council position – amending act Article 14 - paragraph 2 - introductory part

Council position

Amendment

2. The producer shall forthwith inform the Commission of:

2. The producer ***and food business operator or the authority*** shall forthwith inform the Commission of:

Justification

EP first reading amendment 75.

Amendment 91

Council position – amending act Article 14 - paragraph 2 - subparagraph 1 a (new)

Council position

Amendment

All food business operators shall notify the Commission and the competent authorities of the Member State in which they operate of any health problem of which they have been informed by consumers or consumer protection organisations.

Justification

EP first reading amendment 75.

Amendment 92

Council position – amending act

Article 14 - paragraph 2 - subparagraph 1 b (new)

Council position

Amendment

The Member State's competent authority shall report to the Commission within three months of the completion of an inspection. The Commission shall submit a report to the European Parliament and the Council no later than a year after the expiry of the five-year period referred to in paragraph 1.

Justification

EP first reading amendment 75.

Amendment 93

Council position – amending act

Article 15

Council position

Amendment

European Group on Ethics ***in Science*** and New Technologies

The Commission, on its own initiative or at the request of a Member State, ***may*** consult the European Group on Ethics ***in Science*** and New Technologies, with a view to obtaining its opinion on ethical questions relating to science and new technologies of major ethical importance.

The Commission shall make ***this*** opinion available to the public.

European Group on Ethics and New Technologies

Where appropriate, the Commission ***may***, on its own initiative or at the request of a Member State, consult the European Group on Ethics and new Technologies, with a view to obtaining its opinion on ethical questions relating to science and new technologies of major ethical importance.

The Commission shall make ***that*** opinion ***of the European Group on Ethics and new Technologies*** available to the public.

Justification

EP first reading amendment 76.

Amendment 94

Council position – amending act Article 16 - title and paragraph 1 - introductory part

Council position

Authorisation procedure in cases of data protection

1. ***On*** request ***by*** the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and/or scientific data ***supporting*** the application may not be used for the benefit of another application ***during*** a period of five years from the date of the inclusion of the novel food in the Union list ***without the agreement of the prior applicant. This protection shall be granted where:***

Amendment

Data protection

1. ***At the*** request ***of*** the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and ***proprietary*** scientific data ***provided to support*** the applications may not be used for the benefit of another application ***for*** a period of five years from the date of the inclusion of the novel food in the Union list ***unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, and where:***

Justification

EP first reading amendment 77.

Amendment 95

Council position – amending act Article 16 - paragraph 1 - point c a (new)

Council position

Amendment

(ca) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made;

Justification

EP first reading amendment 77.

Amendment 96

Council position – amending act Article 16 - paragraph 1 - point b

Council position

(b) the prior applicant had exclusive right of reference to the proprietary **scientific** data at the time the **first** application was made; and

Amendment

(b) the prior applicant had exclusive right of reference to the proprietary data at the time the **prior** application was made; and

Justification

EP first reading amendment 77.

Amendment 97

Council position – amending act Article 16 - paragraph 1 - point c

Council position

(c) the novel food could not have been authorised without the submission of the proprietary **scientific** data by the prior applicant.

Amendment

(c) the novel food could not have been authorised without the submission of the proprietary data by the prior applicant.

Justification

EP first reading amendment 77.

Amendment 98

Council position – amending act Article 16 - paragraph 1 a (new)

Council position

Amendment

1a. Data from research projects partly or completely paid by the Union and/or public institutions and risk studies or data related to risk studies, like feeding studies, shall be published together with the application and shall be freely available for use by other applicants.

Justification

EP first reading amendment 77.

Amendment 99

**Council position – amending act
Article 16 - paragraph 1 b (new)**

Council position

Amendment

1b. In order to avoid the repetition of studies involving vertebrates, reference by a subsequent applicant to studies on vertebrates and other studies that may prevent animal testing shall be allowed. The owner of the data may claim adequate compensation for the use of the data.

Justification

EP first reading amendment 87.

Amendment 100

**Council position – amending act
Article 16 - paragraph 3**

Council position

Amendment

3. By way of derogation from Article 7(5) of Regulation (EC) No 1331/2008, the updating of the Union list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure referred to in Article 19(2) of this Regulation in cases where proprietary scientific data are protected in accordance with this Article. In this case, the authorisation shall be granted for the period specified in paragraph 1 of this Article.

deleted

Amendment 101

Council position – amending act

Article 16 - paragraph 4

Council position

Amendment

4. In the cases referred to in paragraph 3 of this Article, the entry of a novel food in the Union list shall indicate, in addition to the information referred to in Article 9(2) of this Regulation:

deleted

- (a) the date of entry of the novel food in the Union list;***
- (b) the fact that the entry is based on proprietary newly developed scientific evidence and/or proprietary scientific data protected in accordance with this Article;***
- (c) the name and address of the 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), unless a subsequent applicant obtains authorisation for the food without reference to the proprietary scientific data designated as such by the prior applicant.***

Amendment 102

Council position – amending act

Article 16 - paragraph 5

Council position

Amendment

5. Before the expiry of the period referred to in paragraph 1 of this Article, the Commission shall update the Union list in accordance with the regulatory procedure referred to in Article 19(2) so that, provided that the authorised food still meets the conditions laid down in this Regulation, the specific indications referred to in paragraph 4 of this Article are no longer included.

deleted

Amendment 103

Council position – amending act Article 16 a (new)

Council position

Amendment

Article 16a

Harmonised data protection

Notwithstanding the authorisation of a novel food pursuant to Articles 7 and 14 of Regulation (EC) No 1331/2008 or authorisation of a health claim pursuant to Articles 17, 18 and 25 of Regulation (EC) No 1924/2006, the data concerning the authorisation and the publication of the authorisation in the Official Journal of the European Union shall be identical and the data protection periods shall run concurrently where authorisation is sought for a novel food and for a health claim relating to that food, and where data protection pursuant to the provisions of both Regulations is warranted and requested by the applicant.

Justification

EP first reading amendment 80.

Amendment 104

Council position – amending act Article 17

Council position

Amendment

Article 17

deleted

Information to the public

The Commission shall make available to the public:

- (a) the Union list referred to in Article 7(1) and the list of traditional foods from third countries referred to in Article 7(2), on a single dedicated page of the Commission website;*
- (b) the summaries of the applications submitted under this Regulation;*
- (c) the findings of the consultations*

referred to in Article 4(3).

The Commission may adopt the implementing measures for this Article, including arrangements for making public the outcome of the consultations under point (c) of the first paragraph of this Article, in accordance with the regulatory procedure referred to in Article 19(2).

Amendment 105

**Council position – amending act
Article 17 a (new)**

Council position

Amendment

**Article 17 a
Inspection and control measures**

In order to enforce compliance with this Regulation, official controls are to be carried out in accordance with Regulation (EC) No 882/2004.

Justification

EP first reading amendment 81.

Amendment 106

**Council position – amending act
Article 18**

Council position

Amendment

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

* OJ: please insert date: **24** months after the date of

The Member States shall lay down the rules on penalties applicable to infringements of the provision 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. The Member States shall notify those provisions to the Commission by ...* and shall, without delay, **notify it** of any subsequent amendment affecting them.

* OJ: please insert **12** months from the entry into

entry into force of this Regulation

force of this Regulation

Justification

EP first reading amendment 82.

Amendment 107

**Council position – amending act
Article 18 a (new)**

Council position

Amendment

Article 18a

Privileges of Member States

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

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

Justification

EP first reading amendment 83.

Amendment 108

Council position – amending act Article 19

Council position

Amendment

Article 19

deleted

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

Justification

No need for comitology committee provisions since all comitology procedures have been aligned to delegated act procedures.

Amendment 109

Council position – amending act Article 21– paragraph 1

Council position

Amendment

1. The power to adopt the delegated acts referred to in **Article 20** shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall make a report in respect of the delegated powers at the latest six months before the end of the five-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 22.

1. The power to adopt the delegated acts referred to in **Articles 2(2b), 3(3), 4(3), 4(4), 9(1), 11(6) and 20** shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall make a report in respect of the delegated powers at the latest six months before the end of the five-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council

revokes it in accordance with Article 22.

Amendment 110

Council position – amending act

Article 22 – paragraphs 1 and 2

Council position

1. The delegation of power referred to in **Article 20** may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall inform the other institution and the Commission **at the latest one month** before the final decision is taken, **stating** the delegated powers which could be subject to revocation and **the** reasons for a revocation.

Amendment

1. The delegation of power referred to in **Articles 2(2b), 3(3), 4(3), 4(4), 9(1), 11(6) and 20** may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall **endeavour to** inform the other institution and the Commission **within a reasonable time** before the final decision is taken, **indicating** the delegated powers which could be subject to revocation and **possible** reasons for a revocation.

Amendment 111

Council position – amending act

Article 23

Council position

1. The European Parliament or the Council may object to **the** delegated act within a period of **three** months from the date of notification.
2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, **or if, before that date, the European Parliament and the Council have both informed the**

Amendment

1. The European Parliament or the Council may object to **a** delegated act within a period of **two** months from the date of notification.
At the initiative of the European Parliament or the Council this period shall be extended by two months.
2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act **it shall be published in the Official Journal of the European Union and** shall enter into force

Commission that they have decided not to raise objections, the delegated act shall enter into force **on** the date stated therein.

at the date started therein.

The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to **the** delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

3. If the European Parliament or the Council objects to **a** delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Amendment 112

Council position – amending act Article 24 - paragraph 1

Council position

1. **By ...**,* and in the light of experience gained, the Commission shall **submit** to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of **Articles 3, 11 and 16**, accompanied, where appropriate, by any **legislative** proposals.
* **Five** years after the date of entry into force of this Regulation

Amendment

1. **No later than ...*** 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 **Articles 11 and 16**, accompanied, where appropriate, by any proposals.
* **Three** years **and six months** after the date of entry into force of this Regulation.

Justification

EP first reading amendment 93.

Amendment 113

Council position – amending act Article 24 - paragraph 2

Council position

2. **By ...***, the Commission shall **submit** to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a

Amendment

2. **No later than ...*** the Commission shall **forward** to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a

cloning technique and from their **offspring**, followed, where appropriate, by any legislative proposals.

* **One year** after the date of entry into force of this Regulation

cloning technique and from their **descendants** followed, where appropriate, by any legislative proposals.

* **Three years and six months** after the date of entry into force of this Regulation.

Justification

EP first reading amendment 93.

Amendment 114

Council position – amending act Article 27 - paragraph 1

Council position

1. Any request for placing a novel food on the market **within the Union** submitted to a Member State under Article 4 of Regulation (EC) No 258/97 before ... shall be **transformed into** an application under this Regulation **if an initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, and in cases where the additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97.**

Other **pending** requests submitted under **Article 4** of Regulation (EC) No 258/97 before shall be processed under the provisions of **that** Regulation.

Amendment

1. Any request for placing a novel food on the market submitted to a Member State under Article 4 of Regulation (EC) No 258/97 **in relation to which the initial assessment report provided for under Article 6(3) of that Regulation has not yet been forwarded to the Commission** before ... shall be **considered as** an application under this Regulation.

Other requests submitted under **Articles 3(4), 4 and 5** of Regulation (EC) No 258/97 before ... shall be processed under the provisions of Regulation **(EC) No 258/97.**

Justification

EP first reading amendment 88.

Amendment 115

Council position – amending act Article 27 - paragraph 2

Council position

2. The Commission may, in accordance with the regulatory procedure referred to

Amendment

deleted

in Article 19(2), adopt appropriate transitional measures for the application of paragraph 1 of this Article.

Amendment 116

Council position – amending act

Article 28 - point 2

Regulation (EC) No 1331/2008

Article 1 - paragraphs 1 and 2

Council position

"1. This Regulation lays down **a common procedure for the** assessment and authorisation (hereinafter referred to as the "common procedure") **of** food additives, food enzymes, food flavourings and **source materials** of food flavourings **and of food ingredients with flavouring properties** used or intended for use in or on foodstuffs and novel foods (hereinafter referred to as the "substances or products") which contributes to the free movement of **food** within the Union and to a high level of protection of human health and **to a high level of consumer protection, including the protection of consumer** interests. **This Regulation shall not apply to smoke flavourings falling within the scope of Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods.**

2. The **common** procedure shall **lay down** the procedural arrangements for updating the lists of substances and products the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008, Regulation (EC) No 1332/2008, Regulation (EC) No 1334/2008 and Regulation (EU) No .../... of the European Parliament and of the Council of ... on novel foods (hereinafter referred to as the "sectoral food laws").

Amendment

"1. This Regulation lays down **an** assessment and authorisation **procedure** (hereinafter referred to as the "common procedure") **for** food additives, food enzymes, food flavourings and **sources** of food flavourings used or intended for use in or on foodstuffs and novel foods (hereinafter referred to as the "substances or products"), which contributes to the free movement of **foods** within the Union and to a high level of protection of human health and protection of **consumers'** interests.

2. The procedure shall **set** the procedural arrangements for updating the lists of substances and products the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008, Regulation (EC) No 1332/2008, Regulation (EC) No 1334/2008 and Regulation (EC) No .../... of the European Parliament and of the Council of ... on novel foods (hereinafter referred to as the "sectoral food laws")."

Justification

Article 19, points 2 and 3 from Commission document.

Amendment 117

Council position – amending act

Article 28 - point 3 Regulation (EC) No 1331/2008

Article 1 paragraph 3, Article 2 paragraphs 1 and 2, Article 9 paragraph 2, Article 12 paragraph 1 and Article 13

Council position

3) In Article 1(3), Article 2(1) and (2), , Article 9(2), Article 12(1) and Article 13 the **words "substance" and "substances" are** replaced by "substance or product" or "substances or products" **as appropriate**.

Amendment

3. In Article 1 **paragraph 3**, Article 2 **paragraphs 1** and 2, Article 9 **paragraph 2**, Article 12 **paragraph 1** and Article 13 the **word 'substance' or 'substances' is** replaced by 'substance or product' or 'substances or products'.

Justification

Article 19, point 4 from Commission document.

Amendment 118

Council position – amending act

Article 28 - point 7

Regulation (EC) No 1331/2008

Article 7 - paragraphs 4, 5 and 6

Council position

7) **In Article 7, paragraphs 4, 5 and 6 are replaced by the following:**

"4. The measures, designed to amend non-essential elements of each sectoral food law, with the exception of novel foods, relating to the removal of a substance from the Union list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

5. On grounds of efficiency, the measures designed to amend non-essential elements of each sectoral food law, with the exception of novel foods, inter alia, by supplementing it, relating to the addition of a substance to the Union list and for

Amendment

deleted

adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Union list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(4).

6. With exception of novel foods and on imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14(5) for the removal of a substance from the Union list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Union list.

7. The measures relating to the removal, the adding of a product covered by the Regulation on novel foods to the Union list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of such product on the Union list shall be adopted in accordance with the regulatory procedure referred to in Article 14(2)."

Amendment 119

Council position – amending act Article 29 - Paragraph 3

Council position

However, *Articles 26, 27 and 28* shall apply from ... *Furthermore, by way of derogation from the second paragraph of this Article and by way of derogation from the second paragraph of Article 16 of Regulation (EC) No 1331/2008, applications may be made in accordance with this Regulation as from ... for the authorisation of food referred to in point (iv) of Article 3(2)(a) of this Regulation, where such food is already on the market within the Union at that date.*

Amendment

However, *Article 26* shall apply from

Justification

Article 20 from Commission document.

