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2009 - 2014

Committee on the Environment, Public Health and Food Safety

2008/0002(COD)

29.3.2010

*****II**

DRAFT RECOMMENDATION FOR SECOND READING

on the Council position at first reading for adopting a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001
(11261/3/2009 – C7-0000/2010 – 2008/0002(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Kartika Tamara Liotard

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
majority of the votes cast, to approve the position
majority of Parliament's component Members, to reject or amend the position
- *** Assent procedure
majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
majority of the votes cast, to approve the position
majority of Parliament's component Members, to reject or amend the position
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

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

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council position at first reading for adopting a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001

(11261/2/2009 – C7-0000/2010 – 2008/0002(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

- having regard to the Council position at first reading (112612/2009 – C7-0000/2010),
 - having regard to the Commission proposal to European Parliament and the Council (COM(2007)0872),
 - having regard to Article 251(2) and Article 95(1) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0027/2008),
 - having regard to its position at first reading¹,
 - having regard to Article 294(7) and Article 114(1) of the Treaty on the Functioning of the EU,
 - having regard to the opinion of the Economic and Social Committee,
 - having regard to Rule 66 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A7-0000/2010),
1. Adopts the position at second reading hereinafter set out;
 2. Instructs its President to forward its position to the Council, to the Commission and to the national parliaments.

Amendment 1

Council position – amending act

Recital 1

Council position

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes

Amendment

(1) In implementing Union policy and having regard to the Treaty on the Functioning of the European Union, a

¹ Texts adopted, 25.3.2009, T6(2009)0171.

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.

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.

Or. en

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.***

Or. en

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 shall pay full regard to the welfare requirements of animals when formulating and implementing policies, since animals are sentient beings.

Or. en

Justification

EP first reading amendment 3.

Amendment 4

Council position – amending act
Recital 2 b (new)

Council position

Amendment

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

Or. en

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 Texts adopted, P6_TA(2008)0400.

Or. en

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 are '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 concludes that 'existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles'.

Or. en

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)**

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. **The present Regulation should include measures currently governed by Regulation (EC) No 1852/2001.**

***No 258/97 of the European Parliament
and of the Council should therefore
become obsolete as regards novel foods.***

Or. en

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***.

Or. en

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,***

Amendment

micro-organisms, fungi or algae, new strains of micro-organism with no history of safe use as well as concentrates of substances that naturally occur in plants should be considered as novel foods as defined in this Regulation.

Or. en

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***

Amendment

(6) It should also be clarified that a food ***should*** be considered as novel when ***it is applied to*** a production technology which was not previously used. 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.

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.

Or. en

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.

Or. en

Justification

EP first reading amendment 11.

Amendment 12

Council position – amending act Recital 7

Council position

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

Amendment

(7) The European Group on Ethics in Science and New Technologies *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’.*

¹ The EFSA Journal (2008)767, p.32.

Or. en

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.

Or. en

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 codecision procedure, and not be subject to the common authorisation procedure. Before the date of application of this Regulation, the Commission should put forward 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.

Or. en

Justification

EP first reading amendment 14.

Amendment 15

**Council position – amending act
Recital 8**

Council position

Amendment

(8) Implementing measures should be

(8) Implementing measures should be

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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.

adopted to provide for **further** criteria **in order** to facilitate the assessment of whether a food **has been** used for human consumption to a significant degree within the Union before 15 May 1997. If a food **has been** 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 has been** 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.

Or. en

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**

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.**

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

Or. en

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.

Or. en

Justification

Recital 8 from Commission document.

Amendment 18

Council position – amending act Recital 11

Council position

(11) The provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on

Amendment

(11) The provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on

the Community code relating to medicinal products for human use should apply where, taking into account all its characteristics, a product may fall both within the definition of "medicinal product" and within the definition of a product covered by other Union legislation. In this respect, a Member State, *if* it establishes in accordance with Directive 2001/83/EC that a **product** is a medicinal product, **should be able to** restrict the placing on the market of such product in accordance with Union law **Moreover, medicinal products are excluded from the definition of food as established by Regulation (EC) No 178/2002 and should not be subject to this Regulation.**

the Community code relating to medicinal products for human use¹ should apply where, taking into account all its characteristics, a product may fall both within the definition of 'medicinal product' and within the definition of a product covered by other Union legislation. In this respect, a Member State **may, where** it establishes in accordance with Directive 2001/83/EC that a **substance** is a medicinal product, restrict the placing on the market of such a product in accordance with Union law.

¹ OJ L 311, 28.11.2001, p. 67.

Or. en

Justification

EP first reading amendment 16.

Amendment 19

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 1829/2003, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008, flavourings falling within the scope of Regulation (EC) No 1334/2008, enzymes falling within the scope of Regulation (EC) No 1332/2008 and extraction solvents falling within the scope of Directive 2009/32/EC** should **not be covered by** this Regulation.

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 foods*², extraction solvents falling within the scope of *Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients*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 enzymes*⁴ 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 feed*⁵ 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 OJ L 157, 24.6.1988, p. 28.

⁴ OJ L 354, 31.12.2008, p. 7.

⁵ OJ L 268, 18.10.2003, p. 1.

Or. en

Justification

EP first reading amendment 17.

Amendment 20

Council position – amending act
Recital 14

Council position

(14) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods *and Directive*

Amendment

(14) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of *Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses*, Directive 2002/46/EC *and* Regulation (EC)

2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (recast) should therefore be excluded from the scope of this Regulation. ***However, those specific legal acts do not deal with cases where authorised vitamins and mineral substances are obtained by production methods or using new sources that were not taken into account when they were authorised. Therefore, pending the amendment of those specific legal acts, such vitamins and mineral substances should not be excluded from the scope of this Regulation when the production methods or new sources give rise to significant changes in the composition or structure of the vitamins or minerals which affect their nutritional value, how they are metabolised or the level of undesirable substances.***

No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods should therefore be excluded from the scope of this Regulation.

Or. en

Justification

Recital 11 from the Commission document.

Amendment 21

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 89/398/EEC*** and in the specific Directives referred to in ***Article 4(1) thereof and in Annex I thereof, in***

Justification

Recital 12 from the Commission document..

Amendment 22

**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 23

**Council position – amending act
Recital 17**

Council position

(17) Novel foods should be placed on the

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Amendment

(17) Novel foods should be placed on the

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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.

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.

Or. en

Justification

EP first reading amendment 19.

Amendment 24

Council position – amending act Recital 18

Council position

(18) It is necessary to apply a harmonised centralised procedure for safety assessment and authorisation that is efficient, time-limited and transparent. With a view to further harmonising different ***procedures for the authorisation*** of food, the safety assessment of novel foods and their inclusion in the Union list should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a authorisation procedure for food additives, food enzymes and food flavourings, ***which should be applicable whenever it is not specifically derogated from by this Regulation. Upon receipt of an application for authorisation of a product as a novel food, the Commission should assess the validity and applicability of the application.*** The ***authorisation*** of a novel ***food*** should also take into account other factors relevant to the matter under

Amendment

(18) It is necessary to apply a harmonised centralised procedure for safety assessment and authorisation that is efficient, time-limited and transparent. With a view to further harmonising different ***authorisation procedures*** of food, the safety assessment of novel foods and their inclusion in the Union list should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a authorisation procedure for food additives, food enzymes and food flavourings. The ***approval*** of novel ***foods*** should also take into account other factors relevant to the matter under consideration, including ethical factors.

consideration, including ethical, *environmental, animal welfare* factors *and the precautionary principle*.

Or. en

Justification

EP first reading amendment 20.

Amendment 25

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

Council position

Amendment

(18a) In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation should be undertaken only as a last resort. This Regulation should ensure that testing on vertebrate animals is minimised and that double-testing is avoided, and should promote the use of non-animal test methods and intelligent testing strategies. Existing results from tests on vertebrate animals should be shared in the process of developing novel foods. Moreover, in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes¹, tests on vertebrate animals must be replaced, restricted or refined. Implementation of this Regulation should, where possible, be based on the use of appropriate alternative testing methods. Not later than seven years after the entry into force of this Regulation, the Commission should review the rules on the data protection of results from tests on vertebrate animals and, where necessary, change those rules.

¹ OJ L 358, 18.12.1986, p. 1.

Justification

EP first reading amendment 21.

Amendment 26

**Council position – amending act
Recital 19**

Council position

(19) Criteria for the evaluation of the potential risks arising from novel foods should also be laid down. In order to ensure ***the*** harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ("the Authority").

Amendment

(19) Criteria for the evaluation of the potential risks arising from novel foods should also be laid down. In order to ensure ***a*** harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ("the Authority") ***in cooperation with the Member States' authorities.***

Or. en

Justification

EP first reading amendment 22.

Amendment 27

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

Council position

Amendment

(19a) Ethical and environmental aspects must be considered as part of the risk assessment 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.

Or. en

EP first reading amendment 23.

Amendment 28

Council position – amending act
Recital 20

Council position

(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.*

Amendment

(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.*

Or. en

Amendment 29

Council position – amending act
Recital 22

Council position

(22) *If traditional foods from third 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.

Amendment

(22) As regards the safety assessment and management of traditional food from third countries, their history of safe use in *the third* 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. *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 will 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 30****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 31****Council position – amending act
Recital 25***Council position*

(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

Amendment

(25) Under specific circumstances in order to stimulate research and development within the agri-food industry, and thus innovation, ***it is appropriate to protect the investment made by innovators in gathering the information and data provided in support of an application under this Regulation.*** The newly developed scientific evidence and

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.

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.***

Or. en

Justification

EP first reading amendment 25.

Amendment 32

**Council position – amending act
Recital 26**

Council position

(26) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC ***and, where necessary, to the nutritional labelling requirements laid down in Directive 90/496/EEC***. 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 from third countries, specific conditions of use or labelling obligations may be imposed, which might, inter alia, relate to any specific characteristic or food***

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

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 OJ L 109, 6.5.2000, p. 29.

Or. en

Justification

Recital 21 from the Commission document.

Amendment 33

**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***² 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.***

² OJ L 404, 30.12.2006, p. 9.

Or. en

Justification

EP first reading amendment 27.

Amendment 34

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) established by Commission Decision of 16 December 1997 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.

Or. en

Justification

EP first reading amendment 29.

Amendment 35

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

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**

provided for under Regulation (EC) No 258/97 has not yet been forwarded to the 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.

relation to which an additional assessment report is required in accordance with *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.

Or. en

Justification

EP first reading amendment 89.

Amendment 36

Council position – amending act Recital 30

Council position

(30) Regulation (EC) No 882/2004 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.

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* 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.

Or. en

Justification

Recital 30 from the Commission document.

Amendment 37

Council position – amending act

Recital 32

Council position

(32) Since the ***objective of this Regulation, namely laying down harmonised rules for the placing of novel foods on the market within the Union***, cannot be ***sufficiently*** achieved by the Member States and can therefore be better achieved at ***Union*** level, the ***Union*** may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty ***on European Union***. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve ***that objective***.

Amendment

(32) Since the ***objectives of the action to be taken*** cannot be achieved by the Member States and can therefore be better achieved at ***Union*** level, the ***Union*** may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve ***those objectives***.

Or. en

Justification

Recital 26 from the Commission document.

Amendment 38

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***,

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

where appropriate, the protection of the environment and animal welfare.

transparency and the effective functioning of the internal market and stimulating innovation within the agri-food industry.

Or. en

Justification

EP first reading amendment 30.

Amendment 39

Council position – amending act Article 2 - paragraph 2

Council position

2. This Regulation shall not apply to:
- (a) foods when and in so far as they are used as:
- (i) food additives falling within the scope of Regulation (EC) No 1333/2008;
 - (ii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;
 - (iii) extraction solvents used in the production of foodstuffs and falling within the scope of Directive **2009/32/EC**;
 - (iv) food enzymes falling within scope of Regulation (EC) No 1332/2008;
 - (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**.
- (b) foods falling within the scope of Regulation (EC) No 1829/2003;

Amendment

2. This Regulation shall, ***unless otherwise provided for***, not apply to:
- (a) foods when and insofar as they are used as:
- (i) food additives falling within the scope of Regulation (EC) No 1333/2008;
 - (ii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;
 - (iii) extraction solvents used in the production of foodstuffs and falling within the scope of Directive **88/344/EEC**;
 - (iv) food enzymes falling within scope of Regulation (EC) No 1332/2008;
 - (v) vitamins and minerals falling within the scope of **Directive 89/398/EEC**, Directive 2002/46/EC **or** Regulation (EC) No 1925/2006, 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).
- (b) foods falling within the scope of Regulation (EC) No 1829/2003;

Or. en

Justification

EP first reading amendment 91.

Amendment 40

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 Community 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.***

Or. en

Justification

EP first reading amendment 91.

Amendment 41

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 42

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

Council position

Amendment

(2b) Where necessary, it may be determined in accordance withwhether 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 shall 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 Council¹.

¹ OJ L 136, 30.4.2004, p. 1.

Justification

EP first reading amendment 91.

Amendment 43

**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

(a) "novel food" means:

(i) food that was not used for human

non-traditional breeding technique not used for food production within the Community before 15 May 1997 is applied to the animal and food derived from the offspring of these animals;

consumption to a significant degree within the Union before 15 May 1997;

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 44

**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;***

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 45

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

Council position

(iii) food to which a new production process not used ***for food production within the Union*** before 15 May 1997 is

Amendment

(iii) food to which a new production process not used before 15 May 1997 is applied, ***where*** that production process

applied, **if** that production process 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;

gives rise to significant changes in the composition or structure of the food which affect its nutritional value, **metabolism** or level of undesirable substances;

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 46

Council position – amending act
Article 3 - paragraph 2 - point a - point iv

Council position

(iv) food containing or consisting of engineered nanomaterials;

Amendment

(iv) food containing or consisting of engineered nanomaterials ***not used for food production within the Union before 15 May 1997. The use of a food exclusively as, or in, a food supplement shall not be sufficient to show whether it was used for human consumption to a significant degree within the Union before 15 May 1997. However, where a food was used exclusively as, or in, a food supplement prior to that date, it may be placed on the market within the Union after that date for the same use without being considered as a novel food. Further criteria for assessing if a food was used for human consumption to a significant degree within the Union before 15 May 1997, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with*** ;

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 47

Council position – amending act
Article 3 - paragraph 2 - point a - point v

Council position

Amendment

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

Or. en

Amendment 48

Council position – amending act
Article 3 - paragraph 2 - point a - point vi

Council position

Amendment

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

Or. en

Amendment 49

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

Council position

Amendment

*(b) "offspring" means an animal
produced by a traditional breeding* *deleted*

technique, where at least one of its parents is an animal produced by a non-traditional breeding technique;

Or. en

Amendment 50

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;

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 51

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;

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 52

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 has been, ***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.***

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 53

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;

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 54

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 to technical and scientific progress and with definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with

Or. en

Justification

EP first reading amendments 92 and 35.

Amendment 55

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**

Or. en

Justification

EP first reading amendment 40.

Amendment 56

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

Amendment

1. *The Commission shall collect information from the Member States 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 has been used for human consumption within the Union before 15 May 1997.*

Or. en

Justification

EP first reading amendment 40.

Amendment 57

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.*

Or. en

Justification

EP first reading amendment 40.

Amendment 58

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 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.

Amendment

3. Implementing measures on how to proceed in cases in which the Commission has no information about use for human consumption before 15 May 1997, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with not later than ...*.

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

Or. en

Justification

EP first reading amendment 40.

Amendment 59

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. Implementing measures for the application of paragraph 1, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with

Or. en

Justification

Article 4(2) from the Commission document.

Amendment 60

**Council position – amending act
Article 5**

Council position

Amendment

Article 5

deleted

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 Regulation.

Or. en

Amendment 61

**Council position – amending act
- title - chapter II**

Council position

Amendment

Requirements for placing novel foods on the market within the Union

Requirements and inclusion in the Union list of novel foods

Or. en

Justification

Heading Chapter II from the Commission document.

Amendment 62

**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.

Or. en

Justification

EP first reading amendment 41.

Amendment 63

Council position – amending act
Article 6

Council position

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

Amendment

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

Or. en

Justification

EP first reading amendment 42.

Amendment 64

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

deleted

with Article 2(1) of Regulation (EC) No 1331/2008.

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.

Or. en

Amendment 65

Council position – amending act
Article 8 - title and introductory part

Council position

General conditions for inclusion **of novel foods** in the **lists**

A novel food may be included in the **relevant** list only if it meets the following conditions:

Amendment

Conditions for inclusion in the **Union list**

1. A novel food may be included in the **Union** list only if it meets the following conditions:

Or. en

Justification

EP first reading amendment 43.

Amendment 66

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;

Or. en

Justification

EP first reading amendment 43.

Amendment 67

**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.

Or. en

Justification

EP first reading amendment 45.

Amendment 68

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

Council position

Amendment

(ca) the opinion of the European Environment Agency concerning the extent to which the production process and normal consumption have a harmful impact on the environment shall be taken into account in the assessment;

Or. en

Justification

EP first reading amendment 47.

Amendment 69

**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, concerning the extent to
which there are ethical objections, shall
be taken into account in the assessment;***

Or. en

Justification

EP first reading amendment 48.

Amendment 70

**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;***

Or. en

Justification

EP first reading amendment 49.

Amendment 71

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

Council position

Amendment

(cd) 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;

Or. en

Justification

EP first reading amendment 49.

Amendment 72

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

Council position

Amendment

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

Or. en

Justification

EP first reading amendment 49.

Amendment 73

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

Or. en

Justification

EP first reading amendment 50.

Amendment 74

**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.

Foods from cloned animals or their descendants shall not be placed on the Union list.

Or. en

Justification

EP first reading amendment 51.

Amendment 75

**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.

Or. en

Justification

EP first reading amendment 52.

Amendment 76

**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 Union list shall be updated in accordance with the procedure laid down in Regulation (EC) No 1331/2008 and ***the Commission shall publish it on a dedicated page of its website.***

Or. en

Justification

EP first reading amendment 53.

Amendment 77

**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***

Amendment

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

Article 16(4).

- (a) a specification of the food;*
- (b) the intended use of the food;*
- (c) the conditions of use;*
- (d) the date of entry of the novel food in the Union list and the date of receipt of the application;*
- (e) the name and address of the applicant;*
- (f) the date and results of the last inspection according to the monitoring requirements laid down in Article 14;*
- (g) the fact that the entry is based on newly developed scientific evidence and/or proprietary data protected in accordance with Article 16;*
- (h) 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.*

Or. en

Justification

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

Amendment 78

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.

Or. en

Justification

EP first reading amendment 55.

Amendment 79

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

Council position

Amendment

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

Or. en

Justification

EP first reading amendment 56.

Amendment 80

**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.***

Or. en

Justification

EP first reading amendment 57.

Amendment 81

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.

Or. en

Justification

EP first reading amendment 90.

Amendment 82

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

Council position

Amendment

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

Or. en

Justification

EP first reading amendment 6.

Amendment 83

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

Council position

Amendment

2f. The updating of the Union list shall be

decided in accordance with.... .

Or. en

Justification

EP first reading amendment 61.

Amendment 84

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

Council position

Amendment

2g. Before the expiry of the period referred to in Article 16, the Union list shall be updated to amend non-essential elements of this Regulation in accordance withso that, provided that the authorised food still meets the conditions laid down in this Regulation, the specific indications referred to in point (g) of paragraph 2 of this Article, are no longer included.

Or. en

Justification

Article 7(4) from the Commission document.

Amendment 85

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

Council position

Amendment

2h. For the purposes of updating the Union list through entry 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 Article 7 (3) of Regulation (EC) No 1331/2008.

Or. en

Justification

EP first reading amendment 86.

Amendment 86

**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 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.

Or. en

Justification

EP first reading amendment 62.

Amendment 87

**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 88

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 interested party, it shall, after consulting

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 Member State and the Authority may

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 shall inform the interested party accordingly. If the Commission decides

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 Community and Articles 5 a - 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 within no more 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 5 a.

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).

6. Before ..., detailed rules for the implementation of this Article, designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with*

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

Or. en

Justification

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

Amendment 89

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 a (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.*

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

²⁶ OJ L 253, 16.9.1997, p. 1.

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

Or. en

Justification

EP first reading amendment 69.

Amendment 90

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***:

Or. en

Justification

EP first reading amendment 70.

Amendment 91

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

Amendment

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

Or. en

Justification

EP first reading amendment 71.

Amendment 92

Council position – amending act Article 13 - point b

Council position

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

Amendment

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

Or. en

Justification

Article 10b from the Commission document.

Amendment 93

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).

Or. en

Justification

EP first reading amendment 74.

Amendment 94

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

Council position

Amendment

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.***

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 and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention shall be paid to the categories of the population with the highest dietary intakes.***

Or. en

Justification

EP first reading amendment 75.

Amendment 95

**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.

Or. en

Justification

EP first reading amendment 75.

Amendment 96

**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.

Or. en

Justification

EP first reading amendment 75.

Amendment 97

Council position – amending act

Article 14 - paragraph 2 - introductory part

Council position

2. The producer shall forthwith inform the Commission of:

Amendment

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

Or. en

Justification

EP first reading amendment 75.

Amendment 98

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.

Or. en

Justification

EP first reading amendment 75.

Amendment 99

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.

Or. en

Justification

EP first reading amendment 75.

Amendment 100

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

Council position

Amendment

2a. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies shall be promoted.

Or. en

Justification

EP first reading amendment 75.

Amendment 101

**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*

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

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.

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.

Or. en

Justification

EP first reading amendment 76.

Amendment 102

**Council position – amending act
Article 16 - 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:***

Or. en

Justification

EP first reading amendment 77.

Amendment 103

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

Or. en

Justification

EP first reading amendment 77.

Amendment 104

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.

Or. en

Justification

EP first reading amendment 77.

Amendment 105

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; and

Or. en

Justification

EP first reading amendment 77.

Amendment 106

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.

Or. en

Justification

EP first reading amendment 77.

Amendment 107

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.

Or. en

Justification

EP first reading amendment 87.

Amendment 108

**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*

Or. en

Amendment 109

**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.

Or. en

Amendment 110

**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

Or. en

Amendment 111

**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 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.

Or. en

Justification

EP first reading amendment 80.

Amendment 112

**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 113

Council position – amending act Article 17a (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.

Or. en

Justification

EP first reading amendment 81.

Amendment 114

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.

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 ***within 12 months from the entry into force*** and shall, without delay, ***notify it*** of any subsequent amendment affecting them.

Or. en

Justification

EP first reading amendment 82.

Amendment 115

**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.

Or. en

Justification

EP first reading amendment 83.

Amendment 116

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.

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.*

Or. en

Justification

EP first reading amendment 93.

Amendment 117

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

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 **descendants** followed, where appropriate, by any legislative proposals.

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

Or. en

Justification

EP first reading amendment 93.

Amendment 118

Council position – amending act Article 25

Council position

Regulation (EC) No 258/97 **and Regulation (EC) No 1852/2001** shall be repealed with effect from*, **except with respect to those pending requests governed by Article 27** of this Regulation.

* *OJ: please insert date: 24 months after the entry into force of this Regulation.*

Amendment

Regulation (EC) No 258/97 shall be repealed with effect from **the date of application** of this Regulation.

Or. en

Justification

Article 16 from the Commission document.

Amendment 119

Council position – amending act Article 26

Council position

No later than* the Commission shall establish the Union list by entering novel foods authorised **and/or notified** under **Articles 4, 5 and 7 of** Regulation (EC) No 258/97 **in the Union list**, including any existing authorisation conditions, as appropriate.

* **24 months after** the entry into force of this Regulation.

Amendment

By ... at the latest**, the Commission shall establish the Union list by entering **in this list** novel foods **which are** authorised under Regulation (EC) No 258/97 **and which fall within the scope of this Regulation pursuant to Articles 2 and 3 thereof**, including any existing authorisation conditions, as appropriate.

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

Or. en

Justification

EP first reading amendment 85.

Amendment 120

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.***

Or. en

Justification

EP first reading amendment 88.

Amendment 121

Council position – amending act Article 27 - paragraph 2

Council position

2. The Commission may, in accordance with the regulatory procedure referred to in Article 19(2), adopt appropriate transitional measures for the application of paragraph 1 of this Article.

Amendment

deleted

Or. en

Amendment 122

Council position – amending act

Article 28 - point 2 Regulation (EC) No 1331/2008

Article 1 - paragraphs 1 and 2

Council position

2) In Article 1, paragraphs 1 and 2 are replaced by the following:

"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

2. In Article 1, paragraphs 1 and 2 are replaced by the following:

"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 .../2009 of the European Parliament and of the Council of ... on novel foods (hereinafter referred to as the "sectoral food laws")."

Or. en

Justification

Article 19, points 2 and 3 from Commission document.

Amendment 123

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'.

Or. en

Justification

Article 19, point 4 from Commission document.

Amendment 124

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

Amendment

deleted

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 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).".

Or. en

Amendment 125

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*

Amendment

However, *Article 26* shall apply from ...^{**}.

*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.*

*** The date of entry into force of this Regulation.*

Or. en

Justification

Article 20 from Commission document.

EXPLANATORY STATEMENT

I. Background

As part of the framework to improve and bring coherence to Community legislation from "farm to fork" the Commission announced in the White Paper on Food Safety its intentions to examine the application of the novel food legislation and to make the necessary adaptations to the existing legislation in the light of the conclusions of the report on the implementation of the Regulation (EC) No 258/97 on novel foods and novel ingredients and pursuant to the regulatory framework of Directive 90/220/EEC.

In accordance with these commitments, the proposal of the COM on Novel Food 14.01.2008 (COM 2007 (872)) aims to ensure food safety, protect human health and secure the functioning of the internal market for food. The proposal aims to regulate the placing on the market of novel foods and foods from third countries. Furthermore, it lays down rules for authorisation, supervision, labelling and use of novel foods.

II. First Reading in EP

On 25 March 2009, the European Parliament adopted by 658 votes to 15, with 11 abstentions, a legislative resolution amending, under the first reading of the co-decision procedure, the proposal for a regulation on novel food.

The main amendments were as follows:

Purpose: This Regulation lays down harmonised rules for the placing of novel foods on the market in the Community 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.

Scope: MEPs intend to **exclude foods derived from cloned animals and their offspring** from the scope of this Regulation. Before the date of application of this Regulation, the Commission should put forward a corresponding legislative proposal on foods derived from cloned animals and their descendants. This proposal shall be presented to the European Parliament and the Council. This Regulation shall apply to food additives, food enzymes, flavourings and certain food ingredients with flavouring properties to which is applied a new production process not used before 15 May 1997, which give rise to significant changes in the composition or structure of the food such as engineered nanomaterials. Where a novel food can have an effect on the human body comparable to that of a medicinal product, the Commission shall seek an opinion of the European Medicines Agency (EMA) whether it falls under Regulation (EC) No 726/2004.

Definitions: MEPs have introduced the definition of "cloned animals", "descendants of cloned animals" and "engineered nanomaterial". 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 these definitions to technical and scientific progress and with definitions subsequently agreed at international level.

Other amendments adopted in first reading covered the collection of information regarding the classification of a novel food, the prohibition of non-compliant novel foods, the conditions for the entry of novel foods in the Community list, Information, Monitoring, Labelling, traditional food from a third country, use of non-animal tests and intelligent testing strategies, data protection as well as inspection and control measures.

III. Second Reading

The position of the Council at first reading on novel food was adopted on 15 March 2010.

The Council has taken on board some elements of the first reading in Parliament. However, the most important amendments of the first reading have not been taken into consideration in an appropriate manner by the Council, particularly in view of the issue of cloned animals in food and feed.

Your rapporteur respects the first reading position of the European Parliament as much as possible in her second reading report, as the first reading position was adopted by a very large majority. Almost all of the amendments adopted in the first reading have been reinstated.