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REPORT

on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure]
(COM(2007)0872 – C6-0027/2008 – 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 common position* *majority of Parliament's component Members, to reject or amend the common 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 common position* *majority of Parliament's component Members, to reject or amend the common 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 proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure] (COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0872),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0027/2008),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Agriculture and Rural Development (A6-0512/2008),

1. Approves the Commission proposal as amended;

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

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

Amendment 1

Proposal for a regulation – amending act
Recital 1

Text proposed by the Commission	*Amendment*
(1) ***The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as 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***	(1) ***In implementing Community policy and having regard to the Treaty establishing the European Community, a high level of protection of human health and consumer protection should be guaranteed and also a high level of animal welfare and environmental protection. At all times, moreover, the precautionary principle as laid down in Regulation (EC) No 178/2002 of the***

movement, thereby creating unfair competition conditions.	***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[1],***should be applied.
	[1] OJ L 31, 1.2.2002, p. 1.

Justification

The emphasis should be on food safety and consumer protection. Account should also be taken of protection of animal health and the environment. Lastly, the precautionary principle is of the utmost importance.

Amendment 2

Proposal for a regulation – amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) A high level of human health protection should be assured in the pursuit of Community policies.	(2) A high level of human health protection should be assured in the pursuit of Community policies ***and should be given priority over the functioning of the internal market***.

Justification

The human health protection should be considered as a priority in the authorisation of novel food.

Amendment 3

Proposal for a regulation – amending act
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) Article 13 of the Treaty on 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.

Amendment 4

Proposal for a regulation – amending act
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2b) The standards defined in EU legislation must be applied to all food placed on the Community market, including food imported from third countries.

Justification

It should be re-iterated that the Community standards also apply to imported food.

Amendment 5

Proposal for a regulation – amending act
Recital 2 c (new)

Text proposed by the Commission	*Amendment*
	(2c) The European Parliament called on the Commission, in its resolution of 3 September 2008 on the cloning of animals for food supply, 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.

Amendment 6

Proposal for a regulation – amending act
Recital 2 d (new)

Text proposed by the Commission	*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 draws attention to the conclusion of SCENIHR that 'existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles';

Amendment 7

Proposal for a regulation – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) In order to ensure continuity with Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Community before the date of application of Regulation (EC) No 258/97, namely 15 May 1997, should be kept as criteria for a food to be considered as novel.	(4) In order to ensure continuity with Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Community before the date of application of Regulation (EC) No 258/97, namely 15 May 1997, should be kept as criteria for a food to be considered as novel. ***A use within the Community refers to a use in the Member States, irrespective of the date of their accession to the European Union.***

Justification

This amendment clarifies the extent of the regulation's impact on the internal market and so increases legal certainty for the those concerned, particularly in the Member States in Central and Eastern Europe.

Amendment 8

Proposal for a regulation – amending act
Recital 5

Text proposed by the Commission	*Amendment*
(5) 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 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.	(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 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.

Justification

In order to make the legislation clear, there should be some explanation of the criteria for novelty of a food in the text itself or in the recitals.

Amendment 9

Proposal for a regulation – amending act
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Foods with a new or intentionally modified primary molecular structure, foods consisting of, or isolated from, micro-organisms, fungi or algae, new strains of micro-organism with no history of safe use as well as concentrates of substances that naturally occur in plants are considered as novel under the

definition of this Regulation.

Justification

The amendment clarifies which product categories are in all circumstances covered by the definition of novel food. This non-exhaustive list of food categories thus contributes to legal certainty of the definition of novel food as updated by this Regulation.

Amendment 10

Proposal for a regulation – amending act
Recital 6 a (new)

Text proposed by the Commission	*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 purposes[1], 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 Community list.
	[1] OJ L 221, 8.8.1998, p. 23

Justification

A wide range of scientific research and the Opinion of the European Group on Ethics show that cloning leads to serious health and welfare problems for both the cloned animals and their surrogate mothers. Cloned foetuses are often larger than normal; this leads to difficult births and to many deliveries being by caesarean section. Many clones die during pregnancy or in the early weeks of life from immune deficiencies, cardiovascular failure, respiratory problems and kidney abnormalities.

The animal health and welfare problems caused by cloning mean that this process is incompatible with paragraph 20 of the Annex to Council Directive 98/58/EC.

Amendment 11

Proposal for a regulation – amending act
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) Test methods currently available are not adequate for assessing the risks associated with nanomaterials. Nano-specific non-animal test methods should be developed as a matter of urgency.

Justification

Currently, there are no adequate methods to assess the safety of nanomaterials (see SCENIHR-opinion of Sept. 2005). Nanomaterials should be assessed on the basis of nano-specific non-animal tests. Until nano-specific non-animal tests are available for an adequate safety assessment of nanomaterials in foods, their use should be prohibited in order to protect human health and to prevent animal testing.

Amendment 12

Proposal for a regulation – amending act
Recital 6 c (new)

Text proposed by the Commission	*Amendment*
	(6c) Whereas 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'. Whereas the Scientific Committee of the European Food Safety Authority concluded in its Opinion[1] of 15 July 2008 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, 1-49

Justification

The Opinions of the European Food Safety Authority and the European Group of Ethics in Science and New Technologies show that cloning leads to serious health and welfare

problems for cloned animals and their surrogate dams.

Amendment 13

Proposal for a regulation – amending act
Recital 6 d (new)

Text proposed by the Commission	*Amendment*
	(6d) Nanomaterials present in food packaging should be entered on a list of approved nanomaterials, accompanied by a limit on migration into or onto the food products contained in such packaging.

Justification

Packaging composed of nanomaterials which are in contact with foods should be subject to authorisation.

Amendment 14

Proposal for a regulation – amending act
Recital 6 e (new)

Text proposed by the Commission	*Amendment*
	(6e) Foods derived from cloned animals and their offspring 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 procedure. Pending the entry into force 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 offspring.

Amendment 15

Proposal for a regulation – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) ***If necessary***, implementing measures should be adopted to provide for criteria in order to facilitate the assessment of whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior 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 whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.	(7) ***I***mplementing measures should be 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 Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior 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 whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.

Justification

It is necessary that implementing measures be adopted in order to further describe the criteria for novelty. The word further should be added as some explanation is already given with the amendments to Recital 6.

Amendment 16

Proposal for a regulation – amending act
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) The provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use[1] should apply where, taking into account all its characteristics, a product may fall within the definition of

'medicinal product' and within the definition of a product covered by other Community legislation. In this respect, a Member State may, if it establishes in accordance with Directive 2001/83/EC that a substance is a medicinal product, restrict the placing on the market of such product in accordance with Community law.

[1] OJ L 311, 28.11.2001, p.67.

Justification

As many borderline issues arise when dealing with novel foods, it is important to stress this general principle in the recital. This provides more clarity for industry and consumers about the functioning of the market in relation to borderline products (medicine/food).

Amendment 17

Proposal for a regulation – amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Foods which are intended for technological uses or which are genetically modified should not fall within the scope of this Regulation. Therefore, food used solely as additives falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..], flavourings falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..], 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, enzymes falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..] 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	(10) 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 Community legislations***. Therefore, food used solely as additives falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..], flavourings falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..], 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, enzymes falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..] and genetically modified food falling within the scope of

modified food and feed should be excluded from the scope of this Regulation.	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed should be excluded from the scope of this Regulation.

Justification

It is necessary to clarify that all new food and food ingredients should be covered by a single risk assessment according to Community legislation. Foods, which are already covered by a risk assessment and approval procedure according to another EU legislation, should not also require a risk assessment and approval under the novel food Regulation.

Amendment 18

Proposal for a regulation – amending act
Recital 13

Text proposed by the Commission	*Amendment*
(13) ***Whether a food was used for human consumption to a significant degree before 15 May 1997, should be based on information available in the Member States. Where the Commission*** does not have information on human consumption before 15 May 1997***,*** a simple and transparent procedure for ***collecting that information should be established involving*** the Member States ***and any interested parties***.	(13) ***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

Clarification and simplification of the Commission proposal. It must be clear what responsibilities are being assigned to the Commission when this Regulation enters into force.

Amendment 19

Proposal for a regulation – amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Novel foods should be placed on	(14) Novel foods should be placed on the

the Community market only if they are safe and do not mislead the consumer. 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.	Community market only if they are safe and do not mislead the consumer. ***Their safety assessment should be based on the precautionary principle as laid down in Article 7 of 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[1].*** 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.
	[1] OJ L 31, 1.2.2002, p. 1.

Amendment 20

Proposal for a regulation – amending act
Recital 15

Text proposed by the Commission	*Amendment*
(15) 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 Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No [..] of the European Parliament and of the Council of [date] establishing a common authorisation procedure for the food additives, food enzymes and flavourings.	(15) 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 Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No [..] of the European Parliament and of the Council of [date] establishing a common authorisation procedure for the 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.***

Justification

It is essential that in the process of approving new foods (since this also covers new foods gained from nanotechnologies or cloning processes) all the relevant factors essential for the final decision are taken into account, including the ethical issues.

Amendment 21

Proposal for a regulation – amending act
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) 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. 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 purposes[1], tests on vertebrate animals must also 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 ...*, 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.
	**** Seven years after the entry into force of this Regulation.***

Justification

In line with the requirement in the Protocol on the Protection and Welfare of Animals that the Community and the Member States pay full regard to the welfare requirements of animals in formulating and implementing policies, it should be included that animal testing is kept to an absolute minimum and carried out only as a last resort, and that the use of alternatives is promoted.

Amendment 22

Proposal for a regulation – amending act
Recital 16

Text proposed by the Commission	*Amendment*
(16) 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").	(16) 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***.

Justification

While the centralisation of the authorisation and evaluation procedure for novel foods is to be welcomed, cooperation should also be maintained between EFSA and the Member States' competent authorities, particularly for any market monitoring missions entrusted to them under this legislation. This collaboration will enable them to preserve their expertise and competence.

Amendment 23

Proposal for a regulation – amending act
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) 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.

Justification

Apart from the aspects of protection of health, the interests of consumers and animal health, the risk assessment should also include consideration of ethnical and environmental aspects.

Amendment 24

Proposal for a regulation – amending act
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***Where appropriate and based on*** the conclusions of the safety assessment, post-market monitoring requirements for the use of novel foods ***for human consumption*** should be introduced.	(18) ***On the basis of*** the conclusions of the safety assessment, ***any*** post-market monitoring requirements for the use of novel foods should be introduced.

Justification

Clarification and simplification of the Commission proposal.

Amendment 25

Proposal for a regulation – amending act
Recital 20

Text proposed by the Commission	*Amendment*
(20) 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 Community 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 Community list of novel foods on the basis of their own scientific data.	(20) 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 proprietary data provided in support of an application for inclusion of a novel food in the Community 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 Community 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, however, be respected.***

However, the repetition of studies involving vertebrates should be prohibited. In this context, there should be an obligation to allow access to studies on vertebrates and other studies that may prevent animal testing.

The wording of recital 20 should be aligned with the wording of recital 31 of Regulation 1924/2006 on nutrition and health claims.

In line with Amendment 5 of the draft opinion, but aims to guarantee the protection of producers´ intellectual property rights.

Amendment 26

Proposal for a regulation – amending act
Recital 21

Text proposed by the Commission	*Amendment*
(21) 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 foodstuffs. 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 Community list ***may*** impose specific conditions of use or labelling obligations.	(21) 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 foodstuffs. 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***, which may include information relating to ethical considerations***. Therefore, the inclusion of a novel food in the Community list ***will*** impose specific conditions of use or labelling obligations ***in those cases***. ***Products produced with the aid of***

	nanotechnologies and food produced from animals fed with genetically modified feeding stuffs must be labelled as such.

Justification

Clarification of amendment 12 of the Rapporteur. There is a clear gap in the provisions concerning food produced from animals fed with genetically modified feedingstuffs: Recital 16 of Regulation 1829/2003 is interpreted to mean that foods manufactured from animals fed with genetically modified feedingstuffs are not covered by that regulation. This means that Reg. 1829/2003 contains no provisions on labelling; therefore corresponding rules must be laid down in this regulation in order to fill that gap.
The criteria for additional labelling should also include ethical considerations like cloning. Thus it should be possible to require labelling of foods produced from cloned animals.

Amendment 27

Proposal for a regulation – amending act
Recital 22

Text proposed by the Commission	*Amendment*
(22) 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 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.	(22) 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 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 include requests for the protection of proprietary data, at the request of the applicant, the period of data protection should start together and run concurrently.***

Amendment 28

Proposal for a regulation – amending act
Recital 23

Text proposed by the Commission	*Amendment*
(23) 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*** the Authority have not presented any reasoned safety objections, based on scientific evidence, for example information on adverse health effects, it ***should*** be permissible to place the food on the Community market after notification of the intention to do so.	(23) 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 Community market after notification of the intention to do so***, provided that there are no ethical objections.***

Justification

It must be clear that Member States and/or the Authority can comment. Even if a product is safe, there may be ethical objections.

Amendment 29

Proposal for a regulation – amending act
Recital 24

Text proposed by the Commission	*Amendment*
(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***may*** be consulted***, where appropriate,*** with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.	(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***should*** be consulted ***in substantiated cases*** with a view to obtaining advice on ethical issues regarding ***the use of new technologies and*** the placing on the market of novel foods.

Justification

On substantiated general matters (such as in the use of nanotechnologies or cloning

techniques) it is clearly appropriate that ethical issues should have to be referred to the European Group on Ethics in Science and New Technologies for consultation.

Amendment 30

Proposal for a regulation – amending act
Article 1

Text proposed by the Commission	*Amendment*
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 human health ***and consumers' protection***, whilst ensuring the effective functioning of the internal market.	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.***

Amendment 31

Proposal for a regulation – amending act
Article 2

Text proposed by the Commission	*Amendment*
1. This Regulation shall apply to the placing of novel foods on the market in the Community.	1. This Regulation shall apply to the placing of novel foods on the market in the Community.
2. This Regulation shall not apply to:	2. This Regulation shall not***, unless otherwise provided for,*** apply to:
(a) foods when and insofar as they are used as:	a) foods when and insofar as they are used as:
(i) food additives falling within the scope of Regulation (EC) No [on food additives];	***(1)*** food additives falling within the scope of Regulation (EC) No (on food additives);
(ii) food flavourings falling within the scope of Regulation (EC) No [on food	***(2)*** food flavourings falling within the scope of Regulation (EC) No [on food

flavourings];	flavourings], ***except where the flavourings mentioned in Article 8(1), points (a), (b) and (c) of that Regulation are produced from a novel food***;
(iii) extraction solvents used in the production of foodstuffs and falling within the scope of Council Directive 88/344/EEC;	***(3)*** extraction solvents used in the production of foodstuffs and falling within the scope of Council Directive 88/344/EEC;
(iv) food enzymes falling within scope of Regulation (EC) No [on food enzymes];	***(4)*** food enzymes falling within the scope of Regulation (EC) No (on food enzymes);
(v) vitamins and minerals falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2006.	***(5)*** vitamins and minerals falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2006***, except where the vitamins or minerals are obtained from new sources or using a production process which was not taken into account when they were authorised under the respective piece of legislation***.
(b) foods falling within the scope of Regulation (EC) 1829/2003.	(b) foods falling within the scope of Regulation (EC) 1829/2003;
	(ba) foods derived from cloned animals and their descendants. Before the date of entry into force of this Regulation referred to in Article 20, 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.
	2a. Notwithstanding paragraph 2, 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 giving rise to significant changes in the composition or structure of the food (e.g. nanotechnologies and nanoscience).
3. ***Where*** necessary, it may be determined in accordance with the procedure referred to in Article ***14(2)*** whether a type of food	3. ***When*** necessary, it may be determined in accordance with the procedure referred to in Article ***14(3)*** whether a type of food

falls within the scope of this Regulation.	falls within the scope of this Regulation. ***Where a novel food can have an effect on the human body comparable to that of a medicinal product, the Commission shall ask the European Medicines Agency (EMEA) to assess whether it falls under Regulation (EC) No 726/2004.***

Amendment 32

Proposal for a regulation – amending act
Article 3 – paragraph 2 - point (a) (i) – introductory part

Text proposed by the Commission	*Amendment*
(i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;	(i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997, ***including food which has been approved under the 'fast track' procedure of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients.***

Justification

The 'fast track' procedure introduced a lower level of protection in the field of food safety.

Amendment 33

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point a – point ii

Text proposed by the Commission	*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; and***	(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique***, with the exception of foods derived from cloned animals and their descendants***;

Justification

The decision as to whether or not to place foods from cloned animals and their descendants on the market must not be left to the commitology procedure but should be taken by means of a specific regulation of the European Parliament and of the Council under codecision.

Amendment 34

Proposal for a regulation – amending act
Article 3 – paragraph 2 - point (b)

Text proposed by the Commission	*Amendment*
(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least ***one generation*** in a large part of the population of the country;	(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least ***30 years*** in a large part of the population of the country;

Amendment 35

Proposal for a regulation – amending act
Article 3 – paragraph 2 - point (c)

Text proposed by the Commission	*Amendment*
(c) "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 in the ***normal*** diet of a large part of the population of a country.	(c) "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.

Amendment 36

Proposal for a regulation – amending act
Article 3 – paragraph 2 –point (c a) (new)

Text proposed by the Commission	*Amendment*
	(ca) 'nanomaterial' means an intentionally manufactured material with one or more external dimensions or an internal structure, of the order of 100 nm or less;

Amendment 37

Proposal for a regulation – amending act
Article 3 – paragraph 2 –point (c b) (new)

Text proposed by the Commission	*Amendment*
	(cb) 'produced with the aid of nanotechnology' means a product which contains, consists of or is produced with intentionally manufactured material with one or more external dimensions or an internal structure,
	(i) on the scale from from 1 to 100 nm, or,
	(ii) where larger than 100 nm, is generally scientifically accepted as a product of nanotechnology.

Amendment 38

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point c a (new)

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

Justification

Clarification of the definitions.

Amendment 39

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) "descendants of cloned animals" means animals produced by means of

	sexual reproduction, in cases in which at least one of the parents is a cloned animal;

Justification

Clarification of the definitions.

Amendment 40

Proposal for a regulation – amending act
Article 4 – paragraph 1, 1 a and 1b (new)

Text proposed by the Commission	*Amendment*
Collection of information regarding the ***use of a food for human consumption***	Collection of information regarding the ***classification of a novel food***
1. The Commission ***may*** collect information from the Member States and/or from food business operators to determine ***to what*** extent a food has been used for human consumption within the Community before 15 May 1997.	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 information on the*** extent a food has been used for human consumption within the Community before 15 May 1997 ***to the Commission***.
	1a. The Commission shall publish these data and the conclusions drawn from the data collection and the non-confidential data supporting it.
	1b. 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 the regulatory procedure with scrutiny referred to in Article 14 (3) not later than six months after the entry into force of this Regulation.

Amendment 41

Proposal for a regulation– amending act
Article 5

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

Justification

In order to meet the goal of stimulating innovation, the authorisation should remain available for the exclusive use of the applicant during the period of data protection as defined by Article 12. Other applicants must therefore provide data sufficient to substantiate new authorisations without making reference to the proprietary data of the prior applicant. The mechanism should be the same as in Article 21(2) of Regulation 1924/2006/EC.

Amendment 42

Proposal for a regulation – amending act
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Prohibition of non-compliant novel foods
	Novel foods shall not be placed on the market if their use does not comply with the provisions of this Regulation.

Justification

Prohibition should deter fraudulent operators and enhance consumer protection.

Amendment 43

Proposal for a regulation – amending act
Article 6 – point a

Text proposed by the Commission	*Amendment*
A novel food may be included in the Community list only if it meets the following conditions:	***1.*** A novel food may be included in the Community list only if it meets the following conditions:
(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer ***under normal consumption conditions***;	(a) it does not, on the basis of the scientific evidence available, ***and after application of the precautionary principle, as laid down in Article 7 of Regulation (EC) No 178/2002***, pose a safety concern to the health of the consumer ***and of animals which implies that cumulative and synergistic effects as well as possible adverse effects on particular groups of the population will be taken into account in the risk assessment;***

Justification

New food should not pose any health risks for consumers in any circumstances. Additional provision for normal consumption is superfluous and would only cause interpretation problems in practice and undermine the predictability of practical decision-making for operators in this sector. And the new wording further strengthens consumer protection.

Animal health is also relevant here.

Amendment 44

Proposal for a regulation – amending act
Article 6 – point b

Text proposed by the Commission	*Amendment*
(b) it does not mislead the consumer***, by the way it is presented or by its intended use***;	(b) it does not mislead the consumer;

Justification

The definitions in original Regulation 258/97 are clearer and should be kept.

Amendment 45

Proposal for a regulation – amending act
Article 6 – point c

Text proposed by the Commission	*Amendment*
(c) in the case where it is intended to replace another food, it does not differ from that food ***to*** such ***an extent*** that its normal consumption would be nutritionally disadvantageous for the consumer.	(c) in the case where it is intended to replace another food, it does not differ from that food ***in*** such ***a way*** that its normal consumption would be nutritionally disadvantageous for the consumer.

Justification

The definitions in original Regulation 258/97 are clearer and should be kept.

Amendment 46

Proposal for a regulation – amending act
Article 6 – point (c a) (new)

Text proposed by the Commission	*Amendment*
	(ca) it has no negative impact on the environment, and has no persistent or accumulative effects on the environment after being consumed or becoming waste.

Justification

One of the criteria for entering a food on the Community list of novel foods must be its environmental impact, in particular its persistent or cumulative effects on the environment.

Amendment 47

Proposal for a regulation – amending act
Article 6 – point (c b) (new)

Text proposed by the Commission	*Amendment*
	(c b) 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;

Justification

It is important also to take account of environmental aspects as part of the conditions for inclusion in the Community list.

Amendment 48

Proposal for a regulation – amending act
Article 6 – (c c) (new)

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

Justification

It is important also to take account of ethical aspects as part of the conditions for inclusion in the Community list.

Amendment 49

Proposal for a regulation – amending act
Article 6 – points c d - c f (new)

Text proposed by the Commission	*Amendment*
	(cd) 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;
	(ce) maximum intake levels of a novel food as such or as part of another foodstuff or categories of foodstuffs will be laid down, where safe use so requires;
	(cf) cumulative effects of novel foods that are used in different foodstuffs or categories of foodstuffs have been assessed;

Justification

More attention should be paid to possible risks of the use of novel foods, in particular in relation to vulnerable groups of the population. A broader set of conditions for inclusion of novel foods in the Community list is needed to prevent that unexpected drawbacks appear from the use of a novel food.

Amendment 50

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

Text proposed by the Commission	*Amendment*
	1a. Foods to which production processes have been applied that require specific risk assessment methods (e.g. foods produced using nanotechnologies) may not be included in the Community list until such specific methods have been approved for use, and an adequate safety assessment on the basis of these methods has shown that the use of the respective foods is safe. These methods must not entail the use of vertebrate animals.

Justification

Currently, there are no adequate methods to assess the safety of nanomaterials (see SCENIHR-opinion of Sept. 2005). Nanomaterials should be assessed on the basis of nano-specific non-animal tests. Until nano-specific non-animal tests are available for an adequate safety assessment of nanomaterials in foods, their use should be prohibited in order to protect human health and to prevent animal testing.

Amendment 51

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

Text proposed by the Commission	*Amendment*
	1b. A novel food may be included in the Community 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 Community list.

Justification

The decision as to whether or not to place foods from cloned animals and their descendants on the market must not be left to the commitology procedure but should be taken by means of a specific regulation of the European Parliament and of the Council under codecision.

Amendment 52

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

Text proposed by the Commission	*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 should not be included in the Community list.

Amendment 53

Proposal for a regulation – amending act
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No [common procedure].	1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No [common procedure] ***and the Commission shall publish it on a dedicated page of its website***.

Justification

Similarly, the list of foods from third countries and the list of new Community foods should be made available on the Internet.

Amendment 54

Proposal for a regulation – amending act
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
(2) The entry of a novel food in the Community 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.***	(2) The entry of a novel food in the Community list shall include***:***
	(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 Community 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 11.

Justification

It is important to require these information from ALL novel foods (not only the ones referred to in Article 7- paragraph 3- first subparagraph; as proposed by the Commission!) in order to enable transparency.

Amendment 55

Proposal for a regulation – amending act
Article 7 – paragraph 2 a (new)

Text proposed by the Commission	*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 5 years and when more scientific evidence becomes available. In the monitoring, special attention should be paid to the categories of the population with the highest dietary intakes.

Justification

In order to be informed about adverse effects from the use of a novel food, a post-market monitoring should be required for all novel foods, once 5 years after their introduction onto the European market.

Amendment 56

Proposal for a regulation – amending act
Article 7 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. In the cases referred to in Article 2(2), point (a) the common procedure shall be employed irrespective of the previous use or authorisation of the substance to which a standard production process was applied.

JustificationA food ingredient or additive manufactured using a production technology which has not previously been employed, such as nanotechnology and nanoscience, should be covered by the regulation on novel foods. These substances may have completely new properties. On precautionary consumer protection grounds, a separate assessment is needed which takes no account of the previous standard use of the substance or of its authorisation.

Amendment 57

Proposal for a regulation – amending act
Article 7 – paragraph 2 b (new)

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

Justification

In case a novel food is a substance with a risk linked with consuming too much of it, it should get approval for use with maximum level in certain foods or food categories in order to prevent the risk of over-dosing and consumers should be informed of this through clear

labels.

Amendment 58

Proposal for a regulation – amending act
Article 7 – paragraph 2 c – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	2c. Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC. Additional specific labelling requirements may be laid down for specific novel foods, in particular regarding the description of the food, its source, or its conditions of use. Where this is the case, the labelling requirement shall be mentioned in the Community list.

Justification

The first part takes over the statement of Rec. 21.

Amendment 59

Proposal for a regulation – amending act
Article 7 – paragraph 2 c – subparagraph 2 (new)

Text proposed by the Commission	*Amendment*
	Products produced with the aid of nanotechnologies must be labelled with the words 'produced with the aid of nanotechnologies';

Justification

Consumers might like to know whether a food has been produced by the use of nanotechnologies.

Amendment 60

Proposal for a regulation – amending act
Article 7 – paragraph 2 c – subparagraph 3 (new)

Text proposed by the Commission	*Amendment*
	Products produced from animals fed with genetically modified feeding stuffs must be labelled with the words 'produced from animals fed with genetically modified feeding stuffs';

Justification

Consumers might like to know whether a food has been produced by the use of genetically modified feed. Concerning this, there is a clear gap in the provisions concerning food produced from animals fed with genetically modified feedingstuffs: Recital 16 of Regulation 1829/2003 is interpreted to mean that foods manufactured from animals fed with genetically modified feedingstuffs are not covered by that regulation. This means that Reg. 1829/2003 contains no provisions on labelling; therefore corresponding rules must be laid down in this regulation in order to fill that gap.

Amendment 61

Proposal for a regulation – amending act
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community 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 14(2) in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.	***3. The updating of the Community list shall be decided in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).***

Amendment 62

Proposal for a regulation – amending act
Article 7 a (new)

Text proposed by the Commission	*Amendment*
	Article 7a
	Labelling of novel foods and novel food ingredients
	Without prejudice to the provisions and requirements of Directive No 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, should appear clearly, precisely and in an easily legible and comprehensible manner on their packaging;
	(c) the presence of a novel food or novel ingredient replacing a material or ingredient in a food, whether or not the food is replaced by a novel food, must be stated clearly, precisely and in an easily legible and comprehensible manner on the labelling.
	Where a novel food contains a substance which may pose a high risk to human health in the event of excessive consumption, the consumer must be informed of this by means of clear, precise and easily legible labelling on the packaging of the food.

Justification

Like any other foodstuff placed on the European market, a novel food must be labelled in accordance with the provisions of Directive No 2000/13/EC, currently under review, but also in accordance with the specific provisions of this article, taking account of the specific

qualities of novel foods and novel food ingredients.

Amendment 63

Proposal for a regulation – amending act
Article 8 – paragraph 1 – subparagraph 2

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

Justification

Due to the lack of statistics, it is important to consider data demonstrating the history of safe food use coming from any third country.

Amendment 64

Proposal for a regulation – amending act
Article 8 – paragraph 2

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

Justification

Provision in order to provide high transparency for stakeholders and consumers.

Amendment 65

Proposal for a regulation – amending act
Article 8 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. The notification as referred to in paragraph 1 shall be	In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. The notification as referred to in paragraph 1 shall be

considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common procedure].	considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common procedure]. ***Alternatively, the applicant may choose to withdraw the notification.***

Justification

In comparison to the evidence required to demonstrate history of safe use for a notification under Article 8, the data requirement to support an application would be considerably more extensive. Consequently it is appropriate that the applicant should have the option to withdraw from the process rather than have the notification automatically convert to a full application.

Amendment 66

Proposal for a regulation – amending act
Article 8 – paragraph 3 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Commission shall inform the food business operator concerned accordingly within five months from the date of the notification in accordance with paragraph 1.	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 in accordance with paragraph 1.

Justification

To increase legal certainty applicants (the food business operators) should be informed by the Commission without undue delay and in a demonstrable manner of objections raised in response to the notification.

Amendment 67

Proposal for a regulation – amending act
Article 8 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall publish a list of traditional foods from third countries that may be placed on the market in the Community in accordance with paragraph 4 on a dedicated page of the Commission's	5. The Commission shall publish a list of traditional foods from third countries that may be placed on the market in the Community in accordance with paragraph 4 on a dedicated page of the Commission's

website.	website. ***This page shall be accessible from and linked to the page on the Community list on novel foods referred to in Article 5(1).***

Amendment 68

Proposal for a regulation – amending act
Article 8 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Detailed rules for the implementation of this Article, *which are* designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***may*** be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	6. ***Before the date of application of Article 8,*** 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 the regulatory procedure with scrutiny referred to in Article 14(3).

Justification

To increase legal certainty for business operators active in this sector the Commission will need to lay down clear criteria on which to assess whether food has been used for human consumption to a significant degree within the Community.

Amendment 69

Proposal for a regulation – amending act
Article 9

Text proposed by the Commission	*Amendment*
The Commission shall, where appropriate, in close cooperation with the Authority, 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.	***Notwithstanding the provisions of Article 9(1) (a) of Regulation (common procedure) and before the date of application of this Regulation,*** 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

Comment [M1]: What is this?

	submitting applications under this Regulation. ***Recommendation 97/618/EC 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 more than six months after the date of entry into force of this Regulation, on a publicly accessible page intended for that purpose on the website of the Commission.

Amendment 70

Proposal for a regulation – amending act
Article 10 – introductory part

Text proposed by the Commission	*Amendment*
In assessing the safety of novel foods, the Authority shall:	In assessing the safety of novel foods, the Authority shall, ***on the basis of the requirements specified in Article 6***:

Amendment 71

Proposal for a regulation – amending act
Article 10 – point a

Text proposed by the Commission	*Amendment*
(a) ***compare, where appropriate,*** if the food ***is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace***;	a) ***consider*** if the ***new*** food***, irrespective of whether or not it is intended to replace a food already existing on the market, does not pose any risk of harmful or toxic effects to human health, while also taking into account the implications of any new characteristics;***

Justification

Clarification of Commission's proposed wording. See also Amendment 40 by Mrs Liotard. Foods produced using nanotechnologies, for example, may have novel characteristics that cannot be adequately assessed merely by comparing them to existing products already on the market.

Amendment 72

Proposal for a regulation – amending act
Article 10 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) ask the competent authorities, in connection with scientific evaluations of the risks posed by novel foods or novel food ingredients, to supply it with any scientific evaluation they have carried out on the novel food or novel ingredient in question.

Amendment 73

Proposal for a regulation – amending act
Article 10 - point b

Text proposed by the Commission	*Amendment*
(b) take into account for traditional food from a third country, the history of safe food use.	(b) take into account***:***
	(i) for traditional food from a third country, the history of safe food use***;***
	(ii) the composition of the novel food, particularly the levels of anti-nutrients and naturally occurring toxins;
	(iii) the method of preparation and specifications of a novel food ingredient;
	(iv) the potential for allergenicity of the novel food;
	(v) metabolism/toxicokinetic studies on the novel food ingredient;
	(vi) animal toxicity studies on the novel food ingredient;
	(vii) human toleration studies on the

novel food ingredient.

Justification

When assessing the safety of novel foods, the authority should also consider such aspects as the composition, allergenicity and toxicity of novel foods.

Amendment 74

Proposal for a regulation – amending act
Article 10 – subparagraph 1 a (new)

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

Justification

Bei der Zulassung eines neuartigen Lebensmittels können neben Sicherheitsbedenken auch ethische Bedenken bestehen. Gemäß Erwägungsgrund 24 soll die Europäische Gruppe für Ethik der Naturwissenschaften und der Neuen Technologien gegebenenfalls gehört werden können, um Ratschläge zu ethischen Fragen im Zusammenhang mit dem Inverkehrbringen neuartiger Lebensmittel einzuholen. Der Änderungsvorschlag setzt dies um, in dem er vorsieht, dass im Falle ethischer Bedenken bei der Zulassung eines neuartigen Lebensmittels eine Bewertung durch die „European Group on Ethics in Science and New Technologies (EGE)" durchgeführt wird.

Amendment 75

Proposal for a regulation – amending act
Article 11

Text proposed by the Commission	*Amendment*
1. The Commission ***may*** impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. ***The food business operators placing the food in the Community market shall be responsible for the implementation of the post-marketing requirements specified in the***	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 after five years and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention***

entry of the food concerned in the Community list of novel foods.	***should be paid to the categories of the population with the highest dietary intakes.***
	The monitoring requirements shall also apply to novel foods already on the market, including those approved under the simplified procedure ('notification') of Regulation (EC) No 258/97.
	Member States shall appoint competent authorities that will be responsible for the post-marketing monitoring.
2. The producer shall forthwith inform the Commission of:	2. The producer ***and food business operator*** shall forthwith inform the Commission of:
(a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;	(a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;
(b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.	(b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.
	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.
	The Member States' 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.
	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, and duplicate vertebrate animal testing shall

be prohibited.

Amendment 76

Proposal for a regulation – amending act
Article 11 a (new)

Text proposed by the Commission	*Amendment*
	Article 11a
	European Group on Ethics and new Technologies
	Where appropriate, on ethical questions relating to science and new technologies of major ethical importance, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies, with a view to obtaining its opinion on ethical issues.
	The Commission shall make this opinion available to the public.

Amendment 77

Proposal for a regulation – amending act
Article 12

Text proposed by the Commission	*Amendment*
On request by 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 during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant.	***1.*** On request by 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 during a period of five years from the date of the inclusion of the novel food in the Community list ***unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:***
	(a) the scientific data and other

information has been designated as proprietary by the prior applicant at the time the prior application was made; and

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

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

Justification

Article 21 of Regulation 1924/2006/EC on nutrition and health claims includes a clearer definition of data protection. Article 12 should be revised for consistency of data protection provisions with Regulation 1924/2006/EC.

Amendment 78

Proposal for a regulation – amending act
Article 12 – paragraph 1 a (new)

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

Justification

If public money is involved to generate knowledge, this knowledge should also be accessible to the public.

Amendment 79

Proposal for a regulation – amending act
Article 12 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The repetition of studies involving vertebrates shall be prohibited. In this

context, studies involving tests on vertebrate animals and studies that may prevent animal testing will not be covered by data protection. Thus access to studies on vertebrates and other studies that may prevent animal testing must be allowed.

Justification

It should be included here that the owner of a test or study cannot prevent it being used by another person where this would avoid animal testing.

Amendment 80

Proposal for a regulation – amending act
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12a
	Harmonised data protection
	Notwithstanding authorisation of a novel food pursuant to Articles 7 and 14 of Regulation (EC) No .../... [common procedure] 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.

Justification

See justification concerning recital 22.

Amendment 81

Proposal for a regulation – amending act
Article 12 b (new)

Text proposed by the Commission	*Amendment*
	Article 12b
	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 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.

Justification

In the Commission proposal, inspection and control measures are not referred to in an Article.

Amendment 82

Proposal for a regulation – amending act
Article 13

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

Justification

By setting a clear deadline for notification (12 months) by which the Member States must announce rules for imposing sanctions for infringement of this regulation we can increase

legal certainty. In addition, the amendment is consistent with the longer period set out in other articles for the adoption of implementing arrangements by the European Commission.

Amendment 83

Proposal for a regulation – amending act
Article 13 a (new)

Text proposed by the Commission	*Amendment*
	Article 13a
	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 the measures have entered into force.

Justification

This provision has been taken over from the current legislation (Reg. 258/1997).

Amendment 84

Proposal for a regulation – amending act
Article 15

Text proposed by the Commission	*Amendment*
Review	*Review*
No later than ***[1 January 2015]*** and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation ***and in particular of Article 8,*** accompanied, where appropriate, by any proposals. The report and any proposal shall be made accessible to the public.	***Not*** later than ***31 December 2013*** 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***, particularly of Articles 8 and 12***, ***in view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies,*** accompanied, where appropriate, by any proposals. The report and any proposal shall be made accessible to the public.

For the sake of continuity it is more appropriate for the review of the regulation to be dealt with by the European Parliament in the next parliamentary term. Moreover as regards the new legal instrument for data protection under Article 12, it would seem appropriate for the Commission also to focus on implementation in the Member States in its review.

Amendment 85

Proposal for a regulation – amending act
Article 17

Text proposed by the Commission	*Amendment*
By six months from the date of entry into force of this Regulation [date] at the latest the Commission shall establish the Community list by entering novel foods authorised under Regulation (EC) No 258/97 ***in this Community list***, including any existing authorisation conditions, as appropriate.	By six months from the date of entry into force of this Regulation [date] at the latest the Commission shall establish the Community 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.

Justification

See amendment to Article 16.

EXPLANATORY STATEMENT

The purpose of the Commission proposal is to amend Regulation (EC) No 258/97 on novel foods, with the aim of simplifying and centralising the procedures for authorising novel foods and placing them on the market. Thus it has been decided that new regulation is necessary. The rapporteur considers that if it is decided to adopt regulations, it must be very clear what their purpose is.

In the rapporteur's view, the objectives of the new regulation on novel foods are to attain a high level of food safety, consumer protection, environmental protection and protection of animal health while at all times the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[1] must be observed. All other objectives are of secondary importance.

Novel foods must not endanger or mislead consumers, either. Where novel foods serve to replace another food, the novel foods must not be nutritionally inferior from the consumer's point of view.

The Commission proposal seeks to clarify the definition of novel foods and the associated definitions. The rapporteur endorses this aim, but considers that the Commission has negligently fallen short in achieving it. Its proposal did not include clear definitions, and the rapporteur has therefore clarified the existing definitions and where necessary supplemented them with new ones. These include, for example, a definition of foods derived from cloned animals and foods produced using nanotechnology.

The rapporteur considers it very important that foods derived from cloned animals should be excluded from the scope of the Regulation on novel foods. As no democratic agreement has yet been reached on the desirability of these foods, particularly from the point of view of animal health and welfare, the decision as to whether or not to place on the market foods derived from cloned animals and their descendants cannot be left to the commitology procedure. It must be resolved by means of a specific regulation of the European Parliament and of the Council under the codecision procedure. Lastly, account must also be taken of whether a society regards a novel food as inedible on ethical grounds.

All applications for authorisation of novel foods will be submitted to the Commission and must comply with the criteria laid down in this Regulation; they will then be forwarded for consideration to the European Food Safety Authority (EFSA), which will assess the foods' safety. This assessment must also take account of ethical and environmental aspects. Consequently the opinions of the European Group on Ethics in Science and New Technologies and the European Environment Agency must be involved in the safety assessment. At present, the Commission is promising consumers and citizens that it will take responsibility for environmental and animal welfare aspects, inter alia in view of the problems

[1] OJ L 31, 1.2.2002, pp. 1-24.

of climate change and animal welfare, and European policy must therefore be comprehensive and sound with reference to all relevant fields of legislation and therefore also to the Regulation on novel foods.

The Commission proposal seeks to make the authorisation procedure more effective and transparent and to implement it better. This will contribute to better implementation of the Regulation and give consumers greater power and more options because they will have more information at their disposal. Here too, the Commission has got ahead of itself by taking the view that the Regulation on novel foods should be governed, inter alia, by the Regulation establishing a common authorisation procedure for food additives, food enzymes and flavourings. The European Parliament and the Council have not yet taken a democratic decision on the uniform authorisation procedure. The rapporteur has therefore opted to propose an authorisation procedure based on the procedure laid down in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[1], which was carefully drafted with a view to consumer protection and environmental protection, and also the most recently devised specific procedure for novel foods.

For traditional foods from third countries, the Commission proposes a simpler authorisation procedure, under which safety would be assessed in the light of the history of safe use in the country of origin. It is important that it should be precisely established what period of safe use of such traditional foods from third countries is long enough to guarantee the safety of the product, and the rapporteur proposes a period of 50 years for this, rather than the 'one generation' proposed by the Commission, which is difficult to define.

The Commission proposal aims to achieve a certain level of data protection for a five-year period for applications under this Regulation. This surprises the rapporteur, as the Commission adduced a completely different line of argument during the consideration of the uniform authorisation procedure in the European Parliament. The Commission claimed there that a data protection system would result in an increase in regulation and would render monitoring systems and administrative procedures more complex. In addition, a data protection system would constitute an obstacle to free movement of goods which are safe and meet the criteria of the relevant legislation, which is contrary to the purposes of a measure adopted under Article 95 of the EC Treaty.

This inconsistency in the Commission's legislative proposals is highly unsatisfactory. The rapporteur therefore proposes retaining the system of confidentiality of manufacturing data laid down in 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[2].

The Commission proposal envisages Member States being required to impose penalties on those who violate the provisions of the regulation on novel foods. The rapporteur strongly emphasises that the criminal law is always a matter for Member States. It is highly desirable

[1] OJ L 268, 18.10.2003, pp. 1-23.
[2] OJ L 253, 21.9.2001, pp. 17-18.

that Member States should be able to decide freely whether a penalty is to be imposed under the criminal law or whether it should be administrative or of some other nature. So long as a Member State takes adequate action against violations of the Regulation on novel foods, it will be fulfilling its obligations under Community law.

The rapporteur supports all measures to lessen administrative burdens and improve transparency and efficiency. However, they must never be allowed to detract from the overriding aim of the Regulation on novel foods, namely food safety and consumer protection.

7.10.2008

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

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

on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) N°XXX/XXXX [common procedure]
(COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))

Rapporteur: Zuzana Roithová

SHORT JUSTIFICATION

The objective of the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXX (common procedure) is to ensure food safety, protect human health and secure the functioning of the internal market for food. Authorisation and use of novel foods and food ingredients is harmonised in the European Union since 1997 when Regulation EC No 258/97 was adopted. This regulation lays down the general principles for authorisation of novel foods and food ingredients. The new proposal aims to streamline the existing rules for authorisation procedures, supervision, labelling and use of novel foods, and to clarify the definition of novel food.

The rapporteur supports the proposal, but suggests improvements along the following lines:

- The rapporteur suggests that ethical aspects should be taken into account when considering authorisation of a novel food, and also suggests that the Committee on ethics and new technologies should be consulted where appropriate on ethical issues regarding science and new technologies.

- Furthermore the rapporteur wants to ensure that the implementing measures will be adopted *before* the Regulation enters into force. This will reduce the uncertainties for businesses and confusion over what rules businesses should follow. If the implementing measures are *not* adopted there will still be difficulties with the interpretation and possible differences in the administration among the Member States, which will have a negative effect on the functioning of the internal market. The rapporteur furthermore suggests that the regulation should apply from 12 months after the date of publication instead of 6 months. This will make it possible to adopt the implementing measures before the

application of the regulation.

- There is a borderline affecting medicinal products, which the rapporteur wants to clarify in the proposal. A clarification of when it is a novel food and when it is a medicinal food will make it easier for the food industry to interpret the rules and reduce uncertainties over which rules are to be followed in which areas.

- With traditional foods from third countries, the requirement of use for at least one generation is more clearly specified as 20 years, on the grounds that the wording 'one generation' is much too vague a legal term.

- The use of foods in the Community is assessed irrespective of the entry of individual Member States to the EU, which will help clarify the situation particularly for the new Member States.

- Targets are extended to include the support of innovation in the food industry and the smooth operation of the internal market, which are measures for the benefit of businesspeople in that sector.

- In some places consumer protection has been tightened up – for instance by expressly prohibiting the placing on the market of foods that are not included on the Community's list.

- The report strengthens the transparency of information provided for the public, by making it compulsory for such information to be available on the Internet.

- Legal certainty is improved for businesspeople who invest large sums in preparation for placing on the market new or traditional foods by requiring them to be informed without undue delay and in a demonstrable manner, in the event of objections during the authorisation process.

- The Commission's obligation to provide technical support for applicants is expanded and spelt out, especially for SMEs, including the option of submitting a uniform application by electronic means.

- The requirement is more clearly specified for new foods on the market to be monitored after their approval, by requesting from the Commission the establishment of an adequate, precisely defined period for monitoring, which removes the potential of legal uncertainty for an unlimited period that would influence the attitudes of businesspeople in the competitive environment.

- The report specifies how the protection of personal data is to coexist with the confidentiality (privacy) of such information in accordance with Article 12 of the Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. This combination of a period of protection of data and a period of protection of confidentiality would be guided by the principle of proportionality, which includes strengthening the

sharing of scientific knowledge and the transparency of information for consumers (such as those with allergies, etc.).

- The requirement is more clearly specified for the Member States to announce sanctions under their national legislation within 12 months from publication of the regulation in the EU Official Journal, together with the requirement on the Commission, which in order to preserve continuity will be required to present a report reviewing the situation by the end of 2013, the aim being to enable the European Parliament elected in the June 2009 elections to assess the regulation's effectiveness.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation – amending act
Recital 3

Text proposed by the Commission	*Amendment*
(3) Community 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 should be repealed ***and*** replaced by this Regulation. ***The present Regulation should include measures currently governed by Regulation (EC) No 1852/2001.***	(3) Community 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***. Regulation (EC) No 258/97 should be*** replaced by this Regulation. ***Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market***

of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council[1] should be replaced by revised guidance tailored to novel foods. However, applicants should continue to be able to avail themselves of Commission Recommendation 97/618/EC until it is replaced by revised guidance.

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[1] OJ L 253, 16.9.1997, p. 1.

Justification

The assessment procedure provisions of Regulation (EC) No 1852/2001 are covered by the provisions on a common authorisation procedure in the proposed regulation, and Commission Regulation (EC) No 1852/2001 is therefore no longer needed. The proposed new regulation provides for publication of new guidance to assist applicants. The present guidance should remain in force until it has been replaced by a revised guidance.

Amendment 2

Proposal for a regulation – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) In order to ensure continuity with Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Community before the date of application of Regulation (EC) No 258/97, namely 15 May 1997, should be kept as criteria for a food to be considered as novel.	(4) In order to ensure continuity with Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Community before the date of application of Regulation (EC) No 258/97, namely 15 May 1997, should be kept as criteria for a food to be considered as novel. ***A use within the Community refers to a use in the Member States, independently of the date of their accession to the European Union.***

Justification

This amendment clarifies the extent of the regulation's impact on the internal market and so increases legal certainty for the those concerned, particularly in the Member States in Central and Eastern Europe.

Amendment 3

Proposal for a regulation – amending act
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) However, foods derived from cloned animals and their offspring should 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 procedure. Pending the entry into force 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 offspring.

Amendment 4

Proposal for a regulation – amending act
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 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[1] should apply where, taking into account all its characteristics, a product may fall within the definition of "medicinal product" and within the definition of a product covered by other Community legislation. In this respect, a Member State may, if 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 Community

law.

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[1] OJ L 311, 28.11.2001, p. 67.

Justification

The definition of food according to Regulation 178/2002 implies that a product which is a medicine cannot be a food. As the categorisation of a product as a medicine according to Directive 2001/83 is not totally harmonised among Member States, some differences in categorisation of a product as a medicine exist. This has an implication for harmonisation also in the area of food. Many borderline issues arise when dealing with novel foods. This recital provides more clarity for industry and consumers about the functioning of the market in relation to borderline products.

Amendment 5

Proposal for a regulation – amending act
Recital 13

Text proposed by the Commission	*Amendment*
(13) Whether a food was used for human consumption to a significant degree before 15 May 1997, should be based on information available in the Member States. Where the Commission does not have information on human consumption before 15 May 1997, a ***simple and transparent*** procedure for collecting that information should be established involving the Member States and any interested parties.	(13) Whether a food was used for human consumption to a significant degree before 15 May 1997, should be based on information available in the Member States. Where the Commission does not have information on human consumption before 15 May 1997, a procedure for collecting that information should be established involving the Member States and any interested parties. ***This procedure should be simple and transparent, whilst avoiding any unjustified disruption to the market, and should be adopted no later than six months after the entry into force of this Regulation.***

Justification

The information collection procedure may involve raising questions about products that are ultimately found not to be novel foods. In the process of a transparent collection of data, these products' competitive position should not be negatively affected by incorrect inferences of novel status. The Commission procedure should therefore be sensitive to such problems and avoid any unjustified disruption of the market.

Amendment 6

Proposal for a regulation – amending act
Recital 15

Text proposed by the Commission	*Amendment*
(15) 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 Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No [..] of the European Parliament and of the Council of [date] establishing a common authorisation procedure for the food additives, food enzymes and flavourings.	(15) 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 Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No [..] of the European Parliament and of the Council of [date] establishing a common authorisation procedure for the 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.***

Justification

It is essential that in the process of approving new foods (since this also covers new foods gained from nanotechnologies or cloning processes) all the relevant factors essential for the final decision are taken into account, including the ethical issues.

Amendment 7

Proposal for a regulation – amending act
Recital 20

Text proposed by the Commission	*Amendment*
(20) 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 Community list should not be used to the benefit of another	(20) 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

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 Community list of novel foods on the basis of their own scientific data.	developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Community 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 Community list of novel foods on the basis of their own scientific data.

Justification

The wording of recital 20 should be aligned with the wording of recital 31 of Regulation 1924/2006 on nutrition and health claims.

Amendment 8

Proposal for a regulation – amending act
Recital 21

Text proposed by the Commission	*Amendment*
(21) 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 foodstuffs. 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 Community list may impose specific conditions of use or labelling obligations.	(21) 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 foodstuffs. 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***, which may include information relating to ethical considerations***. Therefore, the inclusion of a novel food in the Community list may impose specific conditions of use or labelling obligations.

Justification

It is essential that when labelling new foods (since they include new foods gained from nanotechnologies or cloning processes) the ethical issues are taken into account in

appropriate cases, as consumers need transparent information to be able to make informed choices and purchases.

Amendment 9

Proposal for a regulation – amending act
Recital 22

Text proposed by the Commission	*Amendment*
(22) 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 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.	(22) 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 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 intends a novel food to carry a health claim authorised in accordance with Articles 17 or 18 of that Regulation, and where the novel food and health claim applications are introduced at the same time and both include a request for the protection of proprietary data, at the request of the applicant the periods of data protection should start together and run concurrently.***

Justification

Related applications for authorisation of a novel food and of a health claim relevant for the same product and both based on proprietary data could proceed according to different schedules. Consequently, the period of data protection under one authorisation could have elapsed to a significant degree before the data protection period of the related authorisation starts. Provision must be made to align the data protection periods of related authorisations if requested by the applicant.

Amendment 10

Proposal for a regulation – amending act
Recital 24

Text proposed by the Commission	*Amendment*
(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***may*** be consulted***, where appropriate,*** with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.	(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***should*** be consulted ***in substantiated cases*** with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.

Justification

On substantiated general matters (such as in the use of nanotechnologies or cloning techniques) it is clearly appropriate that ethical issues should have to be referred to the European Group on Ethics in Science and New Technologies for consultation.

Amendment 11

Proposal for a regulation – amending act
Recital 25

Text proposed by the Commission	*Amendment*
(25) Novel foods placed on the Community market 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 Community list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97***, and for which a final decision has not been take before the date of application of the present Regulation,*** should be considered as applications under this Regulation.	(25) Novel foods placed on the Community market 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 Community list of novel foods established by this Regulation. In addition, ***where the initial assessment report provided for by Article 6(3) of 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 Article 6(3) or (4) of that Regulation before the date of application of this Regulation,*** applications submitted under Regulation (EC) No 258/97 should be considered as applications under this

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

Justification

The Commission's proposed text potentially disadvantages applications for which an initial assessment has already been forwarded to the Commission, since it may be possible to authorize such an application without redirection of the application to EFSA for evaluation if no objections are raised. All applications for which an initial assessment report has already been forwarded to the Commission should continue according to the procedure defined in 258/97/EC.

Amendment 12

Proposal for a regulation – amending act
Article 1

Text proposed by the Commission	*Amendment*
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 human health and consumers' protection, whilst ensuring the effective functioning of the internal market.	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 human health and consumers' protection, whilst ensuring the effective functioning of the internal market ***and stimulating innovation within the relevant industries***.

Justification

As an important Community objective and one of the purposes referred to in the recitals, this goal should be explicitly included within the subject matter.

Amendment 13

Proposal for a regulation – amending act
Article 3 – paragraph 2 - point a - point i - subparagraph 2

Text proposed by the Commission	*Amendment*
The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community 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 the regulatory procedure with scrutiny referred to in Article 14(3).	The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. ***Before the date of application of this Regulation,*** further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***shall*** be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Justification

To increase legal certainty for business operators active in this sector and harmonisation in the internal market (since there are big differences between Member States in how the rules are applied) the Commission will need to lay down clear criteria on which to assess whether food has been used for human consumption to a significant degree within the Community.

Amendment 14

Proposal for a regulation – amending act
Article 3 – paragraph 2 - point b

Text proposed by the Commission	*Amendment*
(b) “traditional food from a third country” means novel food with a history of food use in a third country, meaning that the food in question has been *and continues to be* part of the normal diet for at least ***one***	(b) “traditional food from a third country” means novel food with a history of food use in a third country, meaning that the food in question has been part of the normal diet for ***a period of*** at least ***20 years***

generation in a large part of the population of the country;	in a large part of the population of the country;

Justification

'One generation' is not a clear term in legal parlance. By changing it to a period of 20 years legal certainty is appreciably increased for all stakeholders. At the same time this period provides a margin for gaining experience with using, in particular, scientific data for deciding whether traditional food from a third country can be placed on the internal market.

Amendment 15

Proposal for a regulation – amending act
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission ***may*** collect information from the Member States and/or from food business operators to determine to what extent a food has been used for human consumption within the Community before 15 May 1997.	1. The Commission ***shall*** collect information from the Member States and/or from food business operators to determine to what extent a food has been used for human consumption within the Community before 15 May 1997.

Amendment 16

Proposal for a regulation – amending act
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Prohibition of non-compliant novel foods
	Novel foods shall not be placed on the market if their use does not comply with the provisions of this Regulation.

Justification

Prohibition should deter fraudulent operators and enhance consumer protection.

Amendment 17

Proposal for a regulation – amending act
Article 6 – point a

Text proposed by the Commission	*Amendment*
(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer ***under normal consumption conditions***;	(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer;

Justification

New food should not pose any health risks for consumers in any circumstances. Additional provision for normal consumption is superfluous and would only cause interpretation problems in practice and undermine the predictability of practical decision-making for operators in this sector. And the new wording further strengthens consumer protection.

Amendment 18

Proposal for a regulation – amending act
Article 6 – point b

Text proposed by the Commission	*Amendment*
(b) it does not mislead the consumer***, by the way it is presented or by its intended use***;	(b) it does not mislead the consumer;

Justification

The definitions in original Regulation 258/97 are clearer and should be kept.

Amendment 19

Proposal for a regulation – amending act
Article 6 – point c

Text proposed by the Commission	*Amendment*
(c) in the case where it is intended to replace another food, it does not differ from that food ***to*** such ***an extent*** that its normal consumption would be nutritionally disadvantageous for the consumer.	(c) in the case where it is intended to replace another food, it does not differ from that food ***in*** such ***a way*** that its normal consumption would be nutritionally disadvantageous for the consumer.

Justification

The definitions in original Regulation 258/97 are clearer and should be kept.

Amendment 20

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

Text proposed by the Commission	*Amendment*
	Where there is no scientific evidence as to the health implications of a novel food, the food may not be included in the Community list.

Amendment 21

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

Text proposed by the Commission	*Amendment*
	A novel food may be included in the Community list only if the competent authority has submitted an opinion establishing that the food is not harmful to health.

Amendment 22

Proposal for a regulation – amending act
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No [common procedure].	1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No [common procedure] ***and the Commission shall publish it on a dedicated page of its website***.

Justification

Similarly, the list of foods from third countries and the list of new Community foods should be made available on the Internet.

Amendment 23

Proposal for a regulation – amending act
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community 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 14(2) in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.	***deleted***
In the cases referred to in the first subparagraph the entry of a novel food in the Community list shall indicate, in addition to the information referred to in paragraph 2:	
(a) the date of entry of the novel food in the Community list;	
(b) the fact that the entry is based on newly developed scientific evidence and/or proprietary data protected in accordance with Article 12;	
(c) the name and address of the applicant.	

Justification

It is more appropriate for this whole section to be governed by Article 12, to which these paragraphs have been transferred.

Amendment 24

Proposal for a regulation – amending act
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Before the expiry of the period referred to in Article 12, the Community list shall be updated to amend non-essential elements of this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 14(3) laid down in Regulation (EC) No [common procedure] so that, provided that the authorised food still meets the condition laid down in this Regulation, the specific indications referred to in paragraph 3, second subparagraph of this Article, are no longer included.	***deleted***

Justification

It is more appropriate for this whole section to be governed by Article 12, to which these paragraphs have been transferred

Amendment 25

Proposal for a regulation – amending act
Article 8 – paragraph 1 – subparagraph 2

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

Justification

Due to the lack of statistics, it is important to consider data demonstrating the history of safe food use coming from any third country.

Amendment 26

Proposal for a regulation – amending act
Article 8 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. The notification as referred to in paragraph 1 shall be considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common procedure].	In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. The notification as referred to in paragraph 1 shall be considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common procedure]. ***Alternatively, the applicant may choose to withdraw the notification.***

Justification

In comparison to the evidence required to demonstrate history of safe use for a notification under Article 8, the data requirement to support an application would be considerably more extensive. Consequently it is appropriate that the applicant should have the option to withdraw from the process rather than have the notification automatically convert to a full application.

Amendment 27

Proposal for a regulation – amending act
Article 8 – paragraph 3 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Commission shall inform the food business operator concerned accordingly within five months from the date of the notification in accordance with paragraph 1.	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 in accordance with paragraph 1.

Justification

To increase legal certainty applicants (the food business operators) should be informed by the Commission without undue delay and in a demonstrable manner of objections raised in response to the notification.

Amendment 28

Proposal for a regulation – amending act
Article 8 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Detailed rules for the implementation of this Article, *which are* designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***may*** be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	6. ***Before the date of application of Article 8,*** 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 the regulatory procedure with scrutiny referred to in Article 14(3).

Justification

To increase legal certainty for business operators active in this sector the Commission will need to lay down clear criteria on which to assess whether food has been used for human consumption to a significant degree within the Community.

Amendment 29

Proposal for a regulation – amending act
Article 9

Text proposed by the Commission	*Amendment*
The Commission shall, ***where appropriate,*** in close cooperation with the Authority, ***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.	The Commission shall, in close cooperation with the Authority, ***actively cooperate with*** food business operators and especially small and medium-sized enterprises in preparing and submitting ***their*** applications ***and notifications*** under this Regulation***, and shall provide them with the maximum possible technical guidance and tools, including the option of submitting a uniform electronic application***.

Justification

There is a need to provide technical guidance and tools for operators, and this should be an active duty for the Commission. A practical example might be a uniform electronic application or other elements of e-government normally used in the various Member States.

Amendment 30

Proposal for a regulation – amending act
Article 10 – introductory part

Text proposed by the Commission	*Amendment*
In assessing the safety of novel foods, the Authority shall:	In assessing the safety of novel foods, the Authority shall ***in particular, where it considers it appropriate***:

Justification

Formally specifies the scope of the article's application.

Amendment 31

Proposal for a regulation – amending act
Article 10 – point a

Text proposed by the Commission	*Amendment*
(a) *compare**, where appropriate,** if* the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;	(a) *determine whether* the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;

Justification

There is a need for more stringent wording of the requirement to check the safety of new foods with regard to comparable food categories.

Amendment 32

Proposal for a regulation – amending act
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission may impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. The food business operators placing the food in the Community market shall be responsible for the implementation of the post-marketing	1. The Commission may impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring ***for an appropriate limited period***. ***It shall be possible to extend the appropriate limited period of monitoring of food on the market in***

requirements specified in the entry of the food concerned in the Community list of novel foods.	***justified cases no more than once for a further appropriate limited period.*** The food business operators placing the food in the Community market shall be responsible for the implementation of the post-marketing requirements specified in the entry of the food concerned in the Community list of novel foods.

Justification

Interference with the operation of the free market in the form of monitoring new food after its placing on the market must be treated as the exception, and as such subject to an appropriate and strictly limited period so that operators do not face legal uncertainty for their products for an unlimited period.

Amendment 33

Proposal for a regulation – amending act
Article 11 a (new) (in Chapter II)

Text proposed by the Commission	*Amendment*
	Article 11a
	European Group on Ethics and new Technologies
	Where appropriate, on ethical questions relating to science and new technologies of major ethical importance, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies, with a view to obtaining its opinion on ethical issues.
	The Commission shall make this opinion publicly available, including by publishing it on a dedicated page of its website.

Justification

In justified cases (such as the use of nanotechnologies or cloning techniques)) it is clearly appropriate that ethical issues should have to be referred to the European Group on Ethics in Science and New Technologies for consultation. This consultation process can be launched by the Commission itself or by the Member State. In the interest of transparency and involvement of experts as well as the general public the opinion must be published on the Internet.

Amendment 34

Proposal for a regulation – amending act
Article 12

Text proposed by the Commission	*Amendment*
On request by 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 during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant.	***1.*** On request by 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 during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant. ***Where new scientific evidence and proprietary scientific data that enjoy protection under this Article are at the same time subject to the rules on confidentiality under Regulation (EC) No …/... of the European Parliament and of the Council of ... [establishing a common authorisation procedure for food additives, food enzymes and food flavourings][1], the Commission shall adapt the period of confidentiality proportionately to the five-year period for the protection of information.***
	[1] OJ L ...

Justification

The report specifies how the protection of personal data is to coexist with the rules on the confidentiality (privacy) of such information in accordance with Article 12 of the Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. This combination of a period of protection of data and a period of protection of confidentiality would be guided by the principle of proportionality, which includes strengthening the sharing of scientific knowledge and the transparency of information for consumers (such as those with allergies, etc.).

Amendment 35

Proposal for a regulation – amending act
Article 12 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By way of derogation from Article 7(4) of Regulation (EC) No .../... [common procedure], the updating of the Community list with a novel food, other than a traditional food from a third country, shall be decided on in accordance with the regulatory procedure referred to in Article 14(2) in cases where newly developed scientific evidence and proprietary data are protected in accordance with this Article. In such cases, the authorisation shall be granted for the period specified in the first paragraph.

(This amendment is former Article 7, paragraph 3, subparagraph 1)

Justification

The provision originally in Article 7 is spelt out in greater detail.

Amendment 36

Proposal for a regulation – amending act
Article 12 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. In the cases referred to in paragraph 1a, the entry of a novel food in the Community list shall indicate, in addition to the information referred to in Article 7(2):
	(a) the date of entry of the novel food in the Community list;
	(b) the fact that the entry is based on 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 restricted for placing on the market by the applicant specified in point (c), unless a subsequent applicant obtains authorisation for the food without reference to the proprietary data referred to in point (b).

(This amendment is former Article 7, paragraph 3, subparagraph 2, except for point (d))

Justification

The provision originally in Article 7 is spelt out in greater detail. This provides additional information which must be published in the Community list.

Amendment 37

Proposal for a regulation – amending act
Article 12 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. Before the expiry of the period referred to in paragraph 1, the Community list shall be updated so that, provided that the authorised food still meets the conditions set out in this Regulation, the specific indications referred to in paragraph 3 are no longer included.
	That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Justification

The provision originally in Article 7 is spelt out in greater detail.

Amendment 38

Proposal for a regulation – amending act
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12a
	Harmonised data protection
	Notwithstanding authorisation of a novel food pursuant to Articles 7 and 14 of Regulation (EC) No .../... [common procedure] 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 it is intended to obtain authorisation for a novel food and for a health claim relating to that food, and where data protection pursuant to the provisions of both Regulations is warranted and requested by the applicant.

Justification

See justification concerning recital 22.

Amendment 39

Proposal for a regulation – amending act
Article 13

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

affecting them.	amendment affecting them.

Justification

By setting a clear deadline for notification (12 months) by which the Member States must announce rules for imposing sanctions for infringement of this regulation we can increase legal certainty. In addition, the amendment is consistent with the longer period set out in other articles for the adoption of implementing arrangements by the European Commission.

Amendment 40

Proposal for a regulation – amending act
Article 15

Text proposed by the Commission	*Amendment*
No later than ***[1 January 2015]*** and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of ***Article 8***, accompanied, where appropriate, by any proposals. The report and any proposal shall be made accessible to the public.	No later than ***31 December 2013*** 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 8 and 12***, accompanied, where appropriate, by any proposals. The report and any proposal shall be made accessible to the public.

Justification

For the sake of continuity it is more appropriate for the review of the regulation to be dealt with by the European Parliament in the next parliamentary term. Moreover as regards the new legal instrument for data protection under Article 12, it would seem appropriate for the Commission also to focus on implementation in the Member States in its review.

Amendment 41

Proposal for a regulation – amending act
Article 17

Text proposed by the Commission	*Amendment*
By six months from the date of entry into force of this Regulation [date] at the latest the Commission shall establish the Community list by entering novel foods authorised under Regulation (EC) No 258/97 ***in this Community list***, including	By six months from the date of entry into force of this Regulation [date] at the latest the Commission shall establish the Community list by entering ***in this list*** novel foods ***which are*** authorised under Regulation (EC) No 258/97 ***and which fall***

any existing authorisation conditions, as appropriate.	***within the scope of this Regulation pursuant to Articles 2 and 3 thereof***, including any existing authorisation conditions, as appropriate.

Justification

See amendment to Article 16.

Amendment 42

Proposal for a regulation – amending act
Article 18 – paragraph 1

Text proposed by the Commission	*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 and for which a final decision has not been taken before the date of application of this Regulation*** shall be considered as an application under this Regulation.	1. ***Where the initial assessment report provided for by Article 6(3) of Regulation (EC) No 258/97 has not been forwarded to the Commission by ...+,*** any request for placing a novel food on the market submitted to a Member State under Article 4 of ***that*** Regulation shall be considered as an application under this Regulation. ***Other requests submitted under Article 3(4) and Articles 4 and 5 of Regulation (EC) No 258/97 before ...+ shall be processed under the provisions of that Regulation.***
	+ The date of application of this Regulation.

Justification

The Commission's proposed text potentially disadvantages applications for which an initial assessment has already been forwarded to the Commission, since it may be possible to authorize such an application without redirection of the application to EFSA for evaluation if no objections are raised. All applications for which an initial assessment report has already been forwarded to the Commission should continue according to the procedure defined in 258/97/ec.

Amendment 43

Proposal for a regulation – amending act
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any appropriate transitional measures for the application of paragraph 1, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	***deleted***

Justification

The Commission's proposed text potentially disadvantages applications for which an initial assessment has already been forwarded to the Commission, since it may be possible to authorize such an application without redirection of the application to EFSA for evaluation if no objections are raised. All applications for which an initial assessment report has already been forwarded to the Commission should continue according to the procedure defined in 258/97/EC.

Amendment 44

Proposal for a regulation – amending act
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
It shall apply from ***six months*** after the date of publication of this Regulation [date].	It shall apply from ***12 months*** after the date of publication of this Regulation [date].

Justification

Extending the validity of the regulation from six to 12 months is needed to enable the Commission to adopt implementing rules for individual articles, and provides appropriate time for improving preparations by the Member States and operators in this sector.

PROCEDURE

Title	Novel foods (common procedure)
References	COM(2007)0872 – C6-0027/2008 – 2008/0002(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 17.1.2008
Drafts(wo)man Date appointed	Zuzana Roithová 31.1.2008
Discussed in committee	3.6.2008 24.6.2008 9.9.2008
Date adopted	7.10.2008
Result of final vote	+: 21 –: 2 0: 12
Members present for the final vote	Cristian Silviu Buşoi, Charlotte Cederschiöld, Gabriela Crețu, Mia De Vits, Janelly Fourtou, Evelyne Gebhardt, Małgorzata Handzlik, Christopher Heaton-Harris, Anna Hedh, Iliana Malinova Iotova, Pierre Jonckheer, Kurt Lechner, Toine Manders, Catiuscia Marini, Arlene McCarthy, Nickolay Mladenov, Catherine Neris, Zita Pleštinská, Karin Riis-Jørgensen, Zuzana Roithová, Heide Rühle, Leopold Józef Rutowicz, Christel Schaldemose, Andreas Schwab, Marianne Thyssen, Jacques Toubon, Barbara Weiler, Marian Zlotea
Substitute(s) present for the final vote	Emmanouil Angelakas, Wolfgang Bulfon, Colm Burke, Giovanna Corda, Othmar Karas, José Ribeiro e Castro, Olle Schmidt, Diana Wallis

24.7.2008

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

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

on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending regulation (EC) No XXX/XXXX [common procedure]
(COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))

Draftsman: Vincenzo Lavarra

SHORT JUSTIFICATION

The Commission proposal amends Regulation (EC) No 258/97 on novel foods with a view to simplifying and centralising the procedure for authorising novel foods and placing them on the market.

The Commission intends to define the scope of the Regulation more accurately by excluding categories of foods in respect of which specific legislation already exists. Hence genetically modified organisms, food additives, flavourings, extraction solvents, enzymes, vitamins and minerals will be excluded from the Regulation.

All applications for authorisation will have to be submitted to the Commission and then assigned to the European Food Safety Authority, which will have to carry out safety checks.

Novel foods must not pose any risk to health, they must not mislead consumers and if they are used as a replacement food they must not compromise nutrition.

Once the EFSA has been consulted the Commission - by means of the committee procedure - will decide whether the new product is to be placed on the register of novel foods and whether special extra labelling will be required.

In the case of traditional foods from third countries, the Commission intends to simplify the authorisation thereof and to assess their safety on the basis of the experience of safe use in the country of origin.

The rapporteur agrees with the need to simplify the authorisation procedure, especially since the EFSA is the right body to assess the safety level of foods scientifically.

Although the EFSA is able to provide a full range of scientific guarantees concerning food safety, we should welcome the fact that the European Parliament will retain the power of veto, so as to ensure that in the most sensitive and controversial cases the democratically elected representatives will retain their legitimate power of oversight (regulation-with-oversight procedure).

Although the rapporteur agrees with the need for genetically modified organisms (which are already governed by Regulation (EC) No 1829/2003) to be excluded from the scope of the Regulation, he also considers it essential that foods derived from cloned animals and their offspring should be excluded too, in order to ensure that such ethically sensitive choices will not have to be taken in the future by means of the comitology procedure; he rapporteur also calls upon the Commission to submit a specific proposal providing for the co-decision procedure, so that Parliament will be involved in the adoption of decisions on such a controversial topic..

In addition, the rapporteur is calling for the European Group on Ethics in Science and New Technologies to be consulted in any case involving an ethical problem concerning the use of new food technologies and the placing of novel foods on the market.

As regards traditional foods from a third country, the period of safe use must be precisely defined in order to censure that the product is perfectly safe to use, for which reason the rapporteur is proposing a 50-year period instead of the general expression 'one generation'.

Lastly, the rapporteur maintains that the absolute priority at all stages of the procedure for authorising novel foods must be food safety and the health of consumers, which take priority over commercial interests and the protection of intellectual-property rights, in particular scientific data demonstrating that a product is safe.

In full accordance with the precautionary principle, the EU should provide its citizens with a full range of safeguards concerning health and the quality and transparency of foods.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation – amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) A high level of human health protection	(2) A high level of human health protection

should be assured in the pursuit of Community policies.	should be assured in the pursuit of Community policies ***and should be given priority over the functioning of the internal market***.

Justification

The human health protection should be considered as a priority in the authorisation of novel food.

Amendment 2

Proposal for a regulation – amending act
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The standards defined in EU legislation must be applied to all food placed on the Community market, including food imported from third countries.

Justification

It should be re-iterated that the Community standards also apply to imported food.

Amendment 3

Proposal for a regulation – amending act
Recital 5

Text proposed by the Commission	*Amendment*
(5) 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 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,	(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 of the European Parliament and of the Council of 28 January 2002 laying down the general

establishing the European Food Safety Authority and laying down procedures in matters of food safety.	principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Justification

In order to make the legislation clear, there should be some explanation of the criteria for novelty of a food in the text itself or in the recitals.

Amendment 4

Proposal for a regulation – amending act
Recital 6

Text proposed by the Commission	*Amendment*
(6) It should also be clarified that a food should be considered as novel when it is applied 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. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.	(6) ***The scope of this Regulation should encompass all food which was not used for human consumption to a significant degree within the Community before 15 May 1997. The criteria for novelty in relation to food should include use of new species of organisms such as plants, animals, micro-organisms, fungi or algae, and use of new parts of existing organisms and substances with a new molecular structure . Existing food should be considered novel if it has been modified in a way that changes its chemical composition, molecular structure, particle size or other elements in a way that is likely to have an impact on food safety.*** It should also be clarified that a food should be considered as novel when it is applied 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 ***safety***. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods

Justification

In order to make the legislation clear, there should be some explanation of the criteria for novelty of a food preferably in the text itself or in the recitals. The proposed text aims at describing the way the novel food legislation is working at present. The word "safety" is missing in the second last sentence.

Amendment 5

Proposal for a regulation – amending act
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) Food produced from cloned animals and their offspring should, however, be excluded from the scope of this Regulation. It should be governed by a specific regulation to be enacted through the co-decision procedure instead of through the "common procedure". The Commission should present a legislative proposal to this effect before the date of application of this Regulation. In the light of the opinion of the European Group on Ethics in Science and New Technologies and the provisions of Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, food produced from cloned animals and their offspring[1] should not be placed on the market before the entry into force of the specific regulation governing these products.

[1] OJ L 221, 8.8.1998, p. 23.

Justification

The decision about whether or not to authorise food from cloned animals and their offspring needs in depth consideration of all food safety criteria as well as ethical criteria and potential impacts on animal welfare. It should therefore not be left to the comitology procedure, but be governed by a legislative decision under application of the co-decision procedure. A moratorium should be put in place for such food, until the specific legislation has entered into force.

Amendment 6

Proposal for a regulation – amending act
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) The cloning of animals is incompatible with paragraphs 20 and 21 of the Annex to Directive 98/58/EC. Paragraph 20 prohibits natural or artificial breeding or breeding procedures which cause or are likely to cause suffering or injury to any of the animals concerned. Paragraph 21 prohibits the keeping of animals for farming purposes unless it can reasonably be expected that, on the basis of their genotype or phenotype, they can be kept without a detrimental effect on their health or welfare.

Justification

The animal health and welfare problems caused by cloning mean that this process is incompatible with certain provisions of Council Directive 98/58/EC.

Amendment 7

Proposal for a regulation – amending act
Recital 6 c (new)

Text proposed by the Commission	*Amendment*
	(6c) Little is known at present about the health implications of foods containing nanoparticles manufactured by means of

	nanotechnological procedures. In keeping with the precautionary principle, the use of nanoparticles in the manufacturing of foods should be suspended until scientific findings concerning the implications of their use are available.

Amendment 8

Proposal for a regulation – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) ***If necessary,*** implementing measures should be adopted to provide for criteria in order to facilitate the assessment of whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior 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 whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.	(7) Implementing measures should be 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 Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior 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 whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.

Justification

It is necessary that implementing measures are adopted in order to further describe the criteria for novelty. The word further should be added as some explanation is already given with the amendments to recital 6.

Amendment 9

Proposal for a regulation – amending act
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 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[1] should apply where a product, taking into account all its characteristics, may fall within the definition of "medicinal product" and within the definition of a product covered by other Community legislation. In this respect, a Member State may, if 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 Community law.
	_____
	[1] OJ L 311, 28.11.2001, p. 67.

Justification

As many borderline issues arise when dealing with novel foods, it is important to stress this general principle in the recital. This provides more clarity for industry and consumers about the functioning of the market in relation to borderline products (medicine/food).

Amendment 10

Proposal for a regulation – amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Novel foods should be placed on the Community market only if they are safe and do not mislead the consumer. In addition, they should not differ from the food that they are to replace in any	(14) Novel foods should be placed on the Community market only if they are safe and do not mislead the consumer. ***Their safety assessment should be based on the precautionary principle as laid down in***

way that would be nutritionally disadvantageous for the consumer.	***Article 7 of 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[1].*** 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.
	[1] OJ L 31, 1.2.2002, p. 1.

Amendment 11

Proposal for a regulation – amending act
Recital 20

Text proposed by the Commission	*Amendment*
(20) 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 Community 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 Community list of novel foods on the basis of their own scientific data.	(20) 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 Community 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 Community 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, however, be respected.***

Justification

In line with Amendment 5 of the draft opinion, but aims to guarantee the protection of producers´ intellectual property rights.

Amendment 12

Proposal for a regulation – amending act
Recital 21

Text proposed by the Commission	*Amendment*
(21) 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 foodstuffs. 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 Community list may impose specific conditions of use or labelling obligations.	(21) 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 foodstuffs. 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 ***and which may includeinformation relating to ethical considerations***. Therefore, the inclusion of a novel food in the Community list may impose specific conditions of use or labelling obligations.

Justification

The criteria for additional labelling should also include ethical considerations such as cloning. Thus, it should be possible to require labelling of foods produced from cloned animals.

Amendment 13

Proposal for a regulation – amending act
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) The introduction of a European quality label would allow consumers to

	identify products that are produced in accordance with the European Union´s strict environmental, animal-welfare and food-safety standards and would form another essential part, in addition to this Regulation, of the European Union´s general policy of informing its citizens about the characteristics of products and the circumstances in which they were produced.

Amendment 14

Proposal for a regulation – amending act
Recital 24

Text proposed by the Commission	*Amendment*
(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***may*** be consulted, ***where appropriate***, with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.	(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***should*** be consulted, with a view to obtaining advice on ethical issues regarding ***the use of new technologies and*** the placing on the market of novel foods.

Amendment 15

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

Text proposed by the Commission	*Amendment*
	(ba) food produced from cloned animals or their offspring. The Commission shall present a specific legislative proposal for such food before 31 December 2009.

Justification

The decision about placing on the market of foods produced from cloned animals or their offspring should not be left to a comitology decision, but should be taken in a specific Regulation of the European Parliament and the Council, based on the co-decision procedure.

Amendment 16

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

Text proposed by the Commission	*Amendment*
	2a. Notwithstanding paragraph 2, this Regulation shall apply to food additives, food enzymes, minerals and flavourings and certain food ingredients with flavouring properties to which is applied a new production process not used before 15 May 1997 giving rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances.

Justification

A food ingredient or additive manufactured using a production technology which has not previously been employed, such as nanotechnology and nanoscience, should be covered by the regulation on novel foods. These substances may have completely new properties. On precautionary consumer protection grounds, a separate assessment is needed which takes no account of the previous standard use of the substance or of its authorisation.

Amendment 17

Proposal for a regulation – amending act
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where necessary, it may be determined in accordance with the procedure referred to in ***Article 14(2)*** whether a type of food falls within the scope of this Regulation.	Where necessary, it may be determined in accordance with the procedure referred to in ***Article 14(3)*** whether a type of food falls within the scope of this Regulation.

Amendment 18

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a)"novel food" means:	(a) "novel food" means ***food that was not used for human consumption to a significant degree within the Community before 15 May 1997, including:***
(i) ***food that has not been used for human consumption to a significant degree within the Community before 15 May 1997***; ***The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community 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 the regulatory procedure with scrutiny referred to in Article 14(3).***	(i) ***food of plant or animal origin when a non-traditional breeding technique, other than animal cloning, not commercially used before 15 May 1997 is applied to the plant or animal; and*** ***(ii) food to which is applied a new production process not used before 15 May 1997 givings rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances.***
(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; and	***The use of a food exclusively as, or in, a food supplement shall not be sufficient to show that it was used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food was used exclusively as, or in, a food supplement prior to that date, it may be placed on the Community market after that date for the same use without being considered novel food. Before the date of application of this Regulation, further criteria for assessing whether a food was used for human***

	consumption to a significant degree within the Community 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 the regulatory procedure with scrutiny referred to in Article 14(3).
(iii) food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances.	

Justification

The overall definition of a novel food is given in Article 3.2 a(i). The following two categories (ii) and (iii) are sub-groups under this overall definition. On the other hand, subparagraph 2 in point a (i) relates to all categories mentioned in Article 3, paragraph 2, point a. The implementing measures should be adopted before the application of the Regulation.

Amendment 19

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least ***one generation*** in a large part of the population of the country;	(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least ***25 years*** in a large part of the population of the country;

Justification

The aim of laying down much more precise rules governing traditional food from third countries is a reasonable one. However, the period proposed by the rapporteur (50 years) seems too long, particularly as in other food-related provisions a generation is traditionally seen as amounting to 25 years (see Article 2(1)(b) of Council Regulation (EC) No 509/2006 of

20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed).

Amendment 20

Proposal for a regulation – amending act
Article 3 - paragraph 2 - point c

Text proposed by the Commission	*Amendment*
(c) "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 in the normal diet of a large part of the population of a country.	(c) "history of safe food use" means that the safety of the food in question is confirmed with compositional data and from experience ***over a period of at least 25 years*** of use and continued use in the normal diet of a large part of the population of a country.

Amendment 21

Proposal for a regulation – amending act
Article 6 - point a

Text proposed by the Commission	*Amendment*
(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer under normal consumption conditions;	(a) it does not, on the basis of the scientific evidence available, ***and after application of the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002***, pose a safety concern to the health of the consumer under normal consumption conditions;

Amendment 22

Proposal for a regulation – amending act
Article 6 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) it is considered to be produced under ethically acceptable conditions.

Justification

It should be possible to take into account ethical aspects when considering authorisation of a novel food. Without mentioning ethical aspects as a criterion in Article 6, it is not clear whether ethical aspects can legally be used in relation to authorisation of a novel food.

Amendment 23

Proposal for a regulation – amending act
Article 7 – paragraph 2 a (new)

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

JustificationA food ingredient or additive manufactured using a production technology which has not previously been employed, such as nanotechnology and nanoscience, should be covered by the regulation on novel foods. These substances may have completely new properties. On precautionary consumer protection grounds, a separate assessment is needed which takes no account of the previous standard use of the substance or of its authorisation.

Amendment 24

Proposal for a regulation – amending act
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community 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 14(2)*** in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.	By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 14(3),*** in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.

Amendment 25

Proposal for a regulation – amending act
Article 8 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Detailed rules for the implementation of this Article, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***may*** be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	6. Detailed rules for the implementation of this Article, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***shall*** be adopted ***at the latest six months following the date of application of this Regulation*** in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Justification

In order to guarantee comprehensive consumer protection, the detailed rules for the implementation of the simplified authorisation procedure for traditional foods from third countries must be laid down as soon as possible after the entry into force of the regulation.

Amendment 26

Proposal for a regulation – amending act
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	Opinion of the European Group on Ethics in Science and New Technologies
	Where appropriate, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies with a view to obtaining its opinion on ethical questions relating to science and new technologies of major ethical importance.
	The Commission shall make this opinion publicly available, including by publishing it on a dedicated page of its

website.

Justification

In justified cases (such as the use of nanotechnologies or cloning techniques) it is appropriate that ethical issues should have to be referred to the European Group on Ethics in Science and New Technologies for consultation. This consultation process can be launched by the Commission itself or by the Member State. In the interest of transparency and involvement of experts as well as the general public the opinion must be published on the Internet.

PROCEDURE

Title	Novel foods (common procedure)
References	COM(2007)0872 – C6-0027/2008 – 2008/0002(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	AGRI 17.1.2008
Drafts(wo)man Date appointed	Vincenzo Lavarra 11.3.2008
Previous drafts(wo)man	Luis Manuel Capoulas Santos
Discussed in committee	27.5.2008 24.6.2008 14.7.2008
Date adopted	14.7.2008
Result of final vote	+: 30 –: 0 0: 0
Members present for the final vote	Vincenzo Aita, Sergio Berlato, Bernadette Bourzai, Luis Manuel Capoulas Santos, Giovanna Corda, Albert Deß, Gintaras Didžiokas, Konstantinos Droutsas, Constantin Dumitriu, Michl Ebner, Carmen Fraga Estévez, Lutz Goepel, Friedrich-Wilhelm Graefe zu Baringdorf, Esther Herranz García, Lily Jacobs, Elisabeth Jeggle, Heinz Kindermann, Vincenzo Lavarra, Mairead McGuinness, Rosa Miguélez Ramos, Neil Parish, Vincent Peillon, María Isabel Salinas García, Petya Stavreva, Dimitar Stoyanov, Janusz Wojciechowski
Substitute(s) present for the final vote	Alejandro Cercas, Esther De Lange, Catherine Neris, Maria Petre, Karin Resetarits, Struan Stevenson, Kyösti Virrankoski

PROCEDURE

Title	Novel foods (common procedure)
References	COM(2007)0872 – C6-0027/2008 – 2008/0002(COD)
Date submitted to Parliament	14.1.2008
Committee responsible Date announced in plenary	ENVI 17.1.2008
Committee(s) asked for opinion(s) Date announced in plenary	IMCO AGRI 17.1.2008 17.1.2008
Rapporteur(s) Date appointed	Kartika Tamara Liotard 27.2.2008
Discussed in committee	27.5.2008 14.7.2008 6.11.2008
Date adopted	2.12.2008
Result of final vote	+: 41 –: 0 0: 2
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Mojca Drčar Murko, Jill Evans, Anne Ferreira, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Jens Holm, Holger Krahmer, Urszula Krupa, Riitta Myller, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Daciana Octavia Sârbu, Richard Seeber, Salvatore Tatarella, Antonios Trakatellis, Evangelia Tzampazi
Substitute(s) present for the final vote	Iles Braghetto, Bairbre de Brún, Christofer Fjellner, Johannes Lebech, Kartika Tamara Liotard, Renate Sommer, Bart Staes