EUROPEAN PARLIAMENT

Texts adopted

Wednesday, 25 March 2009 - Strasbourg **Provisional edition**

Novel foods ***I

P6_TA-PROV(2009)0171 A6-0512/2008

European Parliament legislative resolution of 25 March 2009 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.

Text proposed by the Commission	*Amendment*
Amendment 1 **Proposal for a regulation – amending act** **Recital 1**	
(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*	(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,*

provisions concerning the safety assessment and authorisation of novel foods may hinder their free movement, thereby creating unfair competition conditions.	***moreover, the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety 1 ,should be applied*** . ***1 OJ L 31, 1.2.2002, p. 1.***
Amendment 2 **Proposal for a regulation − amending act** **Recital 2**	
(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*** .
Amendment 3 **Proposal for a regulation − amending act** **Recital 2 a (new)**	
	(2a) Article 13 of the Treaty on the Functioning of the European Union clarifies that the Union and the Member States shall pay full regard to the welfare requirements of animals when formulating and implementing policies, since animals are sentient beings.
Amendment 4 **Proposal for a regulation − amending act** **Recital 2 b (new)**	
	(2b) The standards defined in Community legislation must be applied to all foods placed on the Community market, including foods imported from third countries.
Amendment 5 **Proposal for a regulation − amending act** **Recital 2 c (new)**	
	(2c) The European Parliament called on the Commission, in its resolution of 3 September 2008 on the cloning of animals for food supply 1 , to submit proposals prohibiting for food supply purposes (i) the cloning of animals, (ii) the farming of cloned animals or their offspring, (iii) the placing on the market of meat or dairy products derived from cloned animals or their offspring and (iv) the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring. ***1 Texts adopted, P6_TA(2008)0400*** .
Amendment 6	

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

	(2d) The Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted on 28-29 September 2005 an opinion which concluded that there are "major gaps in the knowledge necessary for risk assessment. These include nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate, and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles"; furthermore, the SCENIHR opinion concludes that "existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles";

Amendment 7
Proposal for a regulation – amending act
Recital 4

(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.***

Amendment 8
Proposal for a regulation − amending act
Recital 5

(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.

Amendment 9
Proposal for a regulation − amending act
Recital 5 a (new)

	(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 should be considered as novel under the definition of this Regulation.

Amendment 10
Proposal for a regulation – amending act
Recital 6 a (new)

(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.

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1 OJ L 221, 8.8.1998, p. 23

Amendment 11
Proposal for a regulation − amending act
Recital 6 b (new)

(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.

Amendment 12
Proposal for a regulation − amending act
Recital 6 c (new)

(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".

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1 The EFSA Journal (2008) 767, 1-49

Amendment 13
Proposal for a regulation − amending act
Recital 6 d (new)

(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.

Amendment 14
Proposal for a regulation – amending act

Recital 6 e (new)

	(6e) Foods derived from cloned animals and their descendants should, however, be excluded from the scope of this Regulation. They should be dealt with in a specific regulation, adopted under the codecision procedure, and not be subject to the common authorisation procedure. Before the date of application of this Regulation, the Commission should put forward a corresponding legislative proposal. Pending the entry into force of a regulation on cloned animals, a moratorium should be imposed on the placing on the market of foods manufactured from cloned animals and their descendants .

Amendment 15
Proposal for a regulation − amending act
Recital 7

(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.

Amendment 16
Proposal for a regulation − amending act
Recital 8 a (new)

	(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.

Amendment 17
Proposal for a regulation − amending act
Recital 10

(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 modified food and feed should be excluded from the scope of this Regulation.	(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 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.

Amendment 18
Proposal for a regulation – amending act
Recital 13

(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.***

Amendment 19
Proposal for a regulation − amending act
Recital 14

(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 way that would be nutritionally disadvantageous for the consumer.	(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 Article 7 of Regulation (EC) No 178/2002.*** In addition, they should not differ from the food that they are to replace in any way that would be nutritionally disadvantageous for the consumer.

Amendment 20
Proposal for a regulation – amending act
Recital 15

(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	(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.	Parliament and of the Council of [date] establishing a common authorisation procedure for *food additives* , food enzymes and ***food*** flavourings. ***The approval of novel foods should also take into account other factors relevant to the matter under consideration, including ethical factors.***

Amendment 21
Proposal for a regulation − amending act
Recital 15 a (new)

	(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. Moreover, in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes 1 , tests on vertebrate animals must be replaced, restricted or refined. Implementation of this Regulation should, where possible, be based on the use of appropriate alternative testing methods. Not later than ... * , 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.***

Amendment 22
Proposal for a regulation − amending act
Recital 16

(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*** .

Amendment 23
Proposal for a regulation – amending act
Recital 16 a (new)

	(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.

Amendment 25
Proposal for a regulation − amending act
Recital 20

(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, nevertheless, be respected.***

Amendment 27
Proposal for a regulation − amending act
Recital 22

(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 both include requests for the protection of proprietary data, , the periods of data protection should start together and run concurrently, where the applicant so requests*** .

Amendment 28
Proposal for a regulation – amending act
Recital 23

(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.

Amendment 29
Proposal for a regulation – amending act
Recital 24

(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.

Amendment 89
Proposal for a regulation – amending act
Recital 25

(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, applications submitted under Regulation (EC) No 258/97, ***in relation to which the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97*** has not yet been ***forwarded to the Commission, and in relation to which an additional assessment report is required in accordance with Article 6(3) or 6(4) of Regulation (EC) No 258/97*** before the date of application of ***this*** Regulation should be considered as ***an application*** under this Regulation. ***When required to give an opinion, the Authority and the Member States should take into account the outcome of the initial assessment. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation should be processed under the provisions of Regulation (EC) No 258/97.***

Amendment 30
Proposal for a regulation – amending act
Article 1

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 91
Proposal for a regulation – amending act
Article 2

1. This Regulation shall apply to the placing of novel	1. This Regulation shall apply to the placing of novel

foods on the market in the Community.	foods on the market in the Community.
2. This Regulation shall not apply to:	2. This Regulation shall, ***unless otherwise provided for,*** not 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];	(i) food additives falling within the scope of Regulation (EC) No ***1333/2008*** [on food additives];
(ii) food flavourings falling within the scope of Regulation (EC) No [on food flavourings];	(ii) food flavourings falling within the scope of Regulation (EC) No ***1334/2008*** [on food flavourings];
(iii) extraction solvents used in the production of foodstuffs and falling within the scope of Council Directive 88/344/EEC;	(iii) 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];	(iv) food enzymes falling within scope of Regulation (EC) No ***1332/2008*** [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.	(v) vitamins and minerals falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2006, ***except for vitamin and mineral substances already approved which are obtained by production methods or using new sources that were not taken into account when they were authorised under specific legislation, where these production methods or new sources give rise to significant changes referred to in Article 3(2)(a)(iii).***
(b) foods falling within the scope of Regulation (EC) 1829/2003.	(b) foods falling within the scope of Regulation (EC) 1829/2003.
	(ba) foods derived from cloned animals and their offspring. Before the date of application of this Regulation, 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 offspring. 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, which give rise to significant changes in the composition or structure of the food such as engineered nanomaterials.
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.	3. 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. ***Where a novel food can have an effect on the human body comparable to that of a medicinal product, the Commission shall seek an opinion of the European Medicines Agency (EMEA) whether it falls under Regulation (EC) No***

	726/2004.

Amendments 92 and 35
Proposal for a regulation – amending act
Article 3

1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002 shall apply.	1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002 shall apply.
2. The following definitions shall also apply:	2. The following definitions shall also apply:
(a) "novel food" means:	(a) "novel food" means:
(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;
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).	
(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 not used before 15 May 1997, ***with the exception of foods derived from cloned animals and their offspring;***
(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.	(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.
	(iiia) food containing or consisting of engineered nanomaterials not used for food production 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 to that date, it may be placed on the Community market after that date for the same use without

	being considered as a 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).
(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 ***a natural non-engineered*** novel food with a history of food use in a third country, meaning that the food in question has been***, for at least 25 years [before the date of application of this Regulation],*** and continues to be***,*** part of the normal diet in a large part of the population of the 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 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.
	(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;
	(cb) "offspring 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;
	(cc) "engineered nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale.
	Properties that are characteristic to the nanoscale include:
	(i) those related to the large specific surface area of the materials considered and/or
	(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.
	2a . In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (cd) of paragraph 2 to technical

	and scientific progress and with definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Amendment 40
Proposal for a regulation – amending act
Article 4 – paragraph 1, 1 a and 1b (new)

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 to the Commission information on the*** extent a food has been used for human consumption within the Community before 15 May 1997.
	1a. The Commission shall publish those 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

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.***

Amendment 42
Proposal for a regulation – amending act
Article 5 a (new)

	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.
Amendment 43 **Proposal for a regulation – amending act** **Article 6 – point a**	
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, 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;***
Amendment 44 **Proposal for a regulation – amending act** **Article 6 – point b**	
(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;
Amendment 45 **Proposal for a regulation – amending act** **Article 6 – point c**	
(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.
Amendment 47 **Proposal for a regulation – amending act** **Article 6 – point c b (new)**	
	(ca) the opinion of the European Environment Agency concerning the extent to which the production process and normal consumption have a harmful impact on the environment shall be taken into account in the assessment;
Amendment 48 **Proposal for a regulation – amending act** **Article 6 – point c c (new)**	
	(cb) t he 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.
Amendment 49 **Proposal for a regulation – amending act** **Article 6 – points c d - c f (new)**	
	(cc) a novel food that may have any adverse effects on particular groups of the population will be authorised only where specific measures

	preventing such adverse effects have been implemented;
	(cd) maximum intake levels of a novel food as such or as part of another foodstuff or categories of foodstuffs will be laid down, where safe use so requires;
	(ce) cumulative effects of novel foods that are used in different foodstuffs or categories of foodstuffs have been assessed;
Amendment 50 **Proposal for a regulation – amending act** **Article 6 – paragraph 1 a (new)**	
	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 those methods has shown that the use of the respective foods is safe.
Amendment 51 **Proposal for a regulation – amending act** **Article 6 – paragraph 1 b (new)**	
	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.***
Amendment 52 **Proposal for a regulation – amending act** **Article 6 – paragraph 1 c (new)**	
	1c. In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the precautionary principle shall be applied and the food in question shall not be included in the Community list.
Amendment 53 **Proposal for a regulation – amending act** **Article 7 – paragraph 1**	
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*** .
Amendment 54 **Proposal for a regulation – amending act** **Article 7 – paragraph 2**	

(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.
	(g) the fact that the novel food may only be placed on the market by the applicant specified in point (e), unless a subsequent applicant obtains authorisation for the food without reference to the proprietary data of the original applicant.
Amendment 55 **Proposal for a regulation – amending act** **Article 7 – paragraph 2 a (new)**	
	2a. Post-marketing monitoring shall be required for all novel foods. All novel foods which have been allowed onto the market shall be reviewed after five years and 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.
Amendment 56 **Proposal for a regulation − amending act** **Article 7 − paragraph 2 b (new)**	
	2b. 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.
Amendment 57 **Proposal for a regulation – amending act** **Article 7 – paragraph 2 c (new)**	
	2c. Where a novel food contains a substance which may pose a risk to human health in the event of excessive consumption, it shall require approval for use within maximum limits in certain foods or food categories.

Amendment 90
Proposal for a regulation – amending act
Article 7 – paragraph 2 d

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

Amendment 60
Proposal for a regulation – amending act
Article 7 – paragraph 2 e

	2e. 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" .

Amendment 61
Proposal for a regulation – amending act
Article 7 – paragraph 3 – subparagraph 1

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 86
Proposal for a regulation – amending act
Article 7 – paragraph 4 a (new)

	4a. For the updating of the Community list with a novel food, where the novel food does not consist of or contain food subject to data protection according to Article 12 and: *(a) the novel food is equivalent to existing foods, in composition, metabolism and level of undesirable substances, or* *(b) the novel food consists of or contains food previously approved for food use in the EU, and where the new intended use can be expected not to significantly increase the intake of consumers, including vulnerable groups,* *the notification procedure referred to in [Article 8] shall apply mutatis mutandis, by way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure].*

Amendment 62
Proposal for a regulation – amending act
Article 7 a (new)

	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.
Amendment 63 **Proposal for a regulation – amending act** **Article 8 – paragraph 1 – subparagraph 2**	
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.
Amendment 64 **Proposal for a regulation – amending act** **Article 8 – paragraph 2**	
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.***
Amendment 65 **Proposal for a regulation – amending act** **Article 8 – paragraph 3 – subparagraph 2**	

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.***
Amendment 66 **Proposal for a regulation – amending act** **Article 8 – paragraph 3 – subparagraph 3**	
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.
Amendment 67 **Proposal for a regulation – amending act** **Article 8 – paragraph 5**	
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.	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. ***This page shall be accessible from and linked to the page on the Community list of novel foods referred to in Article 5*** .
Amendment 68 **Proposal for a regulation – amending act** **Article 8 – paragraph 6**	
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 this Regulation,*** 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).
Amendment 69 **Proposal for a regulation – amending act** **Article 9**	
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.	***Without prejudice to the provisions of Article 9(1)(a) of Regulation (EC) No XX/XXX (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 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

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

(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;***

Amendment 74
Proposal for a regulation – amending act
Article 10 – subparagraph 1 a (new)

	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).

Amendment 75
Proposal for a regulation – amending act
Article 11

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 entry of the food concerned in the Community list of novel foods.***	1. The Commission ***shall*** impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. ***This monitoring shall take place five years after the date of inclusion of a novel food in the Community list and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention 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') laid down in Article 5 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 State's competent authority shall report to the Commission within three months of the completion of an inspection. The Commission shall submit a report to the European Parliament and the Council no later than a year after the expiry of the five-year period referred to in paragraph 1.
	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 .
Amendment 76 **Proposal for a regulation – amending act** **Article 11 a (new)**	
	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**	
On request by the applicant, supported by appropriate and verifiable information included in the application	***1.*** On request by the applicant, supported by appropriate and verifiable information included in the

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.	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.***
Amendment 78 **Proposal for a regulation – amending act** **Article 12 – paragraph 1 a (new)**	
	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.
Amendment 87 **Proposal for a regulation – amending act** **Article 12 - paragraph 1 b (new)**	
	1b. In order to avoid the repetition of studies involving vertebrates, reference by a subsequent applicant to studies on vertebrates and other studies that may prevent animal testing shall be allowed. The owner of the data may claim adequate compensation for the use of the data.
Amendment 80 **Proposal for a regulation – amending act** **Article 12 a (new)**	
	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.

Amendment 81
Proposal for a regulation – amending act
Article 12 b (new)

	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.

Amendment 82
Proposal for a regulation – amending act
Article 13

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.

Amendment 83
Proposal for a regulation – amending act
Article 13 a (new)

	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 those measures have entered into force.

Amendment 93
Proposal for a regulation – amending act
Article 15

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.	***1.*** No later than ***3 years after the date of application of this Regulation*** 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. ***2. No later than one year after the date of entry into force of this Regulation the Commission shall forward to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a cloning technique and from their offspring followed, where appropriate, by any legislative proposals.*** The report and any proposal shall be made accessible to the public.

Amendment 85
Proposal for a regulation – amending act
Article 17

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.

Amendment 88
Proposal for a regulation – amending act
Article 18

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. Any request for placing a novel food on the market submitted to a Member State under Article 4 of Regulation (EC) No 258/97 ***in relation to which the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission*** before the date of application of this Regulation shall be considered as an application under this Regulation. ***Other requests submitted under Articles 3(4), 4 and 5 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97.***
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).