

Wednesday 7 July 2010

## Novel foods \*\*\*II

P7\_TA(2010)0266

**European Parliament legislative resolution of 7 July 2010 on the Council position at first reading for adopting a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (11261/3/2009 – C7-0078/2010 – 2008/0002(COD))**

(2011/C 351 E/32)

(Ordinary legislative procedure: second reading)

*The European Parliament,*

- having regard to the Council position at first reading (11261/3/2009 – C7-0078/2010),
  - having regard to the Commission proposal to European Parliament and the Council (COM(2007)0872),
  - having regard to Article 251(2) and Article 95(1) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0027/2008),
  - having regard to its position at first reading <sup>(1)</sup>,
  - having regard to the Communication from the Commission to the European Parliament and the Council entitled ‘Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures’ (COM(2009)0665),
  - having regard to Article 294(7) and Article 114(1) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 29 May 2008 <sup>(2)</sup>,
  - having regard to Rule 66 of its Rules of Procedure,
  - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A7-0152/2010),
1. Adopts the position at second reading hereinafter set out;
  2. Instructs its President to forward its position to the Council, to the Commission and to the national parliaments.

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<sup>(1)</sup> OJ C 117 E, 6.5.2010, p. 236.

<sup>(2)</sup> OJ C 224, 30.8.2008, p. 81.

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**P7\_TC2-COD(2008)0002**

**Position of the European Parliament adopted at second reading on 7 July 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

- (1) *In implementing Union policy and having regard to the Treaty on the Functioning of the European Union (TFEU), a high level of protection of human health and consumer protection should be guaranteed and also a high level of animal welfare and environmental protection. At all times, moreover, the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(3)</sup>, should be applied.*
- (2) A high level of human health protection should be assured in the pursuit of Union policies **and** should be given **priority over the functioning of the internal market**.
- (3) *Article 13 TFEU clarifies that the Union and the Member States are to pay full regard to the welfare requirements of animals when formulating and implementing policies, since animals are sentient beings.*
- (4) *The standards laid down in Union legislation must be applied to all foods placed on the market within the Union, including foods imported from third countries.*
- (5) *The European Parliament called on the Commission, in its resolution of 3 September 2008 on the cloning of animals for food supply <sup>(4)</sup>, 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.*

<sup>(1)</sup> OJ C 224, 30.8.2008, p. 81.

<sup>(2)</sup> Position of the European Parliament of 25 March 2009 (OJ C 117 E, 6.5.2010, p. 236) and Council Position at first reading of 15 March 2010 (OJ C 122 E, 11.5.2010, p. 38), position of the European Parliament of 7 July 2010.

<sup>(3)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(4)</sup> OJ C 295 E, 4.12.2009, p. 42.

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- (6) *The Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted on 28–29 September 2005 an opinion which concluded that there were 'major gaps in the knowledge necessary for risk assessment. These include nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate, and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles'. Furthermore, the SCENIHR opinion concluded that 'existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles'.*
- (7) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(1)</sup> 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 <sup>(2)</sup>. For the sake of clarity, Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 should be repealed and Regulation (EC) No 258/97 should be replaced by this Regulation. Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(3)</sup> should therefore become obsolete as regards novel foods.
- (8) 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 Union before the date of application of Regulation (EC) No 258/97, namely 15 May 1997, should be kept as the criterion for a food to be considered as novel. A use within the Union refers to a use in the Member States irrespective of the date of their accession to the European Union.
- (9) **█** 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**.
- (10) **Foods with a new or intentionally modified primary molecular structure, foods consisting of, or isolated from, micro-organisms, fungi or algae, new strains of micro-organism with no history of safe use and concentrates of substances that naturally occur in plants should be considered as novel foods as defined in this Regulation.**
- (11) It should also be clarified that a food **should** be considered as novel when a production technology which was not previously used for **the production of foods to be marketed and consumed** is applied to that food. In particular, emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from **plants and** animals, produced by non-traditional breeding techniques, and **█** foods **modified** by new production processes, **such as nanotechnology and nanoscience**, which might have an impact on food **█**. Foods derived from new plant varieties, or from animal breeds produced by traditional breeding techniques, should not be considered as novel foods. **█**
- (12) **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 <sup>(4)</sup>, point 20 of the Annex of which states that natural or artificial breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned must not be practised. Food from cloned animals or their descendants must therefore not be placed on the Union list.**

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(2)</sup> OJ L 253, 21.9.2001, p. 17.

<sup>(3)</sup> OJ L 253, 16.9.1997, p. 1.

<sup>(4)</sup> OJ L 221, 8.8.1998, p. 23.

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- (13) **█** The European Group on Ethics in Science and New Technologies, established by Commission Decision of 16 December 1997, **stated in its Opinion (No. 23) of 16 January 2008 on ethical aspects of animal cloning for food supply that it ‘does not see convincing arguments to justify the production of food from clones and their offspring’.** **The Scientific Committee of the European Food Safety Authority (the ‘Authority’) concluded in its Opinion of 15 July 2008 on animal cloning <sup>(1)</sup> 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’.**
- (14) **Foods derived from cloned animals and their descendants should, however, be excluded from the scope of this Regulation. They should be dealt with in a specific regulation, adopted under the ordinary legislative procedure, and should not be subject to the common authorisation procedure. Before the date of application of this Regulation, the Commission should present a corresponding legislative proposal. Pending the entry into force of a regulation on cloned animals, a moratorium should be imposed on the placing on the market of foods manufactured from cloned animals or their descendants.**
- (15) Implementing measures should be adopted to provide for **further** criteria **in order** to facilitate the assessment of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997. If **█** a food was used exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC **of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements <sup>(2)</sup>, prior to that date,** it **can** be placed on the market **█** after that date for the same use without being considered as a novel food. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether **it** was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, **other** uses of the food concerned, **namely** other than **█** food supplement **uses, have to** be authorised in accordance with this Regulation.
- (16) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, **█** it is necessary to develop a uniform definition for engineered **nanomaterials**.
- (17) **Test methods currently available are not adequate for assessing** the risks associated with **█** nano-materials. **Non-animal test methods for testing nanomaterials should be developed as a matter of urgency.**
- (18) **Only nanomaterials entered in a list of approved substances should be present in food packaging, accompanied by a limit on migration into or onto the food products contained in such packaging.**
- (19) **Reformulated** food products produced from **existing** food ingredients **available on the market within the Union,** in particular **those reformulated** by changing **the** composition or **amounts of those food ingredients,** should not be considered as novel food. **█**
- (20) 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 <sup>(3)</sup> should apply where, taking into account all its characteristics, a product may fall both within the definition of ‘medicinal product’ and within the definition of a product covered by other Union legislation. In this respect, a Member State, if it establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, should be able to restrict the placing on the market of such product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as established by Regulation (EC) No 178/2002 and should not be subject to this Regulation.

<sup>(1)</sup> *The EFSA Journal* (2008)767, p. 32.

<sup>(2)</sup> *OJ L 183, 12.7.2002, p. 51.*

<sup>(3)</sup> *OJ L 311, 28.11.2001, p. 67.*

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- (21) Novel foods authorised under Regulation (EC) No 258/97 should maintain their novel food status but authorisation should be required for any new uses of such foods.
- (22) Foods which are intended for technological uses or which are genetically modified should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 <sup>(1)</sup>, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 <sup>(2)</sup>, flavourings falling within the scope of Regulation (EC) No 1334/2008 <sup>(3)</sup>, enzymes falling within the scope of Regulation (EC) No 1332/2008 <sup>(4)</sup> and extraction solvents falling within the scope of Directive 2009/32/EC <sup>(5)</sup> should not be covered by this Regulation.
- (23) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods <sup>(6)</sup> and Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (recast) <sup>(7)</sup> should therefore be excluded from the scope of this Regulation. However, those specific legal acts do not deal with cases where authorised vitamins and mineral substances are obtained by production methods or using new sources that were not taken into account when they were authorised. Therefore, pending the amendment of those specific legal acts, such vitamins and mineral substances should not be excluded from the scope of this Regulation when the production methods or new sources give rise to significant changes in the composition or structure of the vitamins or minerals which affect their nutritional value, how they are metabolised or the level of undesirable substances.
- (24) Novel foods, other than vitamins and minerals, intended for particular nutritional uses, for food fortification or as food supplements, should be assessed in conformity with this Regulation. They should also remain subject to the rules provided for in Directive 2002/46/EC, in Regulation (EC) No 1925/2006, in Directive 2009/39/EC, and in the specific Directives referred to in Directive 2009/39/EC and in Annex I thereto.
- (25) ***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 ... (\*)***
- (26) Novel foods should be placed on the market within the Union only if they are safe and do not mislead the consumer. ***The assessment of their safety should be based on the precautionary principle as laid down in Article 7 of Regulation (EC) No 178/2002.*** In addition, ***they*** should not differ from ***the food that they are to replace*** in any way that would be nutritionally disadvantageous for the consumer.

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

<sup>(2)</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

<sup>(3)</sup> Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

<sup>(4)</sup> Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).

<sup>(5)</sup> Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (recast) (OJ L 141, 6.6.2009, p. 3).

<sup>(6)</sup> OJ L 404, 30.12.2006, p. 26.

<sup>(7)</sup> OJ L 124, 20.5.2009, p. 21.

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

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- (27) It is necessary to apply a harmonised centralised procedure for safety assessment and authorisation that is efficient, time-limited and transparent. With a view to further harmonising different procedures for the authorisation of food, the safety assessment of novel foods and their inclusion in the Union list should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings <sup>(1)</sup>, which should be applicable whenever it is not specifically derogated from by this Regulation. Upon receipt of an application for authorisation of a product as a novel food, the Commission should assess the validity and applicability of the application. The authorisation of a novel food should also take into account other factors relevant to the matter under consideration, including ethical, environmental, animal welfare factors and the precautionary principle.
- (28) Criteria for the evaluation of the potential risks arising from novel foods should also be laid down. In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the Authority.
- (29) ***Ethical and environmental aspects must be considered as part of the risk assessment during the authorisation procedure. Those aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively.***
- (30) In order to simplify procedures, applicants should be allowed to present a single application for foods regulated under different sectoral food laws. Regulation (EC) No 1331/2008 should therefore be amended accordingly. As a consequence of the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union has replaced and succeeded the European Community, and the word 'Community' should be replaced by 'Union' throughout that Regulation.
- (31) If traditional foods from third countries are included in the list of traditional foods from third countries, they should be allowed to be placed on the market within the Union, under conditions that correspond to those for which the history of safe food use has been demonstrated. As regards the safety assessment and management of traditional food from third countries, their history of safe food use in their country of origin should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets.
- (32) 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.
- (33) The inclusion of a novel food in the Union list of novel foods **■** should be without prejudice to the possibility of evaluating the effects of the overall consumption of a substance which is added to, or used for, the manufacture of that food, or of a comparable product in accordance with **Article 8 of Regulation (EC) No 1925/2006**.
- (34) In 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 Union list **■** should not be used to the benefit of **another** applicant during a limited period of time, without the agreement of the **first** applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Union list of novel foods on the basis of their own scientific data. **In addition, the protection of scientific data should not prevent transparency and access to information relating to the data used in the safety assessment of novel foods. Intellectual property rights should, nevertheless, be respected.**

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 1.

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- (35) 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<sup>(1)</sup>. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore, **the inclusion of a novel food in the Union list may be subject to specific conditions of use or labelling obligations.**
- (36) 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<sup>(2)</sup> 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.**
- (37) The European Group on Ethics in Science and New Technologies **should** be consulted **in specific cases** with a view to obtaining advice on ethical issues regarding **the use of new technologies and** the placing on the market **■** of novel foods.
- (38) Novel foods placed on the market within the Union under Regulation (EC) No 258/97 should continue to be placed on the market. Novel foods authorised in accordance with Regulation (EC) No 258/97 should be included in the Union list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97, **in relation to which** the initial assessment report provided for under **Article 6(3) of that Regulation ■** has not yet been forwarded to the Commission **and in relation to which** an additional assessment report is required in accordance with **Article 6(3) or 6(4) of that Regulation before the date of application of this Regulation, should be considered as applications 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.
- (39) Regulation (EC) 882/2004<sup>(3)</sup> lays down general rules for the performance of official controls to verify compliance with food law. The Member States should be requested to carry out official controls in accordance with that Regulation, in order to enforce compliance with this Regulation.
- (40) Requirements in respect of the hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004<sup>(4)</sup> apply.
- (41) Since the objective of this Regulation, namely laying down harmonised rules for the placing of novel foods on the market within the Union, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (42) The Member States should lay down the rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

<sup>(1)</sup> **■** OJ L 109, 6.5.2000, p. 29 **■**.

<sup>(2)</sup> **■** OJ L 404, 30.12.2006, p. 9 **■**.

<sup>(3)</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

<sup>(4)</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

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- (43) **■** The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997, **in respect of the determination of whether a type of food falls within the scope of this Regulation, the adjustment and adaptation of the definition of 'engineered nanomaterial' to technical and scientific progress and in line with definitions subsequently agreed at international level, rules on how to proceed in cases in which the Commission has no information about use of a food for human consumption before 15 May 1997, as well as in respect of rules for the application of Article 4(1) and Article 9 and the update of the Union list.** It is of particular importance that the Commission **carry out appropriate consultations during its preparatory work, including at expert level,**

HAVE ADOPTED THIS REGULATION:

## Chapter I

### Introductory provisions

#### Article 1

##### Subject matter

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

#### Article 2

##### Scope

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



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

3. *Where necessary and taking into account the scope defined in this Article, the Commission may determine, by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22, whether a type of food falls within the scope of this Regulation.*

#### Article 3

#### Definitions

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:

(a) 'novel food' means **■**:

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

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

(iii) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, if that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, how it is metabolised or the level of undesirable substances;

(iv) food containing or consisting of engineered nanomaterials;

**■**

(b) 'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that 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 of the nanoscale.

Properties that are characteristic of the nanoscale include:

(i) those properties 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;

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

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- (c) *'cloned animals'* means animals produced by means of a method of asexual, artificial reproduction with the aim of producing a genetically identical or nearly identical copy of an individual animal;
- (d) *'descendants of cloned animals'* means animals produced by means of sexual reproduction, in cases in which at least one of the progenitors is a cloned animal;
- (e) *'traditional food from a third country'* means **a natural non-engineered** novel food **■** with a history of food use in **a** third country, **meaning** that the food in question **was, for at least 25 years before ... (\*)**, and continues to be, part of the **normal** diet **■** in a large part of the population of the country;
- (f) *'history of safe food use in a third country'* means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use for at least 25 years in the customary diet of a large part of the population of a country.

3. *In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (b) of paragraph 2 of this Article to technical and scientific progress, and in line with definitions subsequently agreed at international level, by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22.*

#### Article 4

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

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 to which a food was used for human consumption within the Union before 15 May 1997.*
2. *The Commission shall publish those data and the conclusions drawn from the data collection and the non-confidential data supporting it.*
3. *In order to ensure the completeness of information regarding the classification of novel foods, the Commission shall, not later than ... (\*), adopt rules on how to proceed in cases in which the Commission has no information about the use of a food for human consumption before 15 May 1997 by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22.*
4. *The Commission may adopt detailed rules on the application of paragraph 1, in particular as regards the type of information to be collected from Member States and/or from food business operators, by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22.*

#### Article 5

##### *Union list of novel foods*

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

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

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## Chapter II

### Requirements for placing novel foods on the market within the Union

#### Article 6

##### Prohibition of non-compliant novel foods

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

#### I

#### Article 7

##### General conditions for inclusion of novel foods in the Union list

1. A novel food may be included in the Union 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 **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;**
  - (b) it does not mislead the consumer;
  - (c) if it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer;
  - (d) **the opinion of the European Environment Agency, which shall be published no later than the day of the publication of the Authority's assessment, concerning the extent to which the production process and normal consumption have a harmful impact on the environment, is taken into account in the risk assessment;**
  - (e) **the opinion of the European Group on Ethics in Science and New Technologies, which shall be published no later than the day of the publication of the Authority's assessment, concerning the extent to which there are ethical objections, is taken into account in the risk assessment;**
  - (f) **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;**
  - (g) **it is not derived from a cloned animal or its descendants;**
  - (h) **maximum intake levels of the novel food as such or as part of another foodstuff or categories of foodstuffs will be laid down, where required in the interests of safe use;**
  - (i) **cumulative effects of novel foods that are used in different foodstuffs or categories of foodstuffs have been assessed.**
2. **Foods to which production processes have been applied that require specific risk assessment methods (for example, foods produced using nanotechnologies) may not be included in the Union list until such specific methods have been approved by the Authority for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective foods is safe.**
3. A novel food may be included in the Union list only if the competent authority has submitted an opinion establishing that the food is not harmful to health.

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

#### Article 8

##### Content of the Union list

**1. The Commission shall update the Union list, *inter alia* in cases of data protection referred to in Article 14, in accordance with the procedure laid down in Regulation (EC) No 1331/2008. By way of derogation from paragraphs 4 to 6 of Article 7 of Regulation (EC) No 1331/2008, the Regulation updating the Union list shall be adopted by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22. The Commission shall publish the Union list on a dedicated page of its website.**

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

- (a) a specification of the food;
- (b) *the intended use of the food;*
- (c) the conditions of use;
- (d) *where appropriate, additional specific labelling requirements to inform the final consumer;*
- (e) *the date of entry of the novel food in the Union list and the date of receipt of the application;*
- (f) *the name and address of the applicant;*
- (g) *the date and results of the last inspection according to the monitoring requirements laid down in Article 12;*
- (h) *the fact that the entry is based on newly developed scientific evidence and/or proprietary data protected in accordance with Article 14;*
- (i) *the fact that the novel food may only be placed on the market by the applicant specified in point (f), unless a subsequent applicant obtains authorisation for the food without prejudice to the proprietary data of the original applicant.*

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

**4. 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.**

**5. 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.**

**6. Before the expiry of the period referred to in Article 14(1), the Union list shall be updated in accordance with paragraph 1 of this Article so that, provided that the authorised food still meets the conditions laid down in this Regulation, the specific indications referred to in point (h) of paragraph 2 of this Article are no longer included.**

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7. For the purposes of updating the Union list through inclusion of a novel food, where the novel food does not consist of or contain food subject to data protection according to Article 14 and:

- (a) the novel food is equivalent to existing foods, in terms of composition, how it is metabolised and level of undesirable substances, or
- (b) the novel food consists of, or contains, food previously approved for food use in the Union, and the new intended use can be expected not to significantly increase the intake of consumers, including consumers in vulnerable groups,

then the notification procedure referred to in Article 9 shall apply *mutatis mutandis*, by way of derogation from paragraph 1 of this Article.

#### Article 9

##### Traditional food from a third country

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

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

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

3. Within four months from the date on which the notification provided for in paragraph 1 is forwarded by the Commission according to paragraph 2, a Member State and the Authority may inform the Commission that they have justified safety objections, based on scientific evidence, to the placing on the market of the traditional food concerned.

In that case, the food shall not be placed on the market in the Union and Articles 5 - 8 shall apply. The notification as referred to in paragraph 1 of this Article shall be considered as an application referred to in Article 3(1) of Regulation (EC) No 1331/2008. Alternatively, the applicant may choose to withdraw the notification.

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

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

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

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6. **In order to ensure the smooth functioning of the notification procedure provided for in this Article, the Commission shall, before ... (\*), adopt detailed rules on the application of this Article by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22.**

## Article 10

## Technical guidance

Without prejudice to the **provisions of Article 9(1)(a)** of Regulation (EC) No 1331/2008 and **before ... (\*)**, the Commission shall, where appropriate, in close cooperation with the Authority, **the food business operators and small and medium-sized enterprises** make available technical guidance and tools to assist **food business operators and especially small and medium-sized enterprises** in preparing and submitting applications under this Regulation. **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 later than ... (\*), on a publicly accessible page intended for that purpose on the website of the Commission.**

## Article 11

## Opinion of the Authority

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

- (a) consider whether the **novel food, irrespective of whether or not it is intended to replace a food** **█** already existing on the market, **poses any risk of harmful or toxic effects to human health, while also taking into account the implications of any new characteristics;**
- (b) take into account, **for traditional food from a third country**, the history of safe food use.

## Article 12

**█** Obligations on **the** food business operators

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

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

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

4. The producer **and food business operator or the authority** 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;
- (b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.

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

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**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.**

#### Article 13

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

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

The Commission shall make **any such** opinion **of the European Group on Ethics in Science and new Technologies** available to the public.

#### Article 14

##### **■** Data protection

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

- (a) newly developed scientific evidence and/or scientific data was designated as proprietary by the applicant at the time the first application was made (proprietary scientific data);
- (b) the prior applicant had exclusive right of reference to the proprietary **■** data at the time the **prior** application was made;
- (c) the novel food could not have been authorised without the submission of the proprietary **■** data by the prior applicant; and
- (d) **the scientific data and other information was designated as proprietary by the prior applicant at the time the prior application was made.**

However, a prior applicant may agree with a subsequent applicant that such data and information may be used.

2. **Data from research projects partly or completely paid by the Union and/or public institutions shall be published together with the application and shall be freely available for use by other applicants.**

3. **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.**

4. The Commission shall determine, in consultation with the applicant, which information should be granted the protection referred to in paragraph 1, and shall inform the applicant, the Authority and the Member States of its decision.

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## Article 15

### Harmonised data protection

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

## Article 16

### 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.**

## Chapter III

### General provisions

## Article 17

### Penalties

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

## Article 18

### 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 grounds for its decision.**

**2. The Commission, in close cooperation with the Authority, 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.**

## Article 19

### Delegated acts

For the purposes of achieving the objectives of this Regulation as set out in Article 1, the Commission shall, no later than ... (\*\*), adopt further criteria for assessing whether a food was used for human consumption to a significant degree within the Union before 15 May 1997, as referred to in Article 3(2)(a), by means of delegated acts in accordance with Article 20 and subject to the conditions of Articles 21 and 22.

(\*) OJ: please insert date: 12 months after the entry into force of this Regulation.

(\*\*) OJ: Please insert date: 24 months after the entry into force of this Regulation.



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## Article 20

### Exercise of the delegation

1. The power to adopt the delegated acts referred to in **Articles 2(3), 3(3), 4(3), 4(4), 8(1), 9(6) and 19** shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall make a report in respect of the delegated powers at the latest six months before the end of the five-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.
2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
3. The power to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.

## Article 21

### Revocation of the delegation

1. The delegation of power referred to in **Articles 2(3), 3(3), 4(3), 4(4), 8(1), 9(6) and 19** may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall **endeavour to** inform the other institution and the Commission **within a reasonable time** before the final decision is taken, **indicating** the delegated powers which could be subject to revocation and **possible** reasons for a revocation.
3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

## Article 22

### Objections to delegated acts

1. The European Parliament or the Council may object to **a** delegated act within a period of **two** months from the date of notification.

***At the initiative of the European Parliament or the Council this period shall be extended by two months.***

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act **it shall be published in the Official Journal of the European Union and** shall enter into force **at** the date started therein.

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

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

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## Article 23

## Review

1. By ... (\*) and in the light of experience gained, the Commission shall submit to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Articles 3, 9 and 14, accompanied, where appropriate, by any legislative proposals.
2. **No later than ...** (\*\*) the Commission shall **forward** to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a cloning technique and from their **descendants**, followed, where appropriate, by any legislative proposals.
3. The reports and any proposals shall be made accessible to the public.

## Chapter IV

## Transitional and final provisions

## Article 24

## Repeal

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 shall be repealed with effect from ... (\*\*), except with respect to those pending requests governed by Article 26 of this Regulation.

## Article 25

## Establishment of the Union list

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

## Article 26

## Transitional measures

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

■

## Article 27

## Amendments to Regulation (EC) No 1331/2008

Regulation (EC) No 1331/2008 is hereby amended as follows:

- 1) The title is replaced by the following:

(\*) OJ: please insert date: 5 years after the entry into force of this Regulation.

(\*\*) OJ: Please insert date: **Three years and six months** after the date of entry into force of this Regulation.

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

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'Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes, food flavourings and novel foods'.

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

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

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

**█**

(\*) OJ L ... (\*\*)

(†) OJ: Please insert number and date of adoption of this Regulation.

(\*\*) OJ: Please insert the publication references of this Regulation.'

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

4) The title of Article 2 is replaced by the following:

'Union list of substances or products'.

5) The following paragraph is added to Article 4:

'3. A single application relating to a substance or product may be made to update the different Union lists regulated under the different sectoral food laws in so far as the application complies with the requirements of each of the sectoral food laws.'

6) The following sentence is inserted at the beginning of Article 6(1):

'In the case of scientific grounds for safety concerns, additional information concerning risk assessment shall be identified and requested from the applicant.'

**█**

7) The term 'Community' shall be replaced by 'Union' throughout the text.

Article 28

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... (\*).

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

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However, Articles 25, 26 and 27 shall apply from ... (\*). Furthermore, by way of derogation from the second paragraph of this Article and by way of derogation from the second paragraph of Article 16 of Regulation (EC) No 1331/2008, applications may be made in accordance with this Regulation as from ... (\*) for the authorisation of food referred to in point (iv) of Article 3(2)(a) of this Regulation, where such food is already on the market within the Union at that date.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at,

For the European Parliament  
The President

For the Council  
The President

(\*) OJ: please insert date: the entry into force of this Regulation.

## **Industrial emissions (integrated pollution prevention and control) (recast) \*\*\*II**

P7\_TA(2010)0267

**European Parliament legislative resolution of 7 July 2010 on the Council position at first reading for adopting a directive of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) (recast) (11962/2/2009 – C7-0034/2010 – 2007/0286(COD))**

(2011/C 351 E/33)

(Ordinary legislative procedure: second reading)

*The European Parliament,*

- having regard to the Council position at first reading (11962/2/2009 – C7-0034/2010),
- having regard to the Commission proposal to Parliament and the Council (COM(2007)0844),
- having regard to Article 251(2) and Article 175(1) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0002/2008),
- having regard to the Commission Communication to Parliament and the Council entitled ‘Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures’ (COM(2009)0665),
- having regard to Article 294(7) and Article 192(1) of the Treaty on the Functioning of the European Union,
- having regard to its position at first reading <sup>(1)</sup>,
- having regard to the opinion of the European Economic and Social Committee of 14 January 2009 <sup>(2)</sup>,

<sup>(1)</sup> OJ C 87 E, 1.4.2010, p. 191.

<sup>(2)</sup> OJ C 182, 4.8.2009, p. 46.