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"A" ITEM NOTE

from :	General Secretariat of the Council
to :	COUNCIL
No. Cion prop. :	5431/08 DENLEG 6 CODEC 59
No. prev. doc. :	10916/1/09 DENLEG 42 CODEC 842 REV 1
Subject :	Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure] **(LA) (First reading)** - *Political agreement*

1. On 15 January 2008, the Commission submitted to the Council and the European Parliament the above-mentioned proposal, based on Article 95 of the Treaty[1]. The proposed Regulation should replace current Regulation (EC) No 258/97 on novel foods and novel food ingredients that is in force since 15 May 1997. The objective of the proposal is to ensure food safety, protection of human health and consumer interests and the effective functioning of the internal market.

[1] 5431/08 (COM(2007) 872 final)

2. On 29 May 2008, the European Economic and Social Committee (EESC) adopted its opinion pursuant to Article 95 of the EC Treaty (obligatory consultation) by 71 votes to one with two abstentions[2].

3. The proposal has been examined by the Working Party on Foodstuffs (hereinafter "Working Party") since January 2008. The results of discussions during the Slovenian and French Presidencies are summed up in the progress reports submitted to the EPSCO Council of 10 June 2008[3] and 16 December 2008[4] respectively.

4. At the beginning of the Czech Presidency, discussions took place between the European Parliament and the Council in view of a possible first reading agreement.

5. The European Parliament decided to proceed with the first reading vote and adopted its first reading opinion on 25 March 2009, passing 80 amendments to the Commission proposal[5].

6. The Permanent Representatives Committee discussed the subject at its meetings on 15 May, 3 June and 10 June 2009 with a view to political agreement.

7. On 16 June 2009, the Permanent Representatives Committee agreed by unanimity to submit the text, as an "A" item, to the Council for political agreement. The Commission maintained its reservation on the inclusion of offspring of cloned animals into the scope of the proposed regulation. The United Kingdom and Greece indicated that they would abstain.

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2 OJ C 224, 30.8.2008, p.81
3 9689/08.
4 17100/08
5 7990/09 (Outcome of the European Parliament's first reading)

8. The Council is therefore invited to:

- reach by unanimity a political agreement on this proposal in the form of the text in the Annex to this note (United Kingdom and Greece abstaining);

- note the statements contained in doc. 10754/09 ADD 1 to be entered in the minutes of the Council meeting;

- to instruct the Committee of Permanent Representatives to proceed with the legal and linguistic verification of the text so that it may be adopted as a common position at one of the forthcoming sessions of the Council.

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Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No 1331/2008 [common procedure] (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[6],

Having regard to the opinion of the European Economic and Social Committee[7],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[8],

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as to their social and economic interests. Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of novel foods may hinder their free movement, thereby creating unfair competition conditions.

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

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6 OJ C 106,26.4.2008, p. 6.
7 OJ C 224, 30.8.2008, p. 81.
8 OJ C […],[…], p. […].

(3) Community rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[9] 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[10]. For the sake of clarity, Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 should be repealed. Recommendation 97/618/EC[11] should become, therefore, obsolete as regards novel foods. Regulation (EC) No 258/97 should be replaced by this Regulation.

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

(5) The rules with regard to food law 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[12] apply. 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.

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9 OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

10 OJ L 253, 21.9.2001, p. 17.

11 OJ L 253, 16.9. 1997, p. 1.

12 OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

(6) It should also be clarified that a food should be considered as novel when it is applied a production technology which was not previously used for food production in the Community. In particular, emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from animals produced by non-traditional breeding techniques and from their offspring, foods derived from plants produced by non-traditional breeding techniques, foods produced by new production processes, which might have an impact on food and foods containing or consisting of engineered nanomaterials. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.

Furthermore, it should be clarified that foods from third countries which are novel in the Community can be considered as traditional only when they are derived from primary production as defined in Article 3 (17) of Regulation 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should not include foods produced from animals or plants to which a non-traditional breading technique was applied and foods produced from offspring of such animals as well as foods to which a new production process is applied.

(6a) However, in the light of the opinion of the European Group on Ethics in Science and New technologies issued on 16 January 2008 and of the opinion of the European Food Safety Authority adopted on 15 July 2008, cloning techniques of animals, such as the somatic nuclear cell transfer technique, have specific characteristics that imply that this Regulation cannot manage all the issues of cloning. Therefore, food produced from animals obtained by using a cloning technique and from their offspring should be subject to a report submitted by the Commission to the European Parliament and the Council, followed, if appropriate, by a legislative proposal. If specific legislation is adopted, the scope of this Regulation should be adapted accordingly.

(7) 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 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[13], prior to 15 May 1997, 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.

(7a)

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

(8) Food products produced from food ingredients that do not fall within the scope of the Regulation, in particular by changing the ingredients of the food, the composition or amounts of those food ingredients, should not be considered as novel food. However, modifications of a food ingredient, e. g. selective extracts or the use of other parts of a plant, that have so far not been used for human consumption within the Community, should still fall within the scope of the Regulation.

[13] OJ L 183, 12.7.2002, p. 51. Directive as amended by Commission Directive 2006/37/EC (OJ L 94, 1.4.2006, p. 32).

(8a) The provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use[14] 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 product is a medicinal product, restrict the placing on the market of such product in accordance with Community law. Moreover, medicinal products are excluded from the definition of food as established by Article 2 of Regulation (EC) No 178/2002 and should not be subject to this Regulation.

(9) Novel foods authorised under the Regulation (EC) No 258/97 should maintain their novel food status but authorisation should be required for any new uses of such foods.

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008[15], flavourings falling within the scope of Regulation (EC) No1334 /2008 of the European Parliament and of the Council of 16 December 2008[16], 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[17], enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008[18] 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[19] are not covered by this Regulation.

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14 OJ L 311, 28.11.2001, p. 67.
15 OJ L 354, 31.12.2008, p. 16
16 OJ L 354, 31.12.2008, p. 34
17 OJ L 157, 24.6.1988, p. 28. Directive as last amended by Regulation (EC) No 1882/2003.
18 OJ L 354, 31.12.2008, p. 7
19 OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

(11) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[20], Directive 2002/46/EC and 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[21] should therefore be excluded from the scope of this Regulation. However, these specific legislations do not deal with the 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 amendments of the specific legislations, those 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 which affects the nutritional value, metabolism or level of undesirable substances.

(12) 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. At the same time they should remain subject to the rules provided for in Directive 89/398/EEC and in the specific Directives referred to in Article 4(1) thereof and in Annex I thereof, in Directive 2002/46/EC and in Regulation (EC) No 1925/2006.

(13) Whether a food was used for human consumption to a significant degree before 15 May 1997, should be based on information submitted by food business operators and, where appropriate, supported by other information available in the Member States. When there is not sufficient information on human consumption before 15 May 1997 available, a simple and transparent procedure, involving the Commission, the Member States and any parties concerned, should be established for collecting that information.

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[20] OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.
[21] OJ L 404, 30.12.2006, p. 26.

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

(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 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for the food additives, food enzymes and food flavourings, which should be applicable whenever it is not specifically derogated by the present Regulation. Upon receipt of an application for approval of a product as a novel food the Commission should asses 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.

(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").

(16a) At present, there is inadequate information on the risks associated with engineered nanomaterials. In order to better assess their safety the Commission, in cooperation with the Authority, should develop test methodologies which take into account specific characteristics of engineered nanomaterials.

(17) 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 of the European Parliament and the Council establishing the common procedure for food additives, food enzymes and food flavourings should therefore be amended accordingly.

(17a) Traditional foods from third countries may be placed on the Community market under conditions that correspond to those for which the history of safe food use has been demonstrated if they are included in the list of traditional foods from third countries. As regards the safety assessment and management of traditional food from third countries, their history of safe food 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.

(18) Where appropriate and based on the conclusions of the safety assessment, post-market monitoring requirements for the use of novel foods for human consumption should be introduced.

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

(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.

(21) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs[22] and, where necessary, to the nutritional labelling requirements laid down in Council Directive 90/496/EEC of 24 of September 1990 on nutrition labelling for foodstuffs. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use. Therefore, the inclusion of a novel food in the Community list or in the list of traditional foods from third countries may impose specific conditions of use or labelling obligations, which may *inter alia* relate to any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population.

(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[23] 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.

(23) […]

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

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22 OJ L 109, 6.5.2000, p. 29. Directive as last amended by Commission Directive 2006/142/EC (OJ L 368, 23.12.2006, p. 110).

23 OJ L 404, 30.12.2006, p. 9. Corrected version (OJ L 12, 18.1.2007, p. 3).

24 SEC (97) 2404.

(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 before the date of application of this Regulation should be transformed as an application under this Regulation where the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other pending requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation should be processed under the provisions of Regulation (EC) No 258/97.

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

(27) 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.

(28) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[25].

[25] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11). Consolidated version (OJ C 255, 21.10.2006, p. 4).

(29) In particular, power should be conferred on the Commission to establish the criteria under which foods may be considered as having been used for human consumption to a significant degree within the Community before 15 May 1997 as well as to clarify certain definitions and to adopt any appropriate transitional measures. Since those measures are of general scope and are designed to amend and/or supplement this Regulation by the addition of new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Furthermore, power should be conferred on the Commission to adjust and adapt Article 3(2)(c) to technical and scientific developments. Since those measures are of general scope and are designed to amend this Regulation by the addition of new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Finally, power should be conferred on the Commission to update the list of traditional foods from third countries and the Community list. Since those measures are of general scope and are designed to supplement this Regulation by the addition of new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(30) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[26] lays down general rules for the performance of official controls to verify compliance with food law. Therefore, the Member States are to carry out official controls in accordance with Regulation (EC) No 882/2004, in order to enforce compliance with the present Regulation. Requirements on the hygiene of the foods as laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council on 29 April 2004 on the hygiene on foodstuffs[27] apply.

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[26] OJ L 165, 30.4.2004, p. 1. Corrected version (OJ L 191, 28.5.2004, p. 1). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

[27] OJ L 139, 30.4.2004, p.1.

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 in the Community with a view to ensuring a high level of protection of human health and consumers' interests, whilst ensuring the effective functioning of the internal market, taking into account, where appropriate, the protection of the environment and animal welfare.

Article 2

Scope

1. This Regulation shall apply to the placing of novel foods on the market in the Community.

2. This Regulation shall not apply to:

   (a) foods when and insofar as they are used as:

      (i) food additives falling within the scope of Regulation (EC) No 1333/2008 [on food additives];
      (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;

(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, 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.

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 food that has not been used for human consumption to a significant degree within the Community before 15 May 1997, including :

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

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

(iii) food to which is applied a new production process not used for food production within the Community 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; and

(iv) food containing or consisting of engineered nanomaterials; and

(v) traditional food from a third country.

Food ingredients used exclusively in food supplements within the Community before 15 May 1997 shall require authorisation according to this Regulation if they are to be used in foods other than food supplements. However, if a food has been used exclusively as or in a food supplement prior that date, it 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, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3), before the date of application of this Regulation.

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

(c) "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;

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

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

3. If appropriate, the Commission may adopt further criteria to clarify the definitions under points (a)(i), (a)(ii), a(iii), (a)(iv), (d) and (e), which are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it, in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

4. In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (c) of paragraph 2 to technical and scientific progress and with definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Article 4

Procedure for determination of novel food status

1. Food business operators shall verify the status of the food they intend to place on the Community market with respect to the scope of this Regulation.

2. In case of doubts, food business operator shall consult the relevant competent authority for novel foods as defined in Article 15 of Regulation No 1331/2008 [common procedure] on the status of this food. On request from the relevant competent authority, food business operator shall submit the information on the extend to which this food has been used for human consumption within Community before 15 May 1997.

3. Where necessary, the competent authority may consult other competent authorities and the Commission concerning the extent to which a food has been used for human consumption within the Community before 15 May 1997. Replies to such a consultation shall be transmitted also to the Commission. The Commission shall summarize the replies received communicate the result of the consultation to the competent authorities.

4. Implementing measures for the application of paragraph 3 may be adopted in accordance with the regulatory procedure referred to in Article 14(2).

Article 4a

Interpretation decisions

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.

Chapter II

Requirements for placing novel foods on the market

Article 5

Lists of novel foods

1. The Commission shall maintain a Community list of authorised novel foods other than traditional foods from third countries (hereinafter "the Community list"), which will be published in accordance with Article 2(1) of Regulation (EC) No 1331/2008 [common procedure].

1a. The Commission shall establish and maintain a list of traditional foods from third countries authorised pursuant to Article 8(5) of this Regulation, which shall be published in the C series of the Official Journal of the European Union.

2. Only novel foods included in the Community list or in the list of traditional foods from third countries may be placed on the market.

Article 5a

Prohibition of non-compliant novel foods

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

Article 6

General conditions for inclusion of novel foods in the lists

A novel food may be included in the lists 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;

(b) it does not mislead 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.

Article 7

Content of the Community list

1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No 1331/2008 [common procedure] and, where applicable, in accordance with Article 12.

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 and, where applicable, information specified in Article 12(3).

Article 7a

Content of the list of traditional foods from third countries

1. The list of traditional foods from third countries shall be updated in accordance with the procedure laid down in Article 8 of this Regulation.

2. The entry of a traditional food from a third country in the list of traditional foods from third countries shall include a specification of the food, and, where appropriate, specify the conditions of use and/or additional specific labelling requirements to inform the final consumer.

Article 8

Traditional food from a third country

1. By way of derogation from the procedure laid down in article 7(1) of this Regulation, an interested party, as referred to in Article 3(1) of Regulation (EC) No 1331/2008 [common procedure], who intends to place on the Community market a traditional food from a third country as referred to in Article 3(2)(d), shall submit an application to the Commission.

   The application shall include:

   (a) the name and description of the food,

   (b) its composition,

   (c) its country of origin,

   (d) documented data demonstrating the history of safe food use in any third country,

   (e) where applicable, the conditions of use and specific labelling requirements,

   (f) a summary of the content of the application.

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

2. The Commission shall forward the valid application as referred to in paragraph 1 without delay to the Member States and the European Food Safety Authority (hereinafter referred to as the Authority).

3. Within six months of receipt of an application, the Authority shall give its opinion. Whenever the Authority seeks supplementary information from the interested party, it shall, after consulting the interested party, lay down a period within which this information shall be provided. The six months time limit shall be automatically extended by this additional period. The supplementary information shall be made available to the Member States and the Commission by the Authority.

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

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

   (b) that the composition of the food and, where applicable the conditions of its use, does not pose health risk to consumers in the Community.

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

5.

   a) Within three months of the Authority giving its opinion, the Commission shall submit to the committee referred to in Article 14 (1) a draft measure to update the list of traditional foods from third countries, taking account of the opinion of the Authority, any relevant provisions of Community Law and any other legitimate factors relevant to the matter under consideration. This measure designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14 (3). The Commission shall inform the interested party accordingly.

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

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

7. Detailed rules for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 14(2), before the date of application of this Regulation provided under Article 20.

Article 9

Technical guidance

Notwithstanding the provisions of Article 9 (1)(a) of Regulation (EC) 1331/2008 [common procedure] and before the date of application of this Regulation the Commission shall, where appropriate, in close cooperation with the Authority and after consultation with interested parties, make available technical guidance and tools to assist interested parties, in particular food business operators and especially small and medium-sized enterprises or other interested parties in preparing and submitting applications under this Regulation.

Article 10

Opinion of the Authority

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

(a) compare 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;

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

Article 11

Special obligations on the food business operators

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.

2. The producer 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.

Article 11a

Committee on Ethics and new Technologies

Where appropriate, on ethical questions relating to science and new technologies of major ethical importance[28], the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies [29], with a view to obtaining its opinion on ethical issues.

The Commission shall make this opinion available to the public.

[28] See OJ L 127, 20.5.2005, p.17.

[29] Established by Commission Decision of 16 December 1997, SEC(97) 2404.

Article 12

Authorisation procedure in cases of data protection

1. On request by the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and/or scientific data to support the application may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

   (a) newly developed scientific evidence and/or scientific data has been designated as proprietary by the applicant at the time the first application was made; and

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

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

1a. 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.

2. By way of derogation from Article 7(5) of Regulation (EC) No 1331/2008 [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) of this Regulation in cases where proprietary newly developed scientific evidence and proprietary data are protected in accordance with this Article. In this case, the authorisation shall be granted for the period specified in the first paragraph.

3. In the cases referred to in the second paragraph the entry of a novel food in the Community list shall indicate, in addition to the information referred to in Article 7(2) of this Regulation:

(a) the date of entry of the novel food in the Community list;

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

(c) the name and address of the applicant;

(d) the fact that the novel food is authorised for placing on the market only by the applicant specified in point (c) unless a subsequent applicant obtains authorisation for the food without reference to that proprietary data.

4. Before the expiry of the period referred to in paragraph 1, the Community list shall be updated to amend non-essential elements of this Regulation by supplementing it in accordance with the regulatory procedure with scrutiny referred to in Article 14(3) of this Regulation so that, provided that the authorised food still meets the condition laid down in this Regulation, the specific indications referred to in paragraph 3, of this Article, are no longer included.

Article 12a

Information of the public

The Commission shall make available to the public:

(a) the Community list specified in paragraph 1 of Article 5 and the list of traditional foods from third countries specified in paragraph 1a of Article 5, on a single dedicated page of the Commission website;

(b) the summaries of the applications submitted under this Regulation;

(c) the findings of the consultations referred to in Article 4(3).

Implementing measures for the application of this Article, including arrangements for making public the outcome of the consultations under point (c), may be adopted in accordance with the regulatory procedure referred to in Article 14(2).

Chapter III
General provisions

Article 13
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 within 24 months after the date of publication of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

Article 14
Committee

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

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 15

Review

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 Article 3, Article 8 and Article 12, accompanied, where appropriate, by any proposals.

2. No later than 1 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.

3. The reports and any proposals shall be made accessible to the public.

Chapter IV
Transitional and final provisions

Article 16

Repeal

Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 shall be repealed with effect from the date of application of this Regulation, except with respect to pending requests which according to Article 18(1) are to be processed under Regulation (EC) No 258/97.

Article 17

Establishment of the Community list

Within 24 months from the date of publication the Commission shall establish the Community list by entering novel foods authorised and/or notified under Articles 4, 5 and 7 of Regulation (EC) No 258/97 in the Community list, including any existing authorisation conditions, as appropriate.

Article 18

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 before the date of application of this Regulation shall be transformed to an application under this Regulation where an initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in cases where the additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other pending requests submitted under Article 4 of Regulation (EC) No 258/97 before 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).

Article 19

Amendments to Regulation (EC) No 1331/2008 [common procedure]

Regulation (EC) No 1331/2008 [common procedure] is amended as follows:

(1) The title is replaced by the following:
"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, paragraph 1, is replaced by the following:

"1 This Regulation lays down a common procedure for the assessment and authorisation (hereinafter referred to as the "common procedure") of food additives, food enzymes, food flavourings and source materials of food flavourings and of food ingredients with flavouring properties used or intended for use in or on foodstuffs and novel foods (hereinafter referred to as the "substances or products") which contributes to the free movement of food within the Community and to a high level of protection of human health and to a high level of consumer protection, including the protection of consumer interests. This Regulation shall not apply to smoke flavourings falling within the scope of Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods[30]."

[30] OJ L 309, 26.11.2003, p. 1.

(3) In Article 1, paragraph 2 is replaced by the following:

"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 Community pursuant to

Regulation (EC) No 1333/2008 on food additives, Regulation (EC) No 1332/2008 on food enzymes, Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and Regulation (EC) No …/2008 [on novel foods] (hereinafter referred to as the "sectoral food laws")."

(4) In Article 1 paragraph 3, Article 2 paragraphs 1 and 2, Article 7 paragraph 4, 5 and 6, Article 9 paragraph 2, Article 12 paragraph 1 and Article 13 the word 'substance' or 'substances' is replaced by 'substance or product' or 'substances or products'.

(5) The title of Article 2 is replaced by the following:
"Community list of substances or products"

(6) In Article 4 the following paragraph 3 is added:

3. A single application relating to a substance or product may be made to update the different Community 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."

(7) The following sentence is added at the beginning of Article 6, paragraph 1:
"In the case of scientific grounds for safety concerns, additional information concerning risk assessment, shall be identified and requested from the applicant."

Article 20

Entry into force

1. This Regulation shall enter into force on [the twentieth day] following that of its publication in the *Official Journal of the European Union*. Subject to paragraphs 2 and 3, it shall apply from [24 months after the date of publication].

2. Articles 17, 18 and 19 shall apply from the date of the entry into force of this Regulation.

3. By way of derogation from Article 16, second paragraph, of Regulation (EC) No 1331/2008, applications may be made in accordance with this Regulation as from its date of entry into force for authorisation of food covered by Article 3(2)(a)(iv) where such food is already on the market as at that date.

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*