

**POSITION (EU) No 6/2010 OF THE COUNCIL AT FIRST READING**

**with a view to the adoption of 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**

**Adopted by the Council on 15 March 2010**

(Text with EEA relevance)

(2010/C 122 E/03)

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) 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 conditions of competition.
- (2) A high level of protection of human health should be assured in the pursuit of Union policies. Due attention should be given, where appropriate, to the protection of the environment and to animal welfare.
- (3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament

and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(3)</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>(4)</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 For the sake of clarity, Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 should be repealed and Regulation (EC) No 258/97 should be replaced by this Regulation.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>(5)</sup> should therefore become obsolete as regards novel foods.

- (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 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.
- (5) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(6)</sup> applies. The existing definition of novel food should be clarified and updated by replacing the existing categories with a reference to the general definition of food in that Regulation.
- (6) It should also be clarified that a food is to be considered as novel when a production technology which was not previously used for food production in the Union is applied to that food. In particular, emerging technologies

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

<sup>(2)</sup> Position of the European Parliament of 25 March 2009 (not yet published in the Official Journal) and Council Position at first reading of 15 March 2010, position of the European Parliament of ... (not yet published in the Official Journal).

<sup>(3)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(4)</sup> OJ L 253, 21.9.2001, p. 17.

<sup>(5)</sup> OJ L 253, 16.9.1997, p. 1.

<sup>(6)</sup> OJ L 31, 1.2.2002, p. 1.

in breeding and food production processes which have an impact on food, and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from animals produced by non-traditional breeding techniques and from their offspring, foods derived from plants produced by non-traditional breeding techniques, foods produced by new production processes which might have an impact on food, and foods containing or consisting of engineered nanomaterials. Foods derived from new plant varieties or animal breeds produced by traditional breeding techniques should not be considered as novel foods. Furthermore, it should be clarified that foods from third countries which are novel in the Union can be considered as traditional only when they are derived from primary production as defined in Regulation (EC) No 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should neither include foods produced from animals or plants to which a non-traditional breeding technique was applied or foods produced from the offspring of such animals, nor foods to which a new production process is applied.

- (7) However, in the light of the opinion of the European Group on Ethics in Science and New Technologies, established by Commission Decision of 16 December 1997, issued on 16 January 2008 and of the opinion of the European Food Safety Authority adopted on 15 July 2008, techniques for the cloning of animals, such as somatic cell nuclear transfer, have specific characteristics such that this Regulation cannot address all the issues of cloning. Therefore, food produced from animals obtained by using a cloning technique and from the offspring thereof should be subject to a report submitted by the Commission to the European Parliament and the Council, followed, if appropriate, by a legislative proposal. If specific legislation is adopted, the scope of this Regulation should be adapted accordingly.
- (8) Implementing measures should be adopted to provide for criteria to facilitate the assessment of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997. If, prior to that date, a food was used exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC<sup>(1)</sup>, it should be allowed to be placed on the market within the Union after that date for the same use without being considered a novel food. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was

used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than in, or as, a food supplement should be authorised in accordance with this Regulation.

- (9) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for engineered nanomaterial at international level. The Union should 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.
- (10) Food products produced from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food, their composition or amount, should not be considered a novel food. However, modifications of a food ingredient, e.g. selective extracts or the use of other parts of a plant, that have so far not been used for human consumption within the Union, should still fall within the scope of this Regulation.
- (11) The provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>(2)</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.
- (12) 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.

<sup>(1)</sup> 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 (OJ L 183, 12.7.2002, p. 51).

<sup>(2)</sup> OJ L 311, 28.11.2001, p. 67.

- (13) Foods which are intended for technological uses or which are genetically modified should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 <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.
- (14) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods <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.
- (15) Novel foods, other than vitamins and minerals, intended for particular nutritional uses, for food fortification or as food supplements, should be assessed in conformity with this Regulation. They should also remain subject to the rules provided for in Directive 2002/46/EC, in Regulation (EC) No 1925/2006, in Directive 2009/39/EC, and in the specific Directives referred to in Directive 2009/39/EC and in Annex I thereto.
- (16) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in the Member States. When there is no or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and any parties concerned, should be established for collecting that information.
- (17) Novel foods should be placed on the market within the Union only if they are safe and do not mislead the consumer. In addition, where the novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally disadvantageous for the consumer.
- (18) It is necessary to apply a harmonised centralised procedure for safety assessment and authorisation that is efficient, time-limited and transparent. With a view to further harmonising different procedures for the authorisation of food, the safety assessment of novel foods and their inclusion in the Union list should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings <sup>(8)</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.

<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.

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

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

<sup>(8)</sup> OJ L 354, 31.12.2008, p. 1.

- (21) 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.
- (22) If traditional foods from third countries are included in the list of traditional foods from third countries, they should be allowed to be placed on the market within the Union, under conditions that correspond to those for which the history of safe food use has been demonstrated. As regards the safety assessment and management of traditional food from third countries, their history of safe food use in their country of origin should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets.
- (23) 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.
- (24) The inclusion of a novel food in the Union list of novel foods or in the list of traditional foods from third countries should be without prejudice to the possibility of evaluating the effects of the overall consumption of a substance which is added to, or used for the manufacture of that food, or of a comparable product in accordance with Regulation (EC) No 1925/2006.
- (25) Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. That data and information should not be used to the benefit of a subsequent applicant, during a limited period of time, without the agreement of the prior applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Union list of novel foods on the basis of their own scientific data.
- (26) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC<sup>(1)</sup>
- and, where necessary, to the nutritional labelling requirements laid down in Directive 90/496/EEC<sup>(2)</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, when a novel food is included in the Union list or in the list of traditional foods from third countries, specific conditions of use or labelling obligations may be imposed, which might, *inter alia*, relate to any specific characteristic or food 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.
- (27) Regulation (EC) No 1924/2006<sup>(3)</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.
- (28) The European Group on Ethics in Science and New Technologies may be consulted, where appropriate, with a view to obtaining advice on ethical issues regarding the placing on the market within the Union of novel foods.
- (29) Novel foods placed on the market within the Union under Regulation (EC) No 258/97 should continue to be placed on the market. Novel foods authorised in accordance with Regulation (EC) No 258/97 should be included in the Union list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97 before the date of application of this Regulation should be transformed into an application under this Regulation where the initial assessment report provided for under Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with that Regulation. Other pending requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation should be processed under the provisions of Regulation (EC) No 258/97.
- (30) Regulation (EC) No 882/2004<sup>(4)</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.

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

<sup>(2)</sup> Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276, 6.10.1990, p. 40).

<sup>(3)</sup> 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 (OJ L 404, 30.12.2006, p. 9).

<sup>(4)</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).

(31) Requirements in respect of the hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004 <sup>(1)</sup> apply.

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

(33) 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.

(34) The measures necessary for the implementation of this Regulation should be adopted in accordance with Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(2)</sup>.

(35) In particular, the Commission should be empowered to clarify certain definitions in order to ensure a harmonised implementation of these provisions by the Member States on the basis of relevant criteria, including the definition of 'engineered nanomaterial', taking into account the technical and scientific developments, and the non-traditional animal breeding technique that includes techniques used for asexual reproduction of genetically identical animals not used for food production within the Union before 15 May 1997. Furthermore, the Commission should be empowered to adopt any appropriate transitional measures and to update the list of traditional foods from third countries and the Union list.

(36) In addition, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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. It is of particular importance that the Commission consult experts in the preparatory phase in accordance with the commitment of the Commission undertaken in the Communication of 9 December 2009 on the implementation of Article 290 of the Treaty on the Functioning of the European Union,

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 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 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;

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

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

- (v) vitamins and minerals falling within the respective scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Directive 2009/39/EC, except for vitamin and mineral substances already authorised, which are obtained by production methods or using new sources that were not taken into account when they were authorised under specific legislation, where those production methods or new sources give rise to the significant changes referred to in point (iii) of Article 3(2)(a) of this Regulation;
- (b) foods falling within the scope of Regulation (EC) No 1829/2003.

### 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 was not used for human consumption to a significant degree within the Union before 15 May 1997, including:
- (i) food of animal origin, when a non-traditional breeding technique not used for food production within the Union before 15 May 1997 is applied to the animal, and food derived from the offspring of these animals;
- (ii) food of plant origin, when a non-traditional breeding technique not used for food production within the Union before 15 May 1997 is applied to the plant, if that non-traditional breeding technique applied to a plant gives rise to significant changes in the composition or structure of the food, which affect its nutritional value, how it is metabolised or the level of undesirable substances;
- (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 nano-materials;
- (v) traditional food from a third country; and

(vi) food ingredients used exclusively in food supplements within the Union before 15 May 1997, if they are to be used in foods other than food supplements. However, if a food has been used exclusively as, or in, a food supplement prior that date, it may be placed on the market within the Union after that date for the same use without being considered a novel food;

(b) 'offspring' means an animal produced by a traditional breeding technique, where at least one of its parents is an animal produced by a non-traditional breeding technique;

(c) '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 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 than the novel food under sub-points (i) to (iv) of point (a), derived from primary production, with a history of food use in any third country, such that the food in question has been and continues to be part of the customary diet for at least 25 years in a large part of the population of the country;
- (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. The Commission may adopt further criteria to clarify the definitions in sub-points (i) to (iv) of point (a), and in points (c), (d) and (e) of paragraph 2 of this Article in accordance with the regulatory procedure referred to in Article 19(2).

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

2. In case of doubt, food business operators shall consult the relevant competent authority for novel foods as defined in Article 15 of Regulation (EC) No 1331/2008 on the status of the food in question. On request from the relevant competent authority, food business operators shall submit information concerning the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

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

4. The Commission may adopt implementing measures for paragraph 3 of this Article in accordance with the regulatory procedure referred to in Article 19(2).

*Article 5***Interpretation decisions**

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 19(2) whether a type of food falls within the scope of this Regulation.

## CHAPTER II

**REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN THE UNION***Article 6***Prohibition of non-compliant novel foods**

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

*Article 7***Lists of novel foods**

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

2. The Commission shall establish and maintain a list of traditional foods from third countries authorised pursuant to Article 11(5) of this Regulation, which shall be published in the C series of the *Official Journal of the European Union*.

3. Only novel foods included in the Union list or in the list of traditional foods from third countries may be placed on the market within the Union.

*Article 8***General conditions for inclusion of novel foods in the lists**

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

- (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) 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.

*Article 9***Content of the Union list**

1. The Union list shall be updated in accordance with the procedure laid down in Regulation (EC) No 1331/2008 and, where applicable, in accordance with Article 16 of this Regulation.

2. The entry for a novel food in the Union list shall include a specification of the food, and, where appropriate, specify the conditions of use, additional specific labelling requirements to inform the final consumer, and/or a post-market monitoring requirement and, where applicable, the information referred to in Article 16(4).

*Article 10***Content of the list of traditional foods from third countries**

1. The list of traditional foods from third countries shall be updated in accordance with the procedure laid down in Article 11.

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

*Article 11***Procedure for including a traditional food from a third country in the list**

1. By way of derogation from the procedure laid down in Article 9(1) of this Regulation, an interested party referred to in Article 3(1) of Regulation (EC) No 1331/2008, who intends to place on the market within the Union a traditional food from a third country, shall submit an application to the Commission.

The application shall include:

- (a) the name and description of the food,
- (b) its composition,
- (c) its country of origin,
- (d) documented data demonstrating the history of safe food use in any third country,
- (e) where applicable, the conditions of use and specific labelling requirements,
- (f) a summary of the content of the application.

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

2. The Commission shall forward the valid application referred to in paragraph 1 without delay to the Member States and the Authority.

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

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

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

- (b) the composition of the food and, where applicable, the conditions of its use, do not pose a health risk to consumers in the Union.

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

5. Within three months of the Authority giving its opinion, the Commission shall, in accordance with the regulatory procedure referred to in Article 19(2), update the list of traditional foods from third countries, taking account of the opinion of the Authority, any relevant provisions of Union law and any other legitimate factors relevant to the matter under consideration. The Commission shall inform the interested party accordingly. If the Commission decides not to proceed with an update of the list of traditional foods from third countries, it shall inform the interested party and the Member States accordingly, indicating the reasons for not considering the update justified.

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

7. By ... (\*), the Commission shall adopt detailed rules for the implementation of this Article in accordance with the regulatory procedure referred to in Article 19(2).

*Article 12***Technical guidance**

Without prejudice to the implementing measures adopted under point (a) of Article 9(1) of Regulation (EC) No 1331/2008 and by ... (\*), the Commission shall, where appropriate, in close cooperation with the Authority and after consultation with interested parties, make available technical guidance and tools to assist interested parties in preparing and submitting applications under this Regulation; in particular, food business operators, especially small and medium-sized enterprises.

*Article 13***Opinion of the Authority**

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

- (a) consider whether the food is as safe as food from a comparable food category already existing on the market within the Union or as safe as the food that the novel food is intended to replace;

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

(\*) 2 years after the entry into force of this Regulation.



*Article 14***Special obligations on food business operators**

1. The Commission may, for food safety reasons and following the opinion of the Authority, impose a requirement for post-market monitoring. The food business operator placing the food on the market within the Union shall be responsible for fulfilling the post-marketing requirements specified in the entry of the food concerned in the Union 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 15***European Group on Ethics in Science and New Technologies**

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

The Commission shall make this opinion available to the public.

*Article 16***Authorisation procedure in cases of data protection**

1. On request by the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and/or scientific data supporting the application may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Union list without the agreement of the prior applicant. This protection shall be granted where:

- (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 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.

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

2. 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.

3. By way of derogation from Article 7(5) of Regulation (EC) No 1331/2008, the updating of the Union list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure referred to in Article 19(2) of this Regulation in cases where proprietary scientific data are protected in accordance with this Article. In this case, the authorisation shall be granted for the period specified in paragraph 1 of this Article.

4. In the cases referred to in paragraph 3 of this Article, the entry of a novel food in the Union list shall indicate, in addition to the information referred to in Article 9(2) of this Regulation:

- (a) the date of entry of the novel food in the Union list;
- (b) the fact that the entry is based on proprietary newly developed scientific evidence and/or proprietary scientific data protected in accordance with this Article;
- (c) the name and address of the applicant;
- (d) the fact that the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c), unless a subsequent applicant obtains authorisation for the food without reference to the proprietary scientific data designated as such by the prior applicant.

5. Before the expiry of the period referred to in paragraph 1 of this Article, the Commission shall update the Union list in accordance with the regulatory procedure referred to in Article 19(2) so that, provided that the authorised food still meets the conditions laid down in this Regulation, the specific indications referred to in paragraph 4 of this Article are no longer included.

*Article 17***Information to the public**

The Commission shall make available to the public:

- (a) the Union list referred to in Article 7(1) and the list of traditional foods from third countries referred to in Article 7(2), on a single dedicated page of the Commission website;
- (b) the summaries of the applications submitted under this Regulation;
- (c) the findings of the consultations referred to in Article 4(3).

The Commission may adopt the implementing measures for this Article, including arrangements for making public the outcome of the consultations under point (c) of the first paragraph of this Article, in accordance with the regulatory procedure referred to in Article 19(2).

### CHAPTER III

#### GENERAL PROVISIONS

##### Article 18

##### Penalties

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

##### Article 19

##### Committee procedure

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.

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

##### Article 20

##### 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 point (a) of Article 3(2), by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23.

##### Article 21

##### Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 20 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 22.

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 22 and 23.

##### Article 22

##### Revocation of the delegation

1. The delegation of power referred to in Article 20 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 inform the other institution and the Commission at the latest one month before the final decision is taken, stating the delegated powers which could be subject to revocation and the 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 23***Objections to delegated acts**

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

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, or if, before that date, the European Parliament and the Council have both informed the Commission that they have decided not to raise objections, the delegated act shall enter into force on the date stated therein.

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

*Article 24***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, 11 and 16, accompanied, where appropriate, by any legislative proposals.

2. By ... (\*\*), the Commission shall submit to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a cloning technique and from their offspring, followed, where appropriate, by any legislative proposals.

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

## CHAPTER IV

**TRANSITIONAL AND FINAL PROVISIONS***Article 25***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 27 of this Regulation.

(\*) 5 years after the entry into force of this Regulation.

(\*\*) 1 year after the entry into force of this Regulation.

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

*Article 26***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 27***Transitional measures**

1. Any request for placing a novel food on the market within the Union submitted to a Member State under Article 4 of Regulation (EC) No 258/97 before ... (\*\*\*) shall be transformed into an application under this Regulation if an initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, and in cases where the additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97.

Other pending requests submitted under Article 4 of Regulation (EC) No 258/97 before ... (\*\*\*) shall be processed under the provisions of that Regulation.

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

*Article 28***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:

'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 a common procedure for the assessment and authorisation (hereinafter referred to as the "common procedure") of food additives, food enzymes, food flavourings and source materials of food flavourings and of food ingredients with flavouring properties used or intended for use in or on foodstuffs and novel foods (hereinafter referred to as the "substances or products") which contributes to the free movement of food within the Union and to a high level of protection of human health and to a high level of consumer protection, including the protection of consumer interests. This Regulation shall not

apply to smoke flavourings falling within the scope of Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (\*).

2. The common procedure shall lay down the procedural arrangements for updating the lists of substances and products the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008, Regulation (EC) No 1332/2008, Regulation (EC) No 1334/2008 and Regulation (EU) No .../2010 of the European Parliament and of the Council of ... on novel foods (\*\*) (hereinafter referred to as the “sectoral food laws”).

(\*) OJ L 309, 26.11.2003, p. 1.

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

3. In Article 1(3), Article 2(1) and (2), Article 9(2), Article 12(1) and Article 13 the words ‘substance’ and ‘substances’ are replaced by ‘substance or product’ or ‘substances or products’ as appropriate.

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. In Article 7, paragraphs 4, 5 and 6 are replaced by the following:

‘4. The measures, designed to amend non-essential elements of each sectoral food law, with the exception of

novel foods, relating to the removal of a substance from the Union list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

5. On grounds of efficiency, the measures designed to amend non-essential elements of each sectoral food law, with the exception of novel foods, inter alia, by supplementing it, relating to the addition of a substance to the Union list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Union list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(4).

6. With exception of novel foods and on imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14(5) for the removal of a substance from the Union list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Union list.

7. The measures relating to the removal, the adding of a product covered by the Regulation on novel foods to the Union list and/or for adding, removing or changing conditions, specifications or restrictions associated with the presence of such product on the Union list shall be adopted in accordance with the regulatory procedure referred to in Article 14(2).’.

8. The term ‘Community’ shall be replaced by ‘Union’.

#### Article 29

##### 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 ... (\*).

However, Articles 26, 27 and 28 shall apply from ... (\*\*). Furthermore, by way of derogation from the second paragraph of this Article and by way of derogation from the second paragraph of Article 16 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.

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

(\*\*) Date of entry into force of this Regulation.

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*

...

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## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 15 January 2008, the Commission submitted a proposal <sup>(1)</sup> for a Regulation on novel foods and amending Regulation (EC) No 1331/2008 of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. The proposal was based on Article 95 of the Treaty establishing the European Community.

Acting in accordance with Article 251 of the Treaty establishing the European Community, the European Parliament adopted its first reading Opinion on 25 March 2009 <sup>(2)</sup>.

The Economic and Social Committee adopted its opinion on 29 May 2008 <sup>(3)</sup>.

In accordance with Article 294(5) of the Treaty on the Functioning of the European Union (TFEU), the Council adopted its position at first reading by unanimity on 15 March 2010.

### II. OBJECTIVE OF THE PROPOSED REGULATION

The Commission announced already in the White Paper on Food Safety adopted on 12 January 2000 <sup>(4)</sup> its intentions to examine the application of the novel food legislation and to make the necessary adaptations to the existing Regulation (EC) No 258/97 on novel foods and novel food ingredients.

The proposal aims at updating and clarifying the regulatory framework for authorisation and placing on the market of novel foods while ensuring food safety, protection of human health and consumer interests and the effective functioning of the internal market. It repeals the current Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

The proposal keeps the date of 15 May 1997 as the threshold date for determination of the novelty of the food and clarifies that the novel food definitions include foods to which new technologies are applied or foods originating from plants or animals to which non-traditional breeding techniques are applied.

The Commission proposed that the placing on the market of novel foods would be subject to a centralised procedure at the Community level in accordance with Regulation (EC) No 1331/2008 establishing the common authorisation procedure that would replace the current system of risk assessment by national authorities. The risk assessment would be carried out by the European Food Safety Authority (EFSA). The inclusion of a novel food in the Community list of novel foods would be considered by the Commission on the basis of the opinion from EFSA. The Commission would be assisted by the Standing Committee on the Food Chain and Animal Health (SCFCAH). The final decision to update the list of novel foods would be made by the Commission via the comitology with scrutiny procedure.

The applicant-linked authorisation would be replaced and the simplified procedure abolished by authorisation decisions addressed to the Community as a general rule. Protection of data could be granted in justified cases concerning newly developed scientific evidence and proprietary data in order to support innovation in the agri-food industry.

The proposal introduced a definition of 'traditional food from a third country', as a category of novel food that should be subject to notification if no reasoned safety objections are presented by EFSA or Member States.

Already authorised novel foods would continue to be marketed and included in the Community list of novel foods.

<sup>(1)</sup> 5431/08.

<sup>(2)</sup> 7990/09.

<sup>(3)</sup> OJ C 224, 30.8.2008, p. 81.

<sup>(4)</sup> 5761/00, COM(1999) 719 final.

### III. ANALYSIS OF THE COUNCIL POSITION

#### 1. *Introductory remarks*

The Council position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced several changes in the text, some of them inspired by the amendments proposed by the European Parliament.

The Commission has accepted all the changes introduced by the Council to its proposal, except the introduction of the definition of offspring of cloned animals in Article 3(2)(b) and the inclusion of offspring in Article 3(2)(a)(i).

#### 2. *The amendments of the European Parliament*

In its plenary vote on 25 March 2009, the European Parliament adopted 76 amendments to the proposal <sup>(1)</sup>. The Council incorporated in its common position 30 amendments, of which 20 in full (amendments **7, 15, 16, 20, 35, 41, 42, 44, 45, 53, 63, 65, 67, 68, 69, 76, 77, 88, 89, 93**), 5 in part (amendments **1, 30, 40, 91, 92**) and 5 in principle (amendments **3, 6, 11, 25, 64**).

#### 2.1. *The main modifications introduced by the Council in the proposal, with reference to EP amendments* <sup>(2)</sup>

- (a) Objectives of the Regulation (Article 1 and recitals 1 and 2) — the Council added the protection of the environment and animal welfare. This partly covers amendments **1** and **30** and reflects the spirit of amendment **3**.
- (b) Scope (Article 2(2)(a)(v) and recitals 13 and 14) — the Council clarified that, pending the respective amendments to Regulation (EC) No 1925/2006, Directive 2002/46/EC and Directive 89/398/EEC, those vitamins and minerals obtained from new sources or using a production process, which were not taken into account at the moment of their authorisation and which give rise to significant changes in the composition or structure of food which affect its nutritional value, metabolism or level of undesirable substances should be within the scope of the novel food Regulation. This is in line with the first part of amendment **91**.
- (c) Definition of novel foods (Article 3 and recitals 6, 8, 10, 11) — the basic criterion for assessing the novelty of the food remains whether it has been used for human consumption to a significant degree within the Union before 15 May 1997. In order to provide legal clarity, the Council agreed that further criteria for assessing human consumption to a significant degree within the Union before 15 May 1997 must be developed before the date of application of the Regulation. The adoption of these criteria has been delegated to the Commission according to Article 290 TFEU. This was coupled with delaying the date of application until 24 months after the date of entry into force.

In order to ensure better clarity, the following changes of definition have been made:

- a distinction has been made between food of animal and food of plant origin. Food of plant origin falls under the scope of this Regulation only if a non-traditional breeding technique applied to the plant gives rise to significant changes in the composition or structure of the food;
- addition of the definition of 'offspring' and 'engineered nanomaterial' (see also points (d) and (e) below);
- ingredients used in food supplements before 15 May 1997 fall under the definition, and consequently require authorisation, only if they are to be used in foods other than food supplements;
- definition of the 'traditional food from a third country' cover food that is derived only from primary production and for which the history of safe food use has been proven in any third country for a continuous period of 25 years in the customary diet of a large part of the population;

<sup>(1)</sup> 7990/09 (P6\_TA(2009)0171)

<sup>(2)</sup> The numbering of recitals and Articles refers to the text of the Council position at first reading.

- it has been noted that the level of harmonisation for medicinal products makes it possible that a Member State may, if it establishes in accordance with Directive 2001/83/EC that a substance is a medicinal product, restrict the placing on the market of such product in accordance with Union law, even if the same product has been authorized as a novel food under the present Regulation.

The Council also agreed that the Commission may, through the regulatory comitology procedure, adopt further criteria to clarify definitions in sub-points (i) to (iv) of point (a) and points (c), (d) and (e) of Article 3(2) in order to ensure their harmonised implementation by the Member States.

These changes cover amendment **15, 16, 35, 63** and most of amendment **92**.

- (d) Food produced from animals obtained by non-traditional breeding techniques and their offspring (Article 3(2)(a)(i) and recitals 6 and 7) — the Council agreed that foods produced from animals obtained by non-traditional breeding techniques (e.g. cloning) and their offspring shall fall within the scope of the Regulation. At the same time, the Council is of the opinion that this Regulation cannot adequately manage all aspects of cloning and that the Commission should study the subject further. To this end, the Commission shall forward, within one year from the date of entry into force of this Regulation, to the European Parliament and the Council a report on all aspect of food production from cloned animals and their offspring, followed, if appropriate, by legislative proposal (Article 20(2)). This is in line with amendment **93**. The Council considered that it was necessary to keep food produced from cloned animals within the scope of the proposed Regulation until any specific legislation has been proposed by the Commission and adopted. This solution avoids a legal vacuum that would be created by excluding such a food from the Regulation as proposed by the European Parliament in the absence of any legislation regulating food production from cloned animals.
- (e) Nanomaterials — the Council recognized the need for systematic safety evaluation and authorisation of foods containing or consisting of engineered nanomaterials irrespective of any changes that the nanomaterials might cause in the properties of such foods. Therefore, the Council made clear that such foods are considered to be novel (Article 3(2)(a)(iv)) and added the definition of 'engineered nanomaterial' (Article 3(2)(c)). The Council thus closed the gap that might have been created if the use of nanotechnologies would have not given rise to significant changes in the composition or structure of the food as defined by Article 3(2)(a)(iii), but the food would have still contained engineered nanomaterials. Recital 9 highlights the need for an internationally agreed definition of nanomaterial. If a different definition is agreed at international level, the adaptation of the definition in this Regulation would be done through the ordinary legislative procedure. The Commission expressed its reservation as it argued that this adaptation should have been delegated to the Commission according to Article 290 TFEU. The Council thus accepted a part of amendment **92**.

The Council followed the thrust of amendments **6** and **11** on the necessity to have appropriate risk assessment methods for engineered nanomaterials, which is reflected in recital 20.

- (f) Determination of the status of food (Article 4 and recital 16) — the Council agreed that the determination of the status of food to be placed on the Union market with respect to the definition of novel food would be a responsibility of food business operators, who must consult their national authority in case of doubt.
- (g) Authorisation of novel foods (Article 9 and recital 18) — the Council agreed that the authorisation of novel foods should be carried out according to the Regulation (EC) No 1331/2008, unless there is provision for a specific derogation in the present Regulation. The Council clarified that ethical, environmental, animal welfare factors and the precautionary principle should be taken into account in authorisation of novel foods. These factors should be considered on a case-by-case basis according to the content of the application. This covers amendment **20**.



- (h) Authorisation of traditional foods from third countries (Article 11 and recital 22) — the Council did not accept the 'notification procedure' as proposed by the Commission. In order to ensure food safety, any authorisation should be based on the EFSA opinion and subsequent authorisation adopted by the Commission through the regulatory comitology procedure. The EFSA evaluation should primarily focus on the evidence of safe food use and the information on the composition of traditional food. In order to speed up the procedure, shorter deadlines should apply — 6 months for EFSA opinion and 3 months for the draft measure submitted by the Commission to SCFCAH. A separate list of authorised traditional foods from third countries would be established (Article 7(2)). The new Council approach nevertheless covers amendments **65** and **68**.
- (i) Technical guidance (Article 12) — the Commission must before the date of application of the Regulation (i.e. 2 years after its entry into force) make available technical guidance and tools to interested parties, in particular food business operators and SMEs. It is self-evident that the Commission Recommendation 97/618/EC will be applicable until the repeal of the of Regulation (EC) No 258/1997. This is in line with amendment **69**.
- (j) European Group on Ethics in Science and new Technologies — EGE (Article 15 and recital 28) — an additional provision was added on the possibility for the Commission to consult the EGE, on its initiative or at the request of a Member State, on ethical issues concerning the novel foods. This corresponds to amendment **76**. If consulted, its opinion will be taken into account at the risk management stage.
- (k) Data protection (Article 16 and recital 25) — in order to promote innovation in industry, the need for the protection of new scientific evidence and/or proprietary scientific data for the period of 5 years was accepted by the Council. Such protected data cannot be used for the benefit of another application without the agreement of the prior applicant and the authorisation is limited to the prior applicant during the period of 5 years unless a subsequent applicant obtains authorisation without reference to that proprietary data. This fully covers amendment **77**. Though amendment **25** was not accepted as such, its spirit is covered by Article 16.
- (l) Information to the public (Article 17) — summaries of applications, findings of any consultations for determination of the status of food and lists of authorised novel foods must be made available to the public, in the latter case on the single dedicated web page. This is in line with amendments **41**, **53** and **67**, part of amendment **40** and covers in principle amendment **64**.
- (m) Transitional measures (Article 23 and recital 29) — pending application submitted according to Article 4 of the Regulation (EC) No 258/97 shall be processed under that Regulation only if the initial assessment report has been provided under Article 6(3) and neither additional assessment was required, nor were any objections raised by Member States. This is in line with amendments **88** and **89**.

In addition to the amendments mentioned above, the common position incorporates amendments **7**, **42**, **44**, **45**, which are of technical/editorial nature and aim at improving the clarity of the text.

Given the entry into force of the Treaty on the Functioning of the European Union on the 1 December 2009, the Council had to adapt the regulatory procedure with scrutiny related provisions of the Commission's proposal to the TFEU. The Council agreed that the following provisions should confer implementing powers on the Commission (Article 291(2) TFEU):

- Article 3(4): the adoption of further criteria to clarify definitions in sub-points (i) to (iv) of point (a) and points (c), (d) and (e) of Article 3(2) that may be adopted;
- Article 11(5): the update of the list of traditional foods from third countries;
- Article 16(5): the update of the Union list in case of data protection before the expiry of the 5 years period for data protection;

- Article 27 (2): the transitional measures for the application of Article 27(1) that may be adopted;
- Article 9: the update of the Union list of novel foods. The Regulation (EC) 1331/2008 would need to be amended for that purpose (see Article 28 of the Council position).

As already mentioned in point c) above, the Council agreed that the adoption of criteria for assessing whether a food has been used for human consumption to a significant degree within the Union before 15 May 1997 by the date of application of this regulation (i.e. 24 months after the entry into force) should be delegated to the Commission according to Article 290 TFEU.

## 2.2. The European Parliament's amendments not accepted

The Council did not accept 46 amendments listed on the following grounds:

- (i) **Amd 2:** high level of protection of human health and consumers' interests in relation to food and effective functioning of the internal market are two main goals of Union law on foodstuffs (Article 1 of Regulation (EC) No 178/2002). These two aspects are covered by recitals 1 and 2.
- (ii) **Amd 9:** as explained in point (c) above, the basic criterion for assessing the novelty of the food remains its use for human consumption to a significant degree within the Union before 15 May 1997. Modified primary molecular structure, micro-organisms, fungi, algae, new strains of micro-organisms and concentrates of substances still fall under this definition and do not need to be listed separately
- (iii) **Amd 22:** EFSA cooperates with Member States when preparing its opinions and may use a network as provided for by Article 36 of Regulation (EC) No 178/2002 and Commission Regulation (EC) No 2230/2004.
- (iv) **Animal testing (amds 21, 87)** — the issue of animal testing, in particular avoidance of testing on vertebrate animals and sharing of testing results, does not fall under the scope of this Regulation. According to Article 9(2) of the Regulation (EC) No 1331/2008 (Common authorisation procedure), EFSA shall present a proposal concerning the data required for risk assessment of novel foods and these should recognise the need to avoid unnecessary animal testing.
- (v) **Prohibition of food production, placing on the market and imports of cloned animals and their offspring (amds 5, 10, 12, 14, 91 (point 2(ba)), 92 (point 2(a)(ii) and 2(ca)), 51 (second part)** — the Council cannot agree with the immediate exclusion of food obtained from cloned animals and their offspring from the scope of the Regulation (see point d) above). It should also be noted that the Commission has a right of initiative in proposing EU legislation and cannot be obliged to make a legislative proposal by a legislative act.
- (vi) **Nanomaterials**
  - (a) **amd 13:** does not fall under the scope of novel foods Regulation; Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food applies.
  - (b) **amd 90:** systematic specific labelling of ingredients in the form of nanomaterials is excessive; there is a requirement to consider specific labelling requirements on a case-by-case basis according to Article 9(2).
  - (c) **amd 50:** in case of doubt concerning the safety of foods containing nanomaterials the precautionary principle would apply. In addition, the date of application of the Regulation has been prolonged to 24 months, thus leaving additional time for the development of risk assessment methods for engineered nanomaterials.
- (vii) **Determination of the status of food (amd 18 and part of amd 40):** the amendments are not compatible with the approach agreed by the Council (see point (d) above).

- (viii) Additional criteria for risk assessment by EFSA
- (d) **amd 70**: reference to Article 6 (Article 8 in the Common position) is not appropriate as it concerns conditions to be considered at risk management stage, not risk assessment conducted by EFSA.
  - (e) **amd 71**: interferes with EFSA internal procedures; in assessing safety of food, EFSA may consider also other aspects than harmful or toxic effects to human health.
  - (f) **amd 74**: does not belong to the risk assessment stage; the opinion of the European Group on Ethics in Science and New Technologies (EGE) could be sought at the request of a Member State and would then be considered at the risk management stage.
- (ix) Additional conditions for authorisation of novel foods (risk management)
- (g) **amd 23**: ethical aspects may be considered at the risk management stage; assessment by European Environment Agency (EEA) is not applicable.
  - (h) **amd 43**: not necessary, aspects covered by this amendment are taken into account by EFSA at the risk assessment stage.
  - (i) **amd 47**: not applicable; it is neither necessary nor possible to ask a opinion of the EEA for every application for novel food authorisation.
  - (j) **amd 48**: the opinion of EGE cannot be requested for every application for novel food authorisation. If it is requested as provided for in Article 15, it will be taken into account at the risk management stage.
  - (k) **amd 49**: aspects covered by this amendment are taken into account by EFSA at risk assessment stage and may be covered by conditions of use and additional specific labelling requirements according to Article 9(2).
- (x) Precautionary principle (amds **1(second part), 19, 52**) — the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002 is always applicable. There is a reference to this principle in recital 18. Therefore, there is no need to repeat it in other recitals and as an additional condition for authorisations.
- (xi) Additional specifications for the entry of novel food in the Union list:
- (l) **amd 54**: all points raised are already covered by the Regulation, except point (f), which is not clear as monitoring requirements and inspections according to Regulation (EC) No 882/2004 on official controls are two different issues.
  - (m) **amd 57**: according to Article 9(2), the presence of undesirable substances in the novel food is already controlled by specifications of the food and limitation of exposure to substances present in novel foods will be covered under 'conditions of use' and may be introduced following the EFSA opinion.
- (xii) Post-marketing monitoring (**amd 55 and 75**) — systematic post market monitoring and revision of authorisations after five years for all novel foods placed on the market is disproportionate. It would place an administrative burden on food business operators and authorities of Member States. Article 14 provides for a possibility to impose post market monitoring on a case-by-case basis. Producers are obliged to inform the Commission of any new scientific or technical information which might influence the safety evaluation in use of novel food already placed on Union market.
- (xiii) Labelling of novel food (**amd 60 and 62**) — the systematic labelling of all novel foods (**amd 62**) is disproportionate and would create an administrative burden. Specific labelling requirements are possible according to Article 9(2). Labelling of products from animals fed with genetically modified feeding stuff (**amd 60**) does not fall under the scope of this Regulation (Regulation (EC) No 1829/2003 is clearly excluded).

- (xiv) Traditional foods from third countries (amds **28**, **64** and **66**): the Council agreed a different procedure for authorisation of these foods than that proposed by the Commission (see point (h) above).
- (xv) Consultation of the EGE (amd **29**): the Council wording of recital 28 better correspond to the content of Article 15 concerning consultations of the EGE (see point (j) above).
- (xvi) Alignment of deadlines for authorisation of health claim and novel food in the case of data protection (amd **27**, **80**) — such an alignment may be desirable, but would be difficult to ensure in practice as evaluations proceed according to different time schedules and the two decisions are taken separately.
- (xvii) Amd **61**: updates of the Union list in the case of data protection are to be decided in accordance with the regulatory procedure as these are individual authorisations and not measures of general scope.
- (xviii) Amd **56** and **91** (subparagraph (2a)): authorisation of food additives, food enzymes and food flavourings, to which a new production process is applied, which gives rise to significant changes is already covered by sectoral legislation on additives (Art. 12 and Recital 11 of Regulation (EC) No 1333/2008), enzymes (Art. 14 and Recital 12 of Regulation (EC) No 1332/2008) and flavourings (Art. 19 of Regulation (EC) No 1334/2008). The common authorization procedure applies to such authorizations.
- (xix) Amd **78**: the Council did not consider the issue of research projects financed from EU and/or public sources.
- (xx) Amd **81**: Regulation (EC) No 882/2004 on official controls to ensure compliance with feed and food law (including novel foods Regulation) is applicable and does not need to be repeated.
- (xxi) Amd **82**: the Council agreed to postpone the date of application of the Regulation until 24 months after the date of its publication. The same deadline was given to Member States to notify provisions concerning penalties.
- (xxii) Amd **83**: Not necessary; duplication of provisions applicable according to the Articles 53 and 54 of Regulation (EC) No 178/2002.

The Council did not accept amds **8** and **85** as they are unclear and amds **4**, **17**, **51** (**first part**), whose content is self-evident and they do not bring any added value.

#### IV. CONCLUSIONS

The Council believes that its position at first reading represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation ensuring a high level of human health and consumer protection.

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