



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 15 March 2010 (17.03)
(OR. en)**

**11261/3/09
REV 3**

**Interinstitutional File:
2008/0002 (COD)**

**DENLEG 51
CODEC 893**

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Position 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

**REGULATION (EU) No .../... OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL**

of

**on novel foods, amending Regulation (EC) No 1331/2008
and repealing Regulation (EC) No 258/97
and Commission Regulation (EC) No 1852/2001**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 224, 30.8.2008, p. 81.

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

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 ingredients¹ 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 258/97². 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 Council³ should therefore become obsolete as regards novel foods.

¹ OJ L 43, 14.2.1997, p. 1.

² OJ L 253, 21.9.2001, p. 17.

³ OJ L 253, 16.9.1997, p. 1.

- (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 safety¹ 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.

¹ OJ L 31, 1.2.2002, p. 1.

- (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 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/EC¹, 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.

¹ 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).

- (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 use¹ 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.

¹ 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 1829/2003¹, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008², flavourings falling within the scope of Regulation (EC) No 1334/2008³, enzymes falling within the scope of Regulation (EC) No 1332/2008⁴ and extraction solvents falling within the scope of Directive 2009/32/EC⁵ should not be covered by this Regulation.

¹ 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).

² 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).

³ 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).

⁴ 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).

⁵ 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).

- (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 foods¹ 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)² 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.

¹ OJ L 404, 30.12.2006, p. 26.

² OJ L 124, 20.5.2009, p. 21.

- (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 flavourings¹, 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.
- (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").

¹ OJ L 354, 31.12.2008, p. 1.

- (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.
- (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/EC¹ and, where necessary, to the nutritional labelling requirements laid down in Directive 90/496/EEC². 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.

¹ 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).

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

- (27) Regulation (EC) No 1924/2006¹ 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.

¹ 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).

- (30) Regulation (EC) No 882/2004¹ 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.
- (31) Requirements in respect of the hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004² 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.

¹ 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).

² 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).

- (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 Commission¹.
- (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.

¹ OJ L 184, 17.7.1999, p. 23.

- (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;
 - (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 nanomaterials;
 - (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).

* OJ: please insert date: 2 years after the entry into force of this Regulation.

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.

^{*} OJ: please insert date: 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.

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

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.

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.

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

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.

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

** OJ: please insert date: 1 year after the entry into force of this Regulation.

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.

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.

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

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.

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

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 .../... 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".

⁺ OJ: please insert the number and the date of this Regulation.

⁺⁺ OJ: please insert the publication reference of this Regulation

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.

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

Done at,

For the European Parliament
The President

For the Council
The President

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

** OJ: Please insert date: the entry into force of this Regulation.