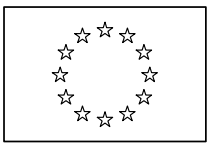

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.1.2008
COM(2007) 872 final

2008/0002 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure]

(presented by the Commission)

[SEC(2008) 12]
[SEC(2008) 13]

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

  As part of the framework to improve and bring coherence to Community legislation from "farm to table" the Commission announced in the White Paper on Food Safety its intentions to examine the application of the novel food legislation and to make the necessary adaptations to the existing legislation in the light of the conclusions of the report on the implementation of the Regulation (EC) No 258/97 on novel foods and novel ingredients (Actions 14 and 51) and in accordance with the regulatory framework of Directive 90/220/EEC on GMO's. This was partly done by adopting the Regulation (EC) on 1829/2003 on GM food and feed. The novel food Regulation needs now to be clarified after removal of GM food from the scope.

  Stakeholder consultations in 2002 on a Commission discussion paper and subsequent evaluation underlined the need to develop and update the Regulation.

  In accordance with these commitments, this proposal aims to ensure food safety, protect human health and secure the functioning of the internal market for food. In order to do this, it aims to streamline the authorisation procedure, develop a more adjusted safety assessment system for traditional food from third countries, which is considered as novel food under the current Regulation, and clarify the definition of novel food, including new technologies with an impact on food, and the scope of the novel food Regulation. Further, there is a need to improve the efficiency, transparency and application of the authorisation system, which also contributes to better implementation of the Regulation and to empower consumers by informing them about food. In addition, legal clarity should be achieved by making necessary changes and updating the legislation.

- **General context**

  Authorisation and use of novel foods and food ingredients is harmonised in the European Union since 1997 when Regulation (EC) No 258/97 on novel foods and novel food ingredients was adopted. The current legislation consists of the novel food Regulation and one Commission Regulation.

- **Existing provisions in the area of the proposal**

  Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients lays down the general principles for authorisation of novel foods and food ingredients in the European Union.

This Regulation is complemented with the Commission Regulation (EC) No 1852/2001 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.

The proposal brings together, develops and updates the above mentioned provisions

- **Consistency with the other policies and objectives of the Union**

The proposal is in line with the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy. The emphasis is on simplifying the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

The opinion of Member States and stakeholders has been sought through consultations, meetings or during bilateral contacts since 2002. The Commission consulted on a discussion paper for the implementation of the Novel Food Regulation (EC) No 258/97 in July 2002. Some 40 stakeholders sent in their comments, which were discussed in a meeting in 2003.

Moreover, from 2 June to 1 August 2006 the Commission carried out, with the general public, an Interactive Policy Making online consultation, including a questionnaire, in order to collect information and data on the possible impacts of the main issues under consideration for the revision of the Regulation. 65 responses to the questionnaire were received. In addition, the Commission organised a stakeholder meeting on the draft impact assessment report in December 2006 inviting all relevant stakeholder groups. 12 organisations took part in this meeting. Finally, the Commission presented the outcome of this meeting in the SANCO Advisory Group of the Food Chain, Animal and Plant Health.

The stakeholders that have been consulted are food industry, consumers, third countries, national and EU authorities and international organisations. The Member State authorities were consulted in the course of several novel food working group meetings in 2005-2007. Further consultation took place through Commission participation at meetings or seminars organised by stakeholders and dedicated to specific issues (e.g. traditional food from third countries, assessment and authorisation procedure) and bilateral meetings with interested parties.

Summary of responses and how they have been taken into account

Stakeholder consultations in 2002-2003 on a Commission discussion paper and the consultation on the impact assessment of the novel food Revision in 2006 have underlined the importance of and the need to develop and update the existing Regulation. The objectives and many of the possible measurers have been broadly supported by the stakeholders consulted since 2002.

Concerning the Commission discussion paper in 2002 on the implementation of the Novel Food Regulation (EC) No 258/97, all comments, the evaluation report including the summary report as well as the executive summary are available at:

http://ec.europa.eu/food/food/biotechnology/novelfood/initiaves_en.htm.

A more detailed summary of the consultation process and its outcome can be found in the Impact Assessment report, which is presented together with this draft Regulation. All contributions have been considered when preparing the draft Impact Assessment Report and the draft Regulation.

The results are available at:
http://ec.europa.eu/food/food/biotechnology/novelfood/initiaves_en.htm.

- **Collection and use of expertise**

  There was no need for external expertise.

- **Impact assessment**

  For each of the measures proposed in the draft Regulation, as appropriate, one to three options and ranging from repealing to mandatory measures, have been examined with regard to their economic, social and environmental impact on the various stakeholders and authorities. In addition, a no-changes scenario was considered as a reference against which to assess the possible impacts of the different options.

  The Commission carried out an Impact Assessment the report of which is presented in parallel to this proposal as a Commission Staff Working Paper. It is also available at
  http://ec.europa.eu/food/food/biotechnology/novelfood/initiaves_en.htm.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

  Adoption of a Regulation of the European Parliament and of the Council on novel foods, that regulates the placing on the market of novel foods. It lays down rules for authorisation, supervision, labelling and use of novel foods.

Repeal Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients laying down the general principles for authorisation of novel foods and food ingredients in the European Union.

Repeal Commission Regulation (EC) No 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to Regulation (EC) No 258/97.

- **Legal basis**

  Article 95 of the EC Treaty.

- **Subsidiarity principle**

  The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

  The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reasons.

  Individual action by Member States could lead to differing levels of food safety and protection of human health and confuse consumers. Repealing the Novel Food Regulation would do away with harmonised food safety rules and would endanger the free movement of (novel) food in the EU.

  Community action will better achieve the objectives of the proposal for the following reasons.

  Effective functioning of the internal market in relation to novel foods while protecting the health and the interest of the European consumers can best be met via a centralised EU level procedure for authorisation.

  A centralised authorisation procedure will improve the efficiency of novel food authorisations. In addition, harmonised food safety rules would apply.

  The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

  The proposal complies with the proportionality principle for the following reasons.

  The proposal harmonises the regulatory framework for novel food approval and thus contributes to the functioning of the (novel) food market in the EU. The proposed measures are sufficient in terms of reaching the objectives of ensuring food safety and securing the functioning of the internal market for food. At the same time they do not impose an excessive or unjustified burden.

The absence of harmonisation could result in the appearance of individual national approval systems, resulting in multiple authorisation work and increased administrative burden in the EU. Financial burden is minimised as the current provisions exist already, they are only simplified.

- **Choice of instruments**

  Proposed instruments: Regulation.

  Other means would not be adequate for the following reasons.

  The area of novel foods is fully harmonised in the EU. Non-legislative action based, for example, on a code of good practice or guidelines could not give sufficient protection and would lack legal certainty. The safe use of novel food depends on pre-market safety evaluations and often on permitted conditions of use of these substances, therefore recommendations or self-regulations would not guarantee the protection of consumer's health.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

- **Simplification**

  The proposal provides for simplification of legislation and administrative procedures for public authorities (EU or national) and private parties.

  There will be only one centralised procedure for the assessment and authorisation of novel foods. The wording of the legislation will be up-dated and clarified.

  National administrative procedures and double work will be abolished.

  Streamlining and increasing the efficiency of authorisation procedure decreases administrative burden also for private parties.

  The proposal is included in the Commission's rolling programme for up-date and simplification of the acquis communautaire and its Work and Legislative Programme under the reference 2007/SANCO/006.

- **Repeal of existing legislation**

  The adoption of the proposal will lead to the repeal of existing legislation.

- **Review/revision/sunset clause**

  The proposal includes a review clause.

- **European Economic Area**

  The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- **Detailed explanation of the proposal**

  Chapter I - Introductory provisions

  Novel foods shall be subject to safety evaluation and approval via community procedure. The definitions are clarified and updated following legal developments. A procedure to collect information on the novelty of a food may be laid down. It may be determined with the comitology procedure if a food falls within the scope of the Regulation.

  Chapter II – Requirements and inclusion in Community list of novel foods

  All novel foods and their use in food shall be evaluated for the following criteria: they should not present a danger to or mislead the consumer and in the case of replacement be of nutritional disadvantages for the consumer.

  In line with the decision to switch to a centralised EU-level procedure and to separate risk management and risk assessment, all applications for the approval of novel food shall be submitted to the Commission and then directed to European Food Safety Authority (EFSA) which will carry out the safety evaluations. The inclusion of a novel food in the Community list of novel foods will be considered by the Commission on the basis of the opinion from EFSA. The Commission will be assisted by the Standing Committee on the Food Chain and Animal Health (SCFCAH).

  The final decision to include a novel food in the Community list of novel foods shall be made by the Commission via the comitology procedure. The applicant-linked authorisation shall 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.

  Without prejudice to Directive 2000/13 on labelling, the decision shall include, where appropriate, specific additional labelling for novel foods sold to the consumer.

For traditional food from third countries, a safety assessment and management based on history of safe food use in the country of origin shall be introduced. If the history of safe food use in the country of origin has been demonstrated, and the Member States and EFSA do not present reasoned safety objections, based on scientific evidence, the food could be placed on the market on basis of a notification of the food business operator intending to market the food. This will allow a more proportional safety assessment and management for food with a history of safe food use. In case reasoned safety objections are presented, the normal comitology procedure will apply.

For every authorised novel food a specification, labelling, conditions of use and, where appropriate, a requirement of post-market monitoring may be laid down.

To ensure that novel foods once authorised are kept under continuous observation and re-evaluated wherever necessary, producers of novel foods will be obliged to inform the Commission of any new information which may affect the safety assessment of the novel food.

Chapter III - General provisions

The Member States shall lay down rules on penalties applicable to infringements of the provisions of the proposed Regulation

Implementation of the measures proposed in the Regulation will be adopted by the Commission in accordance with the regulatory procedure laid down in Council Decision 1999/468/EC. This consists of including the conditions of use and labelling of a novel food as well as laying down specifications and, where appropriate post-market monitoring requirements. As these are matters of high technicality that are adopted on the basis of commonly agreed principles, they should be trusted to the Commission for the sake of efficiency and simplification.

Chapter IV Transitional and final provisions

Already authorised novel foods shall continue be marketed and included the Community list of novel foods.

The Regulation (EC) No [common procedure] is amended to include novel foods in the scope of the Regulation and to enable the applicant to present one single application for foods regulated under different sectoral food laws.

2008/0002 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure]

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

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

(2) A high level of human health protection should be assured in the pursuit of Community policies.

(3) Community rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[4] 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[5]. For the sake of clarity, Regulation (EC) no 258/97 should be repealed and replaced by this Regulation. The present Regulation should include measures currently governed by Regulation (EC) No 1852/2001.

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1 OJ C […],[…], p. […].
2 OJ C […],[…], p. […].
3 OJ C […],[…], p. […].
4 OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
5 OJ L 253, 21.9.2001, p. 17.

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

(5) The existing definition of novel food should be clarified and updated by replacing the existing categories with a reference to the general definition of food in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[6].

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

(7) If necessary, implementing measures should be adopted to provide for criteria in order to facilitate the assessment of whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior that date, it can be placed on the market after that date for the same use without being considered as a novel food. However, that use as or in a food supplement should not be taken into account for the assessment whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.

(8) The reformulation of food products produced from existing food ingredients available on the Community market, in particular by changing the composition or amounts of those food ingredients, should not be considered as novel food.

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

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

(10) Foods which are intended for technological uses or which are genetically modified should not fall within scope of this Regulation. Therefore, food used solely as additives falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..][7], flavourings falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..][8], extraction solvents falling within the scope of Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients[9], enzymes falling within the scope of Regulation (EC) No XX/XXX of the European Parliament and of the Council of [..][10] and genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[11] should be excluded from the scope of this Regulation.

(11) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[12], Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[13] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[14] should therefore be excluded from the scope of this Regulation.

(12) Novel foods, other than vitamins and minerals, intended for particular nutritional uses, for food fortification or as food supplements, should be assessed in conformity with the safety criteria and requirements applicable to all novel foods. At the same time they should remain subject to the rules provided for in Directive 89/398/EEC and in the specific Directives referred to in Article 4(1) thereof and in Annex I thereof, in Directive 2002/46/EC and in Regulation (EC) No 1925/2006.

(13) Whether a food was used for human consumption to a significant degree before 15 May 1997, should be based on information available in the Member States. Where the Commission does not have information on human consumption before 15 May 1997, a simple and transparent procedure for collecting that information should be established involving the Member States and any interested parties.

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7 OJ C […],[…], p. […].
8 OJ C […], […], p. […].
9 OJ L 157, 24.6.1988, p. 28. Directive as last amended by Regulation (EC) No 1882/2003.
10 OJ C […],[…], p. […].
11 OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).
12 OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.
13 OJ L 183, 12.7.2002, p. 51. Directive as amended by Commission Directive 2006/37/EC (OJ L 94, 1.4.2006, p. 32).
14 OJ L 404, 30.12.2006, p. 26.

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

(15) It is necessary to apply a harmonised centralised procedure for safety assessment and authorisation that is efficient, time-limited and transparent. With a view to further harmonising different authorisation procedures of food, the safety assessment of novel foods and their inclusion in the Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No [..] of the European Parliament and of the Council of [date] establishing a common authorisation procedure for the food additives, food enzymes and flavourings[15].

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

(17) In order to simplify procedures, applicants should be allowed to present a single application for foods regulated under different sectoral food laws. Regulation EC No [common procedure] should therefore be amended accordingly.

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

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

(20) Under specific circumstances in order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Community list should not be used to the benefit of another applicant during a limited period of time, without the agreement of the first applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Community list of novel foods on the basis of their own scientific data.

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15 OJ L […],[…], p. […].

(21) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs[16]. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore, the inclusion of a novel food in the Community list may impose specific conditions of use or labelling obligations.

(22) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[17] harmonises the provisions in the Member States which relate to nutrition and health claims. Therefore, claims regarding novel foods should only be made in accordance with that Regulation.

(23) As regards the safety assessment and management of traditional food from third countries, their history of safe use in the third country of origin should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets. If Member States and the Authority have not presented any reasoned safety objections, based on scientific evidence, for example information on adverse health effects, it should be permissible to place the food on the Community market after notification of the intention to do so.

(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997[18] may be consulted, where appropriate, with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.

(25) Novel foods placed on the Community market under Regulation (EC) No 258/97 should continue to be placed on the market. Novel foods authorised in accordance with Regulation (EC) No 258/97 should be included in the Community list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97, and for which a final decision has not been take before the date of application of the present Regulation, should be considered as applications under this Regulation.

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

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

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

18 SEC(97) 2404.

(27) The Member States should lay down the rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

(28) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[19].

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

(30) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[20] lays down general rules for the performance of official controls to verify compliance with food law. Therefore, the Member States are to carry out official controls in accordance with Regulation (EC) No 882/2004, in order to enforce compliance with the present Regulation.

HAVE ADOPTED THIS REGULATION:

Chapter I
Introductory provisions

Article 1
Subject matter

This Regulation lays down harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of human health and consumers' protection, whilst ensuring the effective functioning of the internal market.

Article 2
Scope

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

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

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

2. This Regulation shall not apply to:

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

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

(ii) food flavourings falling within the scope of Regulation (EC) No [on food flavourings];

(iii) extraction solvents used in the production of foodstuffs and falling within the scope of Council Directive 88/344/EEC;

(iv) food enzymes falling within scope of Regulation (EC) No [on food enzymes];

(v) vitamins and minerals falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2006.

(b) foods falling within the scope of Regulation (EC) 1829/2003.

3. Where necessary, it may be determined in accordance with the procedure referred to in Article 14(2) whether a type of food falls within the scope of this Regulation.

Article 3
Definitions

1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002 shall apply.

2. The following definitions shall also apply:

(a) "novel food" means:

(i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;

The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997; and

(iii) food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances.

(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least one generation in a large part of the population of the country;

(c) "history of safe food use" means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use in the normal diet of a large part of the population of a country.

Article 4
Collection of information regarding the use of a food for human consumption

1. The Commission may collect information from the Member States and/or from food business operators to determine to what extent a food has been used for human consumption within the Community before 15 May 1997.

2. Implementing measures for the application of paragraph 1, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to Article 14(3).

Chapter II
Requirements and inclusion in the Community list of novel foods

Article 5
Community list of novel foods

Only novel foods included in the Community list of novel foods (hereinafter "the Community list") may be placed on the market

Article 6
Conditions for inclusion in the Community list

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

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer under normal consumption conditions;

(b) it does not mislead the consumer, by the way it is presented or by its intended use;

(c) in the case where it is intended to replace another food, it does not differ from that food to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

Article 7
Content of the Community list

1. The Community list shall be updated in accordance with the procedure laid down in Regulation (EC) No [common procedure].

2. The entry of a novel food in the Community list shall include a specification of the food, and, where appropriate, specify the conditions of use, additional specific labelling requirements to inform the final consumer and/or a post-market monitoring requirement.

3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure referred to in Article 14(2) in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.

In the cases referred to in the first subparagraph the entry of a novel food in the Community list shall indicate, in addition to the information referred to in paragraph 2:

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

(b) the fact that the entry is based on newly developed scientific evidence and/or proprietary data protected in accordance with Article 12;

(c) the name and address of the applicant.

4. Before the expiry of the period referred to in Article 12, the Community list shall be updated to amend non-essential elements of this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 14(3) laid down in Regulation (EC) No [common procedure] so that, provided that the authorised food still meets the condition laid down in this Regulation, the specific indications referred to in paragraph 3, second subparagraph of this Article, are no longer included.

Article 8
Traditional food from a third country

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

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

2. The Commission shall forward the notification including the demonstration of history of safe food use referred to in paragraph 1 without delay to the Member States and the Authority.

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

   In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. The notification as referred to in paragraph 1 shall be considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common procedure].

   The Commission shall inform the food business operator concerned accordingly within five months from the date of the notification in accordance with paragraph 1.

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

5. The Commission shall publish a list of traditional foods from third countries that may be placed on the market in the Community in accordance with paragraph 4 on a dedicated page of the Commission's website.

6. Detailed rules for the implementation of this Article, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Article 9
Technical guidance

The Commission shall, where appropriate, in close cooperation with the Authority, make available technical guidance and tools to assist food business operators and especially small and medium-sized enterprises in preparing and submitting applications under this Regulation.

Article 10
Opinion of the Authority

In assessing the safety of novel foods, the Authority shall:

(a) compare, where appropriate, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;

(b) take into account for traditional food from a third country, the history of safe food use.

Article 11
Obligations on the food business operators

1. The Commission may impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. The food business operators placing the food in the Community market shall be responsible for the implementation of the post-marketing requirements specified in the entry of the food concerned in the Community list of novel foods.

2. The producer shall forthwith inform the Commission of:

   (a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;

   (b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.

Chapter III
General provisions

Article 12
Data protection

On request by the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and proprietary scientific data provided to support the applications, may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant.

Article 13
Penalties

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

Article 14
Committee

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

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

   The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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

Article 15
Review

No later than [1 January 2015] and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 8, accompanied, where appropriate, by any proposals. The report and any proposal shall be made accessible to the public.

Chapter IV
Transitional and final provisions

Article 16
Repeal

Regulation (EC) No 258/97 shall be repealed with effect from the date of application of this Regulation.

Article 17
Establishment of the Community list

By six months from the date of entry into force of this Regulation [date] at the latest the Commission shall establish the Community list by entering novel foods authorised under Regulation (EC) No 258/97 in this Community list, including any existing authorisation conditions, as appropriate.

Article 18
Transitional measures

1. Any request for placing a novel food on the market submitted to a Member State under Article 4 of Regulation (EC) No 258/97 and for which a final decision has not been taken before the date of application of this Regulation shall be considered as an application under this Regulation.

2. Any appropriate transitional measures for the application of paragraph 1, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Article 19
Amendments to Regulation (EC) No [common procedure]

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

(1) The title is replaced by the following:

"Regulation (EC) No XXX/XXXX of the European Parliament and of the Council of [date] establishing a common authorisation procedure for food additives, food enzymes, food flavourings and novel foods"

(2) In Article 1, paragraph 1, first sub-paragraph is replaced by the following:

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

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

"2. The common procedure shall set the procedural arrangements for updating the lists of substances and products the marketing of which is authorised in the Community pursuant to Regulation (EC) No AAA/2007, Regulation (EC) No BBB/2007, Regulation (EC) No CCC/2007, Regulation (EC) No DDD/DDDD (hereinafter referred to as the "sectoral food laws")."

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

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

"Community list of substances or products"

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

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

(7) The following sentence is added at the beginning of Article 6, paragraph 1:

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

Article 20
Entry into force

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 six months after the date of publication of this Regulation [date].

However, Article 17 shall apply from the date of the entry into force of this Regulation.

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

Done at Brussels,

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