COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 2007
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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(presented by the Commission)

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 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, administrative procedures for public authorities (EU or national) and administrative procedures for 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 - Scope and Definitions

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 shall be laid down. The the results shall be published. 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 approved 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 shall be made by the Commission via the comitology procedure. The applicant-linked authorisation shall be replaced and the simplified procedure abolished by authorisations addressed to the Community as a general rule. Only in justified cases concerning newly developed scientific evidence and/or proprietary data or food safety reasons, the authorisation-holder may have an exclusive right to place a food on the market.

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 a safety assessment to demonstrate the history of safe food use in the country of origin has been carried out and Member States and EFSA do not present scientific grounds of safety concerns, 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 scientific grounds of safety concerns are presented, the normal comitology procedure will apply.

For every authorised novel food a specification, labelling and conditions of use may be laid down.

Chapter III - General and Final Provisions

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

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. 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.

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

2007/.... (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on novel foods and amending Regulation (EC) No XX/XXX [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 Articles 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,

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 assessment and authorisation of novel food may hinder their free movement, creating conditions of unequal and unfair competition.

(2) A high level of protection of human life and health 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[3] and by 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[4].

(4) The existing novel food definition should be clarified and updated by making use of the general definition of food in Regulation (EC) 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

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1 OJ C [...],[...], p. [...].
2 OJ C [...],[...], p. [...].
3 OJ L 43, 14.2.1997, p. 1.
4 OJ L 253, 21.9.2001, p. 17.

down procedures in matters of food safety[5], with a view to take into account technological progress and scientific development.

(5) Emerging future technologies in breeding and food production processes with impact on food and thus on food safety should be covered. Novel food therefore should include foods from plants and animals produced by non-traditional breeding techniques and foods modified by new production processes (for example nanotechnology/nanoscience) with impact on food. Food derived from new plant varieties or animal breeds produced by traditional breeding techniques should not be considered as novel foods.

(6) Reformulation of food product produced from existing food ingredients available in the Community market, in particular by changing composition or amount of these food ingredients, should not constitute novel food.

(7) Following the entry into force of Regulation (EC) No 258/97 no novel food was placed on the market after 15 May 1997 unless it was authorised. The authorised novel foods should maintain their novel food status. However, for any of their new uses an authorisation will be necessary.

(8) All new foods and their different uses entering the market should undergo a harmonised and coherent safety assessment. However, the scope of this Regulation should not cover food products which are intended for technological uses or are genetically modified. Therefore, food used solely as additives falling within the scope of Regulation (EC) No XX/XXX[6], flavourings falling within the scope of Regulation (EC) No XX/XXX[7], extraction solvents falling within the scope of Council Regulation 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients[8], enzymes falling within the scope of Regulation (EC) No XX/XXX[9] and genetically modified food falling within the scope of Regulation (EC) 1829/2003 of the European Parliament and of the Council on genetically modified food and feed[10] should be excluded from the scope of this Regulation.

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

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5 OJ L 31, 1.2.2002, p.1.

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8 OJ L 157, 24.6.1988, p.28. Directive as last amended by Directive 92/115/EEC (OJ 1 409, 31.12.1992, p.31).

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10 OJ L 268, 18.10.2003, p.1.

11 OJ L

12 OJ L 183, 12.7.2002, p. 51.

13 OJ L 404, 30.12.2006, p.26.

(10) 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. Directive 89/398/EEC should be amended in order to ensure the application of one safety assessment and one authorisation procedure.

(11) In order to facilitate the assessment if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, criteria may be laid down through implementing measures. The information on food used exclusively as food supplement prior the mentioned deadline should not be taken into account. That food would require for its other food uses (e.g. non-food supplement use) an authorisation under this Regulation.

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

(13) Novel foods should be placed on the market only if they are safe and do not mislead the consumer. They should not differ from the food that they will replace in any way so that it would be nutritionally disadvantageous for the consumer.

(14) It is necessary to establish harmonised centralised procedures for risk assessment and authorisation, that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from novel foods. In order to ensure a harmonised scientific assessment of foods, such assessments should be carried out by the European Food Safety Authority.

(15) With a view to further harmonise different authorisation procedures of food, the risk 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 establishing a common authorisation procedure for the food additives, food enzymes and flavourings[14].

(16) 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 be amended accordingly.

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

(18) The inclusion of a novel food in the Community list should be without prejudice of 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 to Article 8 of Regulation (EC) No 1925/2006 of the European Parliament

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[14] OJ C [...],[...], p. [...].

and of the Council on addition of vitamins and minerals and of certain other substances to foods.

(19) As a general rule, novel foods included in the Community list and fulfilling the authorisation conditions, if any, could be placed on the market by any food business operator. However, under specific circumstances, the placing on the market of a novel food being included in the Community list of novel foods shall be temporarily restricted to the applicant in order to ensure the protection of newly developed scientific data or to ensure food safety by a way of appropriate post-marketing monitoring measures. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Community list on the basis of their own scientific data.

(20) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC[15]. In certain cases it might be necessary to require 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 provision on labelling of novel food. Claims should only be made in accordance with Regulation (EC) N° 1924/2006 on nutrition and health claims made on foods[16].

(21) For the safety assessment and management of traditional food from third countries their history of safe use in the country of origin should be taken into account. The history safe food use should not include non-food uses or uses not related to normal diets. If Member States and the European Food Safety Authority would not present scientific grounds of safety concerns, the food could be placed on the market in the Community after a notification of the intention to place it on the market.

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

(23) This Regulation should replace Regulation (EC) No 258/97 by repealing it. However, authorisations and notifications for placing on the market under Regulation (EC) No 258/97 on novel foods and novel food ingredients continue to remain in force. Novel food authorised in accordance with Regulation (EC) No 258/97 should be included in the Community list of novel foods established by this Regulation.

(24) The measures necessary for the implementation of this Regulation are to 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[17]. The Commission shall be assisted by the Committee referred to in Article 57(1) of 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,

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15 OJ L 109, 6.5.200, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p.15).

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

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

establishing the European Food Safety Authority and laying down procedures in matters of food safety[18].

(25) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

(26) As provided for by 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[19] Member States are to carry out official controls in order to enforce compliance with this Regulation.

HAVE ADOPTED THIS REGULATION:

Chapter I
Scope and Definitions

Article 1
Subject matter

This Regulation lays down the harmonised rules for the placing of novel foods on the market 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
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' shall mean food that has not been used for human consumption to a significant degree within the Community before 15 May 1997.

   Food derived from new production technologies are included where they fall under the following categories:

   - food from plants and animals produced by non-traditional breeding techniques and

[18] OJ L 31, 1.2.2002, p.1.
[19] OJ L 165, 30.4.2004. Corrected version (OJ L 191, 28.5.2004, p.1).

- food derived from a production process not currently used, 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 third country' shall mean food with a history of food use in a third country;

(c) 'history of food use' shall mean that documented data exist showing that the food in question has been part of the normal diet for at least one generation in a large part of the population of a country and continues to be so;

(d) 'history of safe food use' shall mean that evidence exists for the safety of the food in question from compositional data and from experience of use in a large part of the population of a country and continues to be used.

Article 3
Scope

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

2. This Regulation shall not apply to food when and insofar as they are used as:

- food additives falling within the scope of Regulation (EC) No [on food additives],
- food flavourings falling within the scope of Regulation (EC) No [on food flavourings],
- extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC,
- food enzymes falling within scope of Regulation (EC) ... [on food enzymes],
- vitamins and minerals falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2006,

and to food falling under the scope of Regulation (EC) 1829/2003 of the European Parliament and the Council on genetically modified food and feed.

3. Where necessary, it may be determined in accordance with the procedure laid down in Article 12(2) whether a type of food falls within the scope of this Regulation.

4. The Commission may establish, in accordance with the procedure referred to Article 12(3), implementing measures for assessing if a food has been used for human consumption to a significant degree within the Community. Except for food supplements, the use of a food exclusively as or in a food supplement shall not be sufficient for the use for human consumption to a significant degree within the Community before 15 May 1997.

Article 4

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

1. In case there is a need to collect information on the degree to which a food has been used for human consumption within the Community before 15 May 1997, the procedure laid down in paragraphs (2) to (6) will apply.

2. A Member State or any interested party intending to market a food may make a request to the Commission for the collection of information available in the Member States regarding the use of that food for human consumption.

3. The request shall be forwarded to the Member States and be published on a dedicated page on the Commission's website. Member States shall respond to the request within three months from the date on which the request was transmitted by the Commission.

4. Any interested party may provide the Commission with information regarding the use of the food for human consumption within three months from the date of publication of the Commission's request.

5. The Commission shall ask the Member States, in which the food was used according to the information from an interested party, to verify this information. The Member State shall inform the Commission of the results of the verification within a period of thirty days from the date of the request.

6. The Commission shall make available to the public without delay any information collected in accordance with paragraphs (3) and (4).

7. In cases, where the information collected in accordance with paragraphs (3) and (4) do not clearly show whether a food has been used before 15 May 1997 for human consumption to a significant degree within the Community, or if a Member State or an interested party so requests, the Commission shall adopt, in accordance with the procedure provided for in Article 12(3), a decision on whether the food is a novel food.

Chapter II

Requirements and Inclusion in Community List of Novel Foods

Article 5

Community list of novel foods

1. No person shall place on the market a novel food unless it has been included in the Community list of novel foods (hereinafter "the Community list") to be established and published on a dedicated page of the Commission's website.

2. Inclusion in the Community list as referred to in paragraph 1 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds set out in this Regulation.

Article 6
Conditions for inclusion in the Community list of novel foods

1. 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 health of the consumer,

   (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.

2. In addition to the conditions laid down in paragraph 1, a novel food which is intended for particular nutritional use within meaning of Article 1 of Directive 89/938, shall fulfill the requirements for labelling, presentation, advertisement, composition, quality, hygiene and control, including sampling and analysis, and packaging laid down in that Directive and in the specific Directives referred to in Article 4, paragraph 1 thereof and in Annex 1 thereto.

Article 7
Content of the Community list of novel foods

1. The Community list shall be established and updated in accordance with the procedure referred to in Regulation (EC) No [common procedure].

2. By derogation to Article 7, third paragraph, of Regulation (EC) No [common procedure, the inclusion of a food in the Community list shall be decided in accordance with Article 12(2), in cases

   (a) where the inclusion is decided on the basis of an application supported by newly developed scientific evidence and by proprietary scientific data to which the protection provided for in Article 11 applies;

   (b) where for food safety reasons it is necessary to lay down post-market monitoring requirements, that the applicant shall guarantee and control.

3. The inclusion of a novel food in the Community list shall specify the designation of the food, and, where appropriate, conditions of use and additional specific labelling requirements to inform the final consumer.

4. In the case referred to in paragraph 2 the inclusion shall also indicate:

   (a) the name and address of the authorisation-holder;

   (b) the date of inclusion of the food in the Community list;

   (c) in the case of paragraph 2, point (a) the fact that the inclusion is based on newly developed scientific evidence and/or proprietary scientific data to which

the protection laid down in Article 11 applies for a period of 5 years from the date of the inclusion of the food in the Community list;

(d) in the case of paragraph 2, point (b), the requirements for post-market monitoring.

5. In cases referred to in paragraph 2, the inclusion of the food in the list shall have a validity of 5 years. Before the expiry of the date, the Community list shall be updated in accordance with paragraph 1 so that either the indications referred to in paragraph 4 under (a) to (d) are no longer included or the food is withdrawn from list.

Article 8
Traditional food from third country

1. By way of derogation from Articles 5 to 7, a traditional food from a third country for which a safety assessment has been carried out, can be placed on the market in accordance with paragraphs (2) to (6).

2. The food business operator intending to place a traditional food from a third country on the market shall notify the Commission, indicating the name of the food, its composition and the country of origin. The notification shall be accompanied by a safety assessment demonstrating the history of safe food use in a third country.

3. The Commission shall send the notification referred to in paragraph 2 without delay to the Member States and the European Food Safety Authority (hereinafter "Authority").

4. Within three months from the date of transmission of the notification in accordance with paragraph 3, a Member States and the Authority may inform the Commission that it has safety concerns as regards the placing on the market of the food, based on scientific grounds. In this case, the food cannot be placed on the market and Articles 5 to 7 apply. Within four months from the date of the notification in accordance with paragraph 2, the Commission shall inform the food business operator accordingly.

5. If no safety concerns have been raised, and no information thereof being communicated to the food business operator in accordance with paragraph 4, the food can be placed on the market.

6. The Commission shall make available to the public the list of novel foods notified in accordance with this Article and for which no safety concerns were raised.

7. Detailed rules for implementing this Article may be adopted in accordance with the procedure referred to Article 12(2).

Article 9
Guidance and preparation of opinion of the Authority

1. The Commission, in close cooperation with the Authority, shall make available technical guidance and tools where appropriate to assist the preparation and the

presentation of applications by food business operators and especially small and medium size enterprises.

2. In assessing the safety, the Authority shall take into account:

(a) for traditional food from a third country the history of its safe food use,

(b) that food shall be as safe as food from an comparable food category already existing on the market or, where appropriate, as the food that the novel food is intended to replace,

(c) in case of scientific grounds of safety concerns, additional safety information required to prove that the food is safe, shall be identified and communicated to the applicant in accordance with Article 6 of the Regulation (EC) No [common procedure].

Article 10
Supervision

1. If the inclusion of a food in the Community list includes measures referred to in Article 7 paragraph 2 point (b), the authorisation-holder shall be responsible for the enforcement of such measures

2. The producer or, where appropriate, the authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food. In particular, the producer or authorisation-holder shall forthwith inform the Authority of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

Chapter III

General and Final Provisions

Article 11
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 application, may not be used for the benefit of another applicant during a period of five years from the date of the inclusion of the food in the community list in accordance with Article 7 (2) without the agreement of the authorisation-holder.

Article 12
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, 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 13
Status of existing authorisations

Within 6 months from the date of entry into force of this Regulation the Commission shall enter novel foods authorised under Regulation (EC) No 258/97 in the community list of novel foods, including any existing authorisation conditions, as appropriate.

Article 14
Transitional measures

Any request submitted 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.

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 accompanied, where appropriate, by any appropriate proposals. The report and any proposal shall be made accessible to the public.

Article 16
Repeals

The following Regulations shall be repealed with effect from the date of application of this Regulation:

- Regulation (EC) No 258/97;

- Commission Regulation (EC) No 1852/2001.

Article 17
Amendment to Directive 89/398/EEC

Directive 89/398/ECC is amended as follows:

1. The following paragraph is inserted as paragraph 3 in Article 1:

"This Directive shall not apply to a substance or a product falling within the scope of Regulation (EC) No XX/XXXX on novel foods."

Article 18
Amendments to Regulation (EC) No [common procedure]

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

1. The title of the Regulation is replaced by the following title:

'Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes, food flavourings and novel foods'

2. Article 1 is amended as follows:

(a) paragraph 1 is replaced by the following:

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

(b) paragraph 2 is replaced by the following:

'2. The common procedure shall set the procedural arrangements for updating the lists of food products the marketing 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/2007 (hereinafter referred to as the "sectoral food laws").'

3. 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 and product' or 'substances and products'.

4. The following paragraph is inserted as paragraph 3 in Article 4:

'A single application may be made for different food uses regulated under different sectoral food laws in so far as the application fulfils the requirements of each of the specific sectoral food laws.'

Article 19
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 Communities*.

It shall apply from six months after the date of publication 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
The President

For the Council
The President