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PROPOSAL

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dated: 20 December 2013

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Subject: Proposal for a Regulation of the European Parliament and of the Council on novel foods

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union.

Encl.: COM(2013) 894 final - 2013/0435



Brussels, 18.12.2013
COM(2013) 894 final

2013/0435 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on novel foods

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

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

This proposal aims to ensure food safety, to protect public health and secure the functioning of the internal market for food, while supporting innovation for the food sector.

It aims to streamline the authorisation procedure, to improve its efficiency and transparency. It clarifies the definition of a novel food, including new technologies which have an impact on food.

It introduces a faster and more proportionate safety assessment for traditional foods from third countries having a history of safe food use.

The general criteria for the Novel Food definition remain unchanged: novel foods are foods and food ingredients which were not consumed in the EU to a significant degree before the entry into force (15 May 1997) of the current Novel Food Regulation.

- **General context**

On 14 January 2008, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on Novel Food¹.

The legislative discussions under the Ordinary legislative procedure mainly focused on the provisions applicable to nanomaterials, the cloning of animals for food production, traditional foods from third countries, the criteria to be examined for the risk assessment and risk management and to the procedure for the authorisation of novel foods in accordance with the Treaty on the Functioning of the European Union (Lisbon Treaty).

The discussions reached a stalemate on a limited number of issues (in particular those linked to cloning of animals). The Conciliation Committee did not reach a final agreement at its last meeting on 28 March 2011 and the proposal was not adopted by the Union legislator.

The Commission considers that issues related to cloning of farm animals should be addressed in a separate proposal, based on an impact assessment.

This proposal is therefore limited to the safety of novel food and is based on the overall agreement achieved in Conciliation.

¹ COM(2007) 872 final.

- **Current legislation**

Authorisation and use of novel foods and food ingredients have been harmonised in the European Union since 1997 when Regulation (EC) No 258/97 on Novel Food and novel food ingredients² was adopted. The current legislation consists of the Novel Food Regulation and one Commission Regulation:

- 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.
- Commission Regulation (EC) No 1852/2001 lays 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 258/97³.

Currently, an application for a pre-market authorisation is first assessed by a Member State food assessment body. The initial assessment report is circulated for comments and objections to all Member States by the Commission. If no reasoned safety objections are presented, the novel food may be placed on the market. If reasoned safety objections are presented, an authorisation decision is required by the Commission. This in most cases includes an additional assessment which is carried out by the European Food Safety Authority (EFSA).

The authorisation under current rules is granted to the applicant (individual authorisation). In addition, another applicant may notify to the Commission the placing on the market of a food that is substantially equivalent to the authorised food. This notification has to be substantiated by scientific evidence showing the substantial equivalence of the notified food to the authorised food. These rules have allowed for placing on the market various foods such as Baobab dried fruit pulp, Chia seeds, fish (*Sardinops sagax*) peptide product or synthetic vitamin K2.

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

The proposal brings together and updates the provisions of the above mentioned texts which will be repealed at the time of entry into application of the new legislation.

The proposal pursues the objectives of the Communication on Smart Regulation in the European Union⁴ and of the Europe 2020 Strategy⁵. The

² Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

³ OJ L 253, 21.9.2001, p. 17.

⁴ COM(2010) 543 final.

⁵ COM(2010) 2020 final.

emphasis is on simplifying and streamlining the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining a high level of public health protection and taking global aspects into consideration.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Stakeholders from food industry, consumers, third countries and national authorities and international organisations have been consulted both before and after the adoption of Commission proposal of January 2008. Commission representatives also participated at several meetings or seminars organised by stakeholders and dedicated to specific issues (e.g. traditional food from third countries, assessment and authorisation procedure, nanotechnologies) and bilateral meetings with interested parties.

During the first and second reading and the Conciliation procedure on the 2008 legislative proposal, stakeholders also expressed their positions.

- **Impact assessment**

The Commission carried out an Impact Assessment in 2007. For each of the measures of the 2008 proposal, several options were examined with regard to their economic, social and environmental impact on the various stakeholders and Member States. It is available at

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

Regarding the current proposal, the 2008 impact assessment is still valid, as the rationale for an in-depth revision of the current legislation (the length and cost of the current authorisation procedure, the need for a centralised risk assessment and risk management and for an adjusted procedure for the placing on the EU market of traditional foods from third countries) is unchanged.

The main changes compared to the 2008 proposal are primarily those introduced during the Ordinary legislative procedure whose impact is unchanged as they only clarify the purpose of the measures.

As regards a possible exclusion of micro-enterprises from the scope, it appears that such an exemption would not be compatible with the overall objective of ensuring the safety of the novel foods which are put on the EU market.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Legal basis**

Legal basis of this proposal is Article 114 of the Treaty on the Functioning of the European Union.

- **Subsidiarity principle**

The proposal has to comply with the subsidiarity principle since it does not fall under the exclusive competence of the Union.

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 different 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 food in the EU.
- 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 by action at EU level.

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 authorisation and thus contributes to the functioning of the 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 while reducing the administrative burden.

4. BUDGETARY IMPLICATION

The financial and budgetary impact of the proposal is indicated in the legislative financial statement attached to this proposal.

5. CHOICE OF INSTRUMENTS

The proposed instrument is 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 foods 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.

6. OTHER ISSUES

• **Simplification**

The proposal provides for the simplification of legislation and administrative procedures for public authorities and private parties as compared to the legislation in place:

- There is only one centralised procedure for the assessment and authorisation of novel foods. The wording of the proposal has been updated and clarified.
- National administrative procedures and duplication of work are removed.
- The authorisation procedure is streamlined, increasing its efficiency and reducing the administrative burden in particular for private parties.
- A simplified procedure for the placing on the market of the traditional foods from third countries is introduced.

• **Cost for business, in particular SMEs**

The proposed measures will reduce administrative burden and the length and cost of the authorisation procedure for the food industry (18 months instead of 3 years in average currently). Generic authorisation will avoid the re-submission of new applications by other companies for the same novel food and are expected to benefit in particular SMEs. However, in order to maintain an incentive for developing really innovative food products, a "data protection" regime with the granting of an applicant linked authorisation for a maximum of 5 years is introduced. The measures will also facilitate EU market access for traditional foods from third countries by setting up a simplified and more proportionate procedure.

- **European Economic Area**

The proposed act concerns an European Economic Area (EEA) matter and therefore extends to the EEA.

- **Detailed explanation of the proposal**

Chapter I – Subject matter, scope and definitions

Novel foods shall be subject to safety evaluation and authorisation via a fully harmonised procedure. The definitions are clarified and updated. It may be determined with the examination procedure if a food falls within the scope of the Regulation.

Nanomaterials which are intended for food uses and covered by the definition of "engineered nanomaterials", as laid down in Regulation (EU) n°1169/2011 on Food Information to Consumers, shall be assessed and authorised under this Regulation before being placed on the EU market.

Chapter II – Requirements for placing novel foods on the market within the Union

All novel foods and their use in food have to comply with the following criteria: they should not present a danger to human health and their use should not mislead the consumer.

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

The current system of individual authorisations is replaced by generic authorisations. The so called current "simplified procedure" based on substantial equivalence, which aims to extend an individual authorisation to another company for the same novel food, is removed since authorisations become directly generic.

Already authorised novel foods shall continue to be marketed and will be included in the Union list of novel foods.

Chapter III – Authorisation procedure for a novel food

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 authorisation of novel foods shall be submitted to the Commission. The Commission may then request a scientific opinion on risk assessment from the European Food Safety Authority (EFSA).

The inclusion of a novel food in the Union 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 (SCOFCAH).

For traditional foods from third countries, a safety assessment and a risk management, based on a history of safe food use, is introduced. If a history of safe food use in a third country for at least 25 years has been demonstrated by the applicant, and if the Member States or EFSA do not present reasoned safety objections based on scientific evidence, the food may be included in the Union list.

However, in case reasoned safety objections are presented, an EFSA assessment followed by an EU authorisation procedure, similar to the standard authorisation procedure but with shorter deadlines, is required.

This procedure provides for a more proportionate risk assessment and risk management of traditional foods from third countries and allows for a quicker placing on the EU market for a range of products from primary production without compromising food safety.

Chapter IV – Additional procedural rules and other requirements

The information provided by the applicant should be kept confidential where the disclosure of such information might significantly harm their competitive position.

Chapter V – Data protection

By way of derogation from the generic authorisation in order to support innovation in the EU food industry and only in duly justified cases, individual authorisations with data protection may be granted for a maximum period of five years.

Chapter VI – Penalties and committee procedure

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 this Regulation will mainly be adopted by the Commission in accordance with the examination procedure laid down in Article 5 of Regulation (EU) n°182/2011. 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.

Chapter VII – Transitional and final provisions

Transitional measures are necessary to ensure a smooth transition with on-going applications and notifications, pending the entry into application of this legislation. Furthermore, due to clarification of the definition of the novel food laid down in this Regulation and to enhance legal certainty, a food that was legally placed on the market prior to the application of this Regulation, should be allowed to be continued to be marketed until the risk assessment and authorisation procedures have been concluded.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on novel foods

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee⁶,

Acting in accordance with the ordinary legislative procedure⁷,

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 benefitting their social and economic interests. Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating unfair conditions of competition.
- (2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency.
- (3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council⁸ and by Commission Regulation (EC) No 1852/2001⁹. Those rules need to be updated to simplify the current authorisation

⁶ OJ C [...], [...], p. [...].

⁷ OJ C [...], [...], p. [...].

⁸ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁹ 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 (OJ L 253, 21.9.2001, p. 17).

procedures and to take account of recent developments in Union law. For the sake of clarity of Union legislation, Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and Regulation (EC) No 258/97 should be replaced by this Regulation.

- (4) Foods which are intended to be used for technological purposes and genetically modified food should not fall within the scope of this Regulation as they are already covered by other Union rules. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council¹⁰, enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council¹¹, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹², flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council¹³ and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council¹⁴ should be excluded from the scope of this Regulation.
- (5) The existing categories of novel food laid down in Article 1 of Regulation (EC) No 258/97 should be clarified and updated by replacing the existing categories with a reference to the general definition of food provided for in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council¹⁵.
- (6) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997, should be maintained as a criterion for a food to be considered as a novel food. A use within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union.
- (7) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, it should also be clarified that a food should be considered as a novel food where a production process which was not previously used for food production in the Union is applied to that food or when foods contain or

¹⁰ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

¹¹ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).

¹² Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

¹³ Regulation (EC) No 1334 /2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

¹⁴ Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (recast) (OJ L 141, 6.6.2009, p. 3).

¹⁵ 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 (OJ L 31, 1.2.2002, p. 1).

consist of engineered nanomaterials, as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council¹⁶.

- (8) Vitamins, minerals and other substances intended to be used in food supplements or to be added to food including infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control are subject to the rules provided for in Directive 2002/46/EC of the European Parliament and of the Council¹⁷, in Regulation (EC) No 1925/2006 of the European Parliament and of the Council¹⁸ and in Regulation (EU) No 609/2013 of the European Parliament and of the Council¹⁹. Those substances should also be assessed in accordance with the rules laid down in this Regulation when they fall within the definition of novel food laid down in this Regulation.
- (9) When there is a significant change in the production process of a substance that has been used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, or a change in particle size of such a substance, for example through nanotechnology, it may have an impact on food and thereby on food safety. Therefore, that substance should be considered a novel food under this Regulation and should be re-evaluated first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.
- (10) If, prior to 15 May 1997, a food was used exclusively as, or in, a food supplement, as defined in point (a) of Article 2 of Directive 2002/46/EC, it should be allowed to be placed on the market within the Union after that date for the same use without being considered a novel food for the purposes of this Regulation. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than in, or as, a food supplement should be subject to this Regulation.
- (11) The placing on the market within the Union of traditional foods from third countries should be facilitated, where the history of safe food use in a third country has been

¹⁶ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulation (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directive 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

¹⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

¹⁸ 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 (OJ L 404, 30.12.2006, p. 26).

¹⁹ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

demonstrated. Those foods should have been consumed in a third country for at least 25 years as a part of the customary diet within a large part of the population of the country. The history of safe food use should not include non-food uses or uses not related to normal diets.

- (12) It should be clarified that foods from third countries which are regarded as novel foods in the Union should only be considered as traditional foods from third countries when they are derived from primary production as defined in Article 3 of Regulation (EC) No 178/2002, regardless of whether or not they are processed or unprocessed foods. Therefore, where a new production process has been applied to this food or where the food contains or consists of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011, the food should not be considered to be traditional.
- (13) Food products produced from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food, their composition or amount, should not be considered as novel foods. However, modifications of a food ingredient, such as selective extracts or the use of other parts of a plant, that have so far not been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.
- (14) Directive 2001/83/EC of the European Parliament and of the Council²⁰ applies where a product, taking into account all its characteristics, may fall both within the definition of "medicinal product" as laid down in Article 1(2) of that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as laid down in Article 2 of Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.
- (15) Implementing powers should be conferred to the Commission to decide whether a particular food falls within the definition of a novel food and is thereby subject to rules on novel food laid down in this Regulation.
- (16) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in the Member States. Food business operators should consult Member States if they are unsure of the status of the food they intend to place on the market. When there is no information or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information. Implementing powers should be conferred on the Commission to specify the procedural steps of such consultation process.
- (17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their use should not mislead the

²⁰ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

- (18) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, by means of an implementing act, a Union list of novel foods by entering novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. As those novel foods have already been evaluated for their safety, have been legally produced and marketed in the Union and have not given rise to health concerns in the past, the advisory procedure should be used for the initial establishment of the Union list.
- (19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.
- (20) Criteria for the evaluation of the safety risks arising from novel foods should also be laid down. In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ("EFSA").
- (21) As regards the possible use of nanomaterials for food use, EFSA considered in its opinion of 6 April 2011²¹ on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. In order to better assess the safety of nanomaterials for food use, the Commission is developing test methods which take into account specific characteristics of engineered nanomaterials.
- (22) When a novel food is authorised and included in the Union list, the Commission should have the power to introduce post-market monitoring requirements to monitor the use of the authorised novel food to ensure that the use is within safe limits as established in the safety assessment by EFSA.
- (23) Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by innovators in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation. The newly developed scientific evidence and proprietary data provided in support of an

²¹ EFSA Journal 2011;9(5):2140.

application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the prior applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Union list on the basis of their own scientific data or by referring to the protected data with the agreement of the prior applicant. However, the overall five year period of data protection which has been granted to the prior applicant should not be extended due to the granting of data protection to subsequent applicants.

- (24) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use to ensure that consumers are sufficiently informed of the nature of the novel food.
- (25) For those applications which have been submitted under Regulation (EC) No 258/97 before the date of application of this Regulation risk assessment and authorisation procedures should be concluded in accordance with this Regulation. Furthermore, due to clarification of the definition of novel food laid down in this Regulation and to enhance legal certainty, a food that was legally placed on the market at the date of application of this Regulation, should in principle be allowed to be placed on the market until the risk assessment and authorisation procedures have been concluded. Therefore, transitional rules should be laid down to ensure a smooth transition to the rules of this Regulation.
- (26) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (27) In order to ensure uniform conditions for the implementation of this Regulation with regard to updating the Union list concerning the adding of a traditional food from a third country where no reasoned safety objections have been expressed, implementing powers should be conferred on the Commission.
- (28) The implementing powers relating to the definition of ‘novel food’, the consultation process for determination of novel food status, other updates of the Union list, the drafting and presentation of applications or notifications for the inclusion of foods in the Union list, the arrangements for checking the validity of applications or notifications, confidentiality treatment and transitional provisions, should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²².

²² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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

HAVE ADOPTED THIS REGULATION:

Chapter I

Subject matter, scope and definitions

Article 1 *Subject matter and scope*

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests.
2. This Regulation shall not apply to:
 - (a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;
 - (b) foods when and in so far as they are used as:
 - (i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;
 - (ii) food additives falling within the scope of Regulation (EC) No 1333/2008;
 - (iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;
 - (iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC;
 - (c) food falling within the scope of Council Directive XXX/XX/EU on [on the placing on the market of food from animal clones].

Article 2 *Definitions*

1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.

2. The following definitions shall also apply:

- (a) "novel food" means all food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular:
- (i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;
 - (ii) food containing or consisting of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;
 - (iii) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
 - a new production process has been applied as referred to in point (i) of this paragraph; or
 - such substances contain or consist of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;
 - (iv) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;
- (b) "traditional food from a third country" means novel food, other than the novel food as referred to in point (a)(i) to (iii), which is derived from primary production, with a history of safe food use in a third country;
- (c) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a large part of the population of a third country, prior to a notification referred to in Article 13;
- (d) "the applicant" means the Member State, the third country or the interested party, who may represent several interested parties, who has submitted an application in accordance with Article 9 or 15 or a notification in accordance with Article 13 to the Commission;
- (e) "valid application" and "valid notification" mean an application or a notification which falls in the scope of this Regulation and contains the information required for risk assessment and authorisation procedure.

Article 3

Implementing power concerning the definition of novel food in Article 2(2)(a)

In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Article 4

Procedure for determination of novel food status

1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.
2. Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997.
3. The Commission may, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Chapter II

Requirements for placing novel foods on the market within the Union

Article 5

Union list of novel foods

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ("the Union list").
2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such and used in or on foods under the conditions of use specified therein.

Article 6
*General conditions for inclusion of
novel foods in the Union list*

The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

- (a) it does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- (b) its use does not mislead the consumer;
- (c) where it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Article 7
Initial establishment of the Union list

No later than ...²³ the Commission shall, by means of an implementing act, establish the Union list by entering novel foods authorised or notified under Articles 4, 5 or 7 of Regulation (EC) N° 258/97 in the Union list, including any existing authorisation conditions.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).

Article 8
Contents of the Union list

1. The Commission shall authorise a novel food and update the Union list in accordance with the rules laid down in:
 - (a) Articles 9, 10 and 11 and, where applicable, in accordance with Article 25 or
 - (b) Articles 13 to 18.
2. The authorisation of a novel food and updating of the Union list provided for in paragraph 1 shall consist of one of the following:
 - (a) adding a novel food to the Union list;
 - (b) removing a novel food from the Union list;
 - (c) adding, removing or changing the conditions, specifications or restrictions associated with the inclusion of a novel food on the Union list.

²³ Publications Office: please insert date: 24 months after the entry into force of this Regulation.

3. The entry for a novel food in the Union list provided for in paragraph 2 shall include where relevant:
 - (a) a specification of the novel food;
 - (b) the conditions under which the novel food may be used, in order to avoid, in particular, possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;
 - (c) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;
 - (d) a post-market monitoring requirement in accordance with Article 23.

Chapter III

Authorisation procedure for a novel food

SECTION I

GENERAL RULES

Article 9

The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list

1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 8 shall start either on the Commission's initiative or following an application to the Commission by an applicant.

The application shall include:

 - (a) the name and description of the novel food;
 - (b) the composition of the novel food;
 - (c) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
 - (d) where applicable, a proposal for the conditions of use and a proposal for specific labelling requirements which do not mislead the consumer.
2. The Commission may request EFSA to render its opinion if the update is liable to have an effect on human health.

3. The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 8 shall end with the adoption of an implementing act in accordance with Article 11.
4. By way of derogation from paragraph 3, the Commission may end the authorisation procedure and decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.

Where applicable, it shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.

In such cases, the Commission shall inform the applicant and all Member States directly, indicating the reasons for not considering the update justified.

5. The applicant may withdraw its application referred to in paragraph 1 at any time before the adoption of EFSA's opinion referred to in paragraph 2, thereby terminating the procedure for authorising a novel food and updating the Union list.

Article 10 *Opinion of EFSA*

1. Where the Commission requests an opinion from EFSA, it shall forward the valid application to EFSA. EFSA shall adopt its opinion within nine months from the date of receipt of a valid application.

In assessing the safety of novel foods, EFSA shall, where appropriate, consider the following:

- (a) whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
 - (b) whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union.
2. EFSA shall forward its opinion to the Commission, the Member States and, where applicable, to the applicant.
 3. In duly justified cases, where EFSA requests additional information from the applicant, the period of nine months provided for in paragraph 1 may be extended.

After consulting the applicant, EFSA shall specify a period within which that additional information may be provided and shall inform the Commission of the additional period required.

Where the Commission does not object within eight working days of being informed by EFSA, the period of nine months provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

4. Where the additional information referred to in paragraph 3 is not sent to EFSA within the additional period referred to in that paragraph, it shall finalise its opinion on the basis of the information already provided to it.
5. Where applicants submit additional information on their own initiative, they shall send it to the Commission and to EFSA.

In such cases, EFSA shall give its opinion within the period of nine months provided for in paragraph 1.

6. EFSA shall make the additional information referred to in paragraph 3 available to the Commission and to the Member States.

Article 11

Authorisation of a novel food and updating the Union list

1. Within nine months from the date of publication of EFSA's opinion, the Commission shall submit to the committee referred to in Article 27(1) a draft implementing act updating the Union list taking account of:
 - (a) the conditions provided for in Article 6 where applicable;
 - (b) any relevant provisions of Union law;
 - (c) the EFSA's opinion;
 - (d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).

2. Where the Commission has not requested an opinion from EFSA in accordance with Article 9(2), the nine-month period provided for in paragraph 1 shall start from the date on which the Commission received a valid application in accordance with Article 9(1).

Article 12

Implementing power concerning administrative and scientific requirements for applications

By ...²⁴ at the latest, the Commission shall adopt implementing acts concerning:

- (a) the contents, drafting and presentation of the application referred to in Article 9(1);
- (b) the arrangements for checking the validity of those applications;
- (c) the type of information required to be included in the opinion of EFSA referred to in Article 10.

²⁴ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

SECTION II

SPECIFIC RULES FOR TRADITIONAL FOODS FROM THIRD COUNTRIES

Article 13

Notification of traditional foods from third countries

An applicant, who intends to place on the market within the Union a traditional food from a third country, shall notify that intention to the Commission.

The notification shall include the following information:

- (a) the name and a description of the traditional food;
- (b) its composition;
- (c) its country of origin;
- (d) documented data demonstrating the history of safe food use in a third country;
- (e) where applicable, the conditions of use and specific labelling requirements, which do not mislead the consumer.

Article 14

Procedure for traditional foods from third countries

1. The Commission shall forward the valid notification provided for in Article 13 without delay to the Member States and to EFSA.
2. Within four months from the date on which the valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or EFSA may submit to the Commission reasoned safety objections, based on scientific evidence, to the placing on the market within the Union of the traditional food concerned.
3. The Commission shall inform the Member States, EFSA and the applicant of the outcome of the procedure referred to in paragraph 2.
4. Where no reasoned safety objections are made in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update without delay the Union list.
5. Where reasoned safety objections, based on scientific evidence, are submitted to the Commission in accordance with paragraph 2, the Commission shall not authorise the placing on the market of the traditional food concerned nor update the Union list.

In that case, the applicant may submit an application to the Commission in accordance with Article 15.

Article 15
Application for a traditional food from a third country

The application provided for in Article 14(5) shall include in addition to the information already provided in accordance with Article 13, documented data relating to the reasoned safety objections submitted in accordance with Article 14(5).

The Commission shall forward the valid application without undue delay to EFSA and make it available to the Member States.

Article 16
Opinion of EFSA on a traditional food from a third country

1. EFSA shall adopt its opinion within six months from the date of receipt of a valid application.
2. In assessing the safety of a traditional food from a third country, EFSA shall consider the following matters:
 - (a) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant in accordance with Articles 13 and 15;
 - (b) whether the composition of the food and the conditions of its use, do not pose a safety risk to human health in the Union.
3. EFSA shall forward its opinion to the Commission, the Member States and the applicant.
4. In duly justified cases, where EFSA requests additional information from the applicant, the period of six months provided for in paragraph 1 may be extended.

After consulting the applicant, EFSA shall specify a period within which that additional information may be provided and shall inform the Commission of the additional period needed.

Where the Commission does not object within eight working days of being informed by EFSA, the period of six months provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

5. Where the additional information referred to in paragraph 4 is not sent to EFSA within the additional period referred to in that paragraph, it shall finalise its opinion on the basis of the information already provided to it.
6. Where applicants submit additional information on their own initiative, they shall send it to the Commission and to EFSA.

In such cases, EFSA shall give its opinion within the period of six months provided for in paragraph 1.

7. EFSA shall make the additional information available to the Commission and to the Member States.

Article 17

Authorisation of a traditional food from a third country and update of the Union list

1. Within three months of the date of publication of EFSA's opinion, the Commission shall submit to the Committee referred to in Article 27(1) a draft implementing act to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:
 - (a) the conditions provided for in Article 6 where applicable;
 - (b) any relevant provisions of Union law;
 - (c) the EFSA's opinion;
 - (d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).

2. By way of derogation from paragraph 1, the Commission may end the authorisation procedure and decide not to proceed with an update, at any stage of the procedure, where it considers that such an update is not justified.

Where applicable, it shall take account of the views of Member States, the EFSA's opinion and any other legitimate factors relevant to the update under consideration.

In such cases, the Commission shall inform the applicant and all Member States directly, indicating the reasons for not considering the update justified.

3. The applicant may withdraw its application referred to in Article 15 at any time before the adoption of EFSA's opinion referred to in Article 16, thereby terminating the procedure for authorising a traditional food from a third country and updating the Union list.

Article 18

Updates to the Union list as regards authorised traditional foods from third countries

For removing a traditional food from a third country from the Union list or for adding, removing or changing conditions, specifications or restrictions associated with the inclusion of a traditional food from a third country on the Union list, Articles 9 to 12 apply.

Article 19

Implementing power concerning administrative and scientific requirements concerning traditional foods from third countries

By ...²⁵ the Commission shall adopt implementing acts concerning:

²⁵ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

- (a) the contents, drafting and presentation of the notification provided for in Article 13 and of the application provided for in Article 14(5);
- (b) the arrangements for checking the validity of those notifications and applications;
- (c) the procedural steps for the exchange of information with the Member States and with EFSA for submitting reasoned safety objections as referred to in Article 14(2), (4) and (5);
- (d) the type of information required to be included in the opinion of EFSA referred to in Article 16.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Chapter IV

Additional procedural rules and other requirements

Article 20

Additional information concerning risk management

1. Where the Commission requests additional information from an applicant on matters concerning risk management, it shall determine, together with the applicant, the period within which that information must be provided.

In such cases, the time period provided for in Article 11(1) or (2) or in Article 17(1) may be extended accordingly. The Commission shall inform the Member States of that extension and shall make the additional information available to the Member States once it has been received.

2. Where the additional information referred to in paragraph 1 is not received within the extended period referred to in that paragraph, the Commission shall act on the basis of the information already provided.

Article 21

Extension of time periods

In exceptional circumstances, the Commission may extend the time periods provided for in Articles 10(1), 11(1) or (2), 16(1) and 17(1) on its own initiative or, where applicable, at EFSA's request, where the nature of the matter in question so justifies.

In such cases the Commission shall inform the Member States and the applicant of the extension and the reasons for it.

Article 22
Confidentiality of the application for updating of the Union list

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may significantly harm their competitive position.
2. For the purposes of paragraph 1, applicants shall indicate which of the information provided they wish to be treated as confidential and provide all the necessary information to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.
3. After being informed of the Commission's position on the request, applicants may withdraw their application within three weeks so as to preserve the confidentiality of the information provided.

Confidentiality shall be preserved until that period expires.

4. After expiry of the time period referred to in paragraph 3, the Commission may decide after consulting with the applicants which information may remain confidential and, in the case a decision has been taken, shall notify the Member States and the applicants accordingly.

However, confidentiality shall not apply to the following information:

- (a) the name and address of the applicant;
 - (b) the name and description of the novel food;
 - (c) the proposed use of the novel food;
 - (d) a summary of the studies submitted by the applicant;
 - (e) where applicable, the analysis method(s).
5. The Commission, the Member States and EFSA shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation in accordance with paragraph 4, except for information which is required to be made public in order to protect human health.
 6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and EFSA shall not disclose confidential information, including information the confidentiality of which is the subject of disagreement between the Commission and the applicant.
 7. The application of paragraphs 1 to 6 shall not affect the circulation of information concerning the application between the Commission, the Member States and EFSA.
 8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Article 23
Post-market monitoring

1. The Commission may, for food safety reasons and taking into account the opinion of EFSA, impose a requirement for post-market monitoring of a novel food to ensure that the use of the authorised novel food is within safe limits.
2. The food business operators 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 any third country in which the novel food is placed on the market.

Chapter V
Data protection

Article 24
Authorisation procedure in case of data protection

1. On request by the applicant, supported by appropriate and verifiable information included in the application provided for in Article 9(1), newly developed scientific evidence or scientific data supporting the application may not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation and the inclusion of the novel food in the Union list without the agreement of the prior applicant.
2. That data protection shall be granted where the following conditions are met:
 - (a) the newly developed scientific evidence or scientific data was designated as proprietary by the prior applicant at the time the first application was made;
 - (b) the prior applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made and
 - (c) the novel food could not have been authorised without the submission of the proprietary scientific evidence or scientific data by the prior applicant.

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

3. Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.

Article 25

Authorisation of a novel food and inclusion in the Union list based on protected proprietary scientific evidence or scientific data

1. Where a novel food is authorised and included in the Union list based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 24(1), the entry of a novel food in the Union list shall indicate, in addition to the information referred to in Article 8(3):
 - (a) the date of entry of the novel food in the Union list;
 - (b) the fact that that entry is based on proprietary scientific evidence and scientific data protected in accordance with Article 24;
 - (c) the name and address of the applicant;
 - (d) the fact that the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) during the period of data protection, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data designated as such by the prior applicant or with the agreement of the prior applicant;
 - (e) the end date of the data protection provided for in Article 24.
2. Scientific evidence or scientific data protected in accordance with Article 24 or for which the protection period under that Article has expired shall not be protected again.

Chapter VI

Penalties and committee procedure

Article 26

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ...²⁶ at the latest and shall notify it without delay of any subsequent amendment affecting them.

²⁶ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

Article 27
Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be the committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Chapter VII **Transitional and final provisions**

Article 28
Repeal

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 are hereby repealed.

Article 29
Transitional measures

1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before ...²⁷ shall be considered as an application under this Regulation.
2. Foods which are lawfully placed on the market at the date of entry into force of this Regulation and which fall within the definition of novel foods laid down in this Regulation may continue to be placed on the market subject to the following conditions:

²⁷ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

- (a) An application for authorisation of a novel food in accordance with Article 9(1) or a notification or application for authorisation of a traditional food from a third country in accordance with Articles 13 and 15 shall be submitted by [date of application of implementing rules according to Article 12(a) or 19(a) + 24 months] at the latest. That application or notification shall be forwarded by the Commission to the Member States and EFSA.
 - (b) If no reasoned safety objections are made by a Member State or EFSA within four months from the date of receipt of the application or of the notification referred to in point (a), the food may continue to be placed on the market until a final decision on the application or notification has been taken in accordance with Article 11, 14 or 17.
 - (c) If reasoned safety objections are made by a Member State or EFSA, the Commission shall take an interim decision on the placing on the market of the food within the Union within four months of the date of receipt of such objections.
3. The Commission may, by means of implementing acts, adopt transitional measures for the application of paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Article 30
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 ...²⁸.

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

²⁸ Publications Office: please insert date: 24 months after the date of entry into force of this Regulation.

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
 - 3.2.1. *Summary of estimated impact on expenditure*
 - 3.2.2. *Estimated impact on operational appropriations*
 - 3.2.3. *Estimated impact on appropriations of an administrative nature*
 - 3.2.4. *Compatibility with the current multiannual financial framework*
 - 3.2.5. *Third-party participation in financing*
- 3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on novel foods

1.2. Policy area(s) concerned in the ABM/ABB structure²⁹

Novel Food and Food Safety

1.3. Nature of the proposal/initiative

- The proposal/initiative relates to **a new action**
- The proposal/initiative relates to **a new action following a pilot project/preparatory action**³⁰
- The proposal/initiative relates to **the extension of an existing action**
- The proposal/initiative relates to **an action redirected towards a new action**³¹

1.4. Objectives

1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

In the field of novel foods, the proposals aim

(1) to ensure a high level of **public health** and the good functioning of the **internal market**,

(2) to facilitate market access for traditional foods from third countries which have a long history of safe food use,

(3) to promote **innovation** for the food sector.

1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

Specific objective 1: Simplification of legislation and of administrative procedures for public authorities and food business operators through streamlined and fully centralised authorisation procedure.

²⁹ ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

³⁰ As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

³¹ The applications currently sent to the Member States will be sent to the Commission and the risk assessment currently managed by the Member States will be performed by EFSA (fully centralised procedure).

ABM/ABB activity(ies) concerned

Health within the heading 3 Security and Citizenship.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

On food business operators: the authorisation procedure is streamlined and fully centralised with deadlines for each step of the procedure. The administrative burden is reduced (removal of current double risk assessment). Time and related costs for getting a Novel Food authorisation are reduced.

Individual authorisations are becoming generic which facilitates market access in particular for SMEs. The introduction of the "data protection" regime stimulates innovation in the food sector.

On operators from third countries: Better EU market access for traditional foods from third countries through simplified procedure (notification).

On EU consumers: a high level of public health is ensured by a systematic centralised risk assessment by EFSA followed by an EU authorisation decision.

On Member State authorities: The workload for ensuring the national assessment is removed.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

- The average length for applicants to get an authorisation decision.
- Number of notifications agreed per year for traditional foods from third countries.
- Number and ratio of authorisations with data protection regime granted to innovative foods per year.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The existing regulatory framework is being criticised for being particularly burdensome, lengthy and costly to get a Novel Food authorisation. As a consequence most EU food businesses do not want to develop and put on the market new foods or food ingredients which would fall under the Novel Food scope, in particular SMEs.

At international level, the EU is much criticized at WTO level by third countries which consider that the Novel Food authorisation is a barrier to trade and prevents EU market access to foods which have a long history of safe food use in their country of origin.

The present revision aims to address these weaknesses of current EU legislation and to put in place a streamlined and adapted regulatory framework, thus ensuring a high level of public health.

1.5.2. Added value of EU involvement

The proposed revision of the existing Regulation concerning novel foods can only be achieved at Union level. The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU).

1.5.3. Lessons learned from similar experiences in the past

The removal of the national assessment has already been achieved for other food ingredients (additives, flavourings and enzymes) under Regulation (EC) N° 1331/2008 establishing a common authorisation procedure. The Novel Food authorisation procedure is similar.

1.5.4. Coherence and possible synergy with other relevant instruments

The Novel Food Regulation addresses mainly the authorisation procedure to ensure that novel foods are safe. The requirements of the food law also apply to novel foods.

1.6. Duration and financial impact

Proposal/initiative of **limited duration**

- Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

- Implementation with a start-up period from end 2014 to end 2016, followed by full-scale operation.

1.7. Management mode(s) envisaged³²

Centralised direct management by the Commission.

Centralised indirect management with the delegation of implementation tasks to:

- executive agencies
- bodies set up by the Communities³³
- national public-sector bodies/bodies with public-service mission
- persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

Shared management with the Member States

Decentralised management with third countries

Joint management with international organisations (*to be specified*)

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments

The Commission intends to ensure the services concerned via centralised direct management with the EFSA in charge of the scientific risk assessment.

³² Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

³³ As referred to in Article 185 of the Financial Regulation.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The Novel Food expert working group composed of Member State experts and the SCOFCAH committee (Member State Authorities) provide regular platforms to discuss issues related to the implementation of the new regulatory framework.

Five years after entry into force, the Commission should report to the European Parliament and to the Council about the implementation of the new Regulation including on indicators and results. The report should address the impact of the new rules in particular on the simplified procedure for traditional foods from third countries.

2.2. Management and control system

2.2.1. Risk(s) identified

It is the responsibility of food business operators to check if their products need a Novel Food authorisation to be put on the EU market.

The main risk for food safety is that foods which are novel may be on the EU market without a Novel Food Authorisation and therefore illegal.

2.2.2. Control method(s) envisaged

Member States shall establish annual official control plans for all types of foods which are submitted to Commission for authorisation.

Regular meetings with stakeholders and Member States will be organised to ensure that the EU Regulation is respected.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

In addition to the application of all regulatory control mechanisms, DG Health and Consumers will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure *inter alia* that its internal anti-fraud related controls are fully aligned with the CASF and that the fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing implementing activities of the Novel Food Regulation will be set up; In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing implementing activities of the Novel Food regulation will expressly entitle the Commission,

including OLAF and the Court of Auditors to conduct audits, on the spot checks and inspections;

- during the evaluation phase of a call for proposals/tenders, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

No new resources will be needed. Operational resources which are necessary for implementation of this initiative will be covered by redeployment within the contribution granted to EFSA during the annual budgetary procedure, in accordance with the financial programming set by the Communication from the Commission to the European Parliament and the Council (reference COM (2013) 519 final).

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description: EFSA]	Diff./non-diff. (³⁴)	from EFTA ³⁵ countries	from candidate ³⁶ countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
3	17.03.11.	Diff/ non-diff.	YES/ NO	YES/NO	YES/NO	YES/NO

³⁴ Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations.

³⁵ EFTA: European Free Trade Association.

³⁶ Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure (in current prices)

EUR million (to 3 decimal places)

Heading of multiannual financial framework:		Number	Security and Citizenship							TOTAL
			3	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years	
DG SANCO	• Operational appropriations									
	Commitments	(1)	0	0	0	0	0	0	0	0
	Payments	(2)	0	0	0	0	0	0	0	0
Number of budget line: 17.03.11										
Appropriations of an administrative nature financed from the envelope for specific programmes ³⁷										
Number of budget line:		(3)								
TOTAL appropriations for DG SANCO	Commitments	=1+1a+3	0	0	0	0	0	0	0	0
	Payments	=2+2a+3	0	0	0	0	0	0	0	0

³⁷

Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Payments	(5)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes	(6)																		
TOTAL appropriations under HEADING 3 of the multiannual financial framework	Commitments	=4+6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Payments	=5+6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(4)																		0
	Payments	(5)																		
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes	(6)																			
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Payments	=5+6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Heading of multiannual financial framework:	5	" Administrative expenditure "
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EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years	TOTAL
DG SANCO							
• Human resources	0	0	0	0	0	0	0
• Other administrative expenditure	0	0	0	0	0	0	0
TOTAL DG SANCO	0	0	0	0	0	0	0

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)						
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EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years	TOTAL
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	0	0	0	0	0	0	0
	0	0	0	0	0	0	0

Commitments

Payments

3.2.2. Estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ↓	Type of output	Average cost of the output	OUTPUTS												TOTAL
			Year 2014		Year 2015		Year 2016		Year 2017		Year 2018		2019 et sq years		
			Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	
SPECIFIC OBJECTIVE No 1															
Simplification of legislation and of administrative procedures for public authorities and food business operators through streamlined and fully centralised authorisation procedure.															
- Output	Technical and scientific opinions and advice and scientific guidelines		0	0	0	0	0	0	0	0	0	0	0	0	0
Sub-total for specific objective N°1			0	0	0	0	0	0	0	0	0	0	0	0	0
Total costs															
			0	0	0	0	0	0	0	0	0	0	0	0	0

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years	TOTAL
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HEADING 5 of the multiannual financial framework								
Human resources								
Other administrative expenditure								
Subtotal HEADING 5 of the multiannual financial framework								

Outside HEADING 5³⁸ of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	0	0	0	0	0	0	0	0
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Additional administrative costs will be covered through re-allocation within Commission services (DG SANCO).

³⁸ Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year >2019
• Establishment plan posts (officials and temporary agents)							
17 01 01 01 (Headquarters and Commission's Representation Offices)	0	0	1	1	1	0	0
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• External personnel (in Full Time Equivalent unit: FTE)³⁹							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
XX 01 04 yy ⁴⁰							
XX 01 05 02 (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							

³⁹ CA= Contract Agent; INT= agency staff ("Intérimaire"); JED= "Jeune Expert en Délégation" (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert.

⁴⁰ Under the ceiling for external personnel from operational appropriations (former "BA" lines).

⁴¹ Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

TOTAL									
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The human resources required will be met by staff from DG Health and Consumers who are already assigned to the management of the action and who will be redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	To transform existing individual authorisation decisions and notifications (around 100) into a consolidated Union list with harmonised specifications and conditions of use (2016-2017).
External personnel	To manage in parallel pending applications under current provisions and applications under new provisions (transitional period).

3.2.4. *Compatibility with the current multiannual financial framework*

– Proposal/initiative is compatible with the new multiannual financial framework 2014-2020.

– Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework⁴².

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

⁴²

See points 19 and 24 of the Inter-institutional Agreement.

3.2.5. *Third-party contributions*

- **X** The proposal/initiative does not provide for co-financing by third parties
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)	Total
<i>Specify the co-financing body</i>						
TOTAL appropriations cofinanced						

3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
 1. on own resources
 2. on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative ⁴³				
		2014	2015	2016	2017	Subsequent years
Article	0	0	0	0	0	0

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

⁴³

As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.

ANNEX to the NOVEL FOOD LEGISLATIVE FINANCIAL STATEMENT

(Information received from EFSA)

1. Number and cost of human resources considered necessary

- The proposal/initiative does not require the use of human resources
 The proposal/initiative requires the use of human resources, described as follows:

EUR million (to 3 decimal places)

EFSA	Staff	Year 2014		Year 2015		Year 2016		Year 2017		Year 2018		Year 2019		Year 2020		Total (Sum 2014-2020)	
		FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations
	AD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	AST																

2. Cost of other expenditure of an administrative nature

- The proposal/initiative does not require the use of any appropriation of an administrative nature
 The proposal/initiative requires the use of appropriations of an administrative nature, described as follows:

EUR million (to 3 decimal places)

EFSA	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	TOTAL (Sum 2014-2020)
	Contractual agents	0,052	0,052	0,260	0,260	0,260	0,260	0,260
Scientific Meetings				0,169	0,169	0,169	0,169	0,676
Scientific Cooperation				0,150	0,150	0,150	0,150	0,600
Staff Missions	0,010	0,010	0,010	0,010	0,010	0,010	0,010	0,070

Total ⁴⁴	0,062	0,062	0,270	0,589	0,589	0,589	0,589	0,589	2,750
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⁴⁴ The required financial resources will be met by the budget already allocated to EFSA and will be redeployed within EFSA, together, if necessary, with any additional allocation which may be granted to EFSA under the annual allocation procedure and in the light of budgetary constraints.

3. Methods of calculation used to estimate costs

General considerations

Regulation (EC) No 258/97 of January 1997 lays down detailed rules for the authorisation of novel foods and novel food ingredients. These rules include an initial safety assessment by a Member State. If concerns from other Member States with respect to this assessment are raised, EFSA is asked to perform an additional risk assessment. At present around 2/3 of all novel food applications in Europe are subject to this further assessment by EFSA.

The revised novel food legislation foresees amongst other that **all novel food applications are to undergo a centralised risk assessment by EFSA** and that a simplified notification procedure for traditional foods from third countries with the involvement of EFSA is established in order to allow easier market access for these types of products.

It is expected that EFSA will receive **around 15 applications** for Novel Food per year. Also, the transfer from a partially decentralised to a fully centralised procedure alone will result in an increase in workload for EFSA.

It is also expected **that EFSA will receive per year around 10 notifications for traditional foods from third countries** with a high peak to be expected immediately after the date of application of the Regulation. This is expected to be driven by botanicals used in traditional Chinese and Ayurvedic medicine which currently cannot enter the market because of their Novel Food status.

EFSA will also be requested to **revise the scientific guidelines** for the risk assessment of Novel Food as well as to develop **technical guidance and tools to assist food business operators** (EU and 3rd country operators) for submitting an application or a notification.

Currently, the workload under the existing Novel Food Regulation (around 8 applications per year) is covered by 2 FTE (1.5 scientists, 0.5 administrative support) and EFSA's risk assessment can rely on preparatory work performed by Member States.

The data provided under points 1 and 2 of this Annex provides for the needs of EFSA on the basis of the increased workload compared to the current legal framework.

EFSA will need to carry out administrative tasks to support the increased workload, including organisation of meetings, document management, and procurement as well as organisation of missions and additional financial transactions. EFSA will absorb those needs by internal redeployment of resources and by further gains of efficiency in the provision of administrative and support services.