Basic information

2008/0002(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure lapsed or withdrawn
Novel foods **Subject** 3.10.04.02 Animal protection 3.10.10 Foodstuffs, foodstuffs legislation 4.20 Public health 4.60.04.04 Food safety	

Key players

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	3053	2010-12-06
Agriculture and Fisheries	2952	2009-06-22
Environment	3002	2010-03-15

European Commission

Commission DG	Commissioner
Health and Food Safety	DALLI John

Key events

Date	Event	Reference	Summary
14/01/2008	Legislative proposal published	COM(2007)0872	Summary
17/01/2008	Committee referral announced in Parliament, 1st reading		
02/12/2008	Vote in committee, 1st reading		Summary
18/12/2008	Committee report tabled for plenary, 1st reading	A6-0512/2008	
24/03/2009	Debate in Parliament		
25/03/2009	Decision by Parliament, 1st reading	T6-0171/2009	Summary
25/03/2009	Results of vote in Parliament		
15/03/2010	Council position published	11261/3/2009	Summary
25/03/2010	Committee referral announced in Parliament, 2nd reading		
04/05/2010	Vote in committee, 2nd reading		Summary
10/05/2010	Committee recommendation tabled for plenary, 2nd reading	A7-0152/2010	
06/07/2010	Debate in Parliament		

07/07/2010	Decision by Parliament, 2nd reading	T7-0266/2010	Summary
06/12/2010	Parliament's amendments rejected by Council		Summary
01/02/2011	Formal meeting of Conciliation Committee		Summary
29/03/2011	Final decision by Conciliation Committee		Summary
11/05/2011	Debate in Parliament		

Technical information

Procedure reference	2008/0002(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the European Union TFEU 114-p1
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	CODE/7/03527

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE409.414	26/06/2008	
Committee opinion	AGRI	PE405.878	24/07/2008	
Committee opinion	IMCO	PE407.801	07/10/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0512/2008	18/12/2008	
Text adopted by Parliament, 1st reading/single reading		T6-0171/2009	25/03/2009	Summary
Committee draft report		PE428.273	29/03/2010	
Committee recommendation tabled for plenary, 2nd reading		A7-0152/2010	10/05/2010	
Text adopted by Parliament, 2nd reading		T7-0266/2010	07/07/2010	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	06163/2010	05/03/2010	
Council position	11261/3/2009	15/03/2010	Summary

European Commission

Document type	Reference	Date	Summary

Legislative proposal	COM(2007)0872	14/01/2008	Summary
Document attached to the procedure	SEC(2008)0012	14/01/2008	
Document attached to the procedure	SEC(2008)0013	14/01/2008	
Commission response to text adopted in plenary	SP(2009)3060	04/06/2009	
Commission communication on Council's position	COM(2010)0124	24/03/2010	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2010)0570	11/10/2010	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0991/2008	28/05/2008	

Additional information		
Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Novel foods

2008/0002(COD) - 07/07/2010 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council's position at first reading for adopting a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

Parliament’s position adopted at second reading under the ordinary legislative procedure (formerly known as the codecision procedure) amends the Council’s position at first reading as follows:

Purpose: this Regulation lays down harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of protection of human life and health, animal health and welfare, the environment and the interests of consumers whilst ensuring transparency and the effective functioning of the internal market and stimulating innovation within the agri-food industry.

Scope: Parliament intends to **exclude foods derived from cloned animals and their offspring** from the scope of this Regulation. In the six months before the application of this Regulation, the Commission should put forward a legislative proposal on foods derived from cloned animals and their descendants. This proposal shall be presented to the European Parliament and the Council.

Definitions: Parliament has introduced the definition of “cloned animals”, “offspring of cloned animals”. In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt these definitions to technical and scientific progress and with definitions subsequently agreed at international level.

Collection of information regarding the classification of a novel food: the Commission shall collect information from the Member States and/or from food business operators or any other interested party to determine whether a food falls within the scope of this Regulation. Member States, business

operators and other interested parties shall transmit to the Commission information on the extent a food was used for human consumption within the Union before 15 May 1997. The Commission shall publish those data and the conclusions drawn from the data collection and the non-confidential data supporting it.

Union list of novel foods: only novel foods included in the Union list of novel foods ("the Union list") may be placed on the market. The Commission shall keep and publish the Union list on a publicly accessible page intended for that purpose on the website of the Commission.

Prohibition of non-compliant novel foods: a new provision stipulates that novel foods shall not be placed on the market if their use does not comply with the provisions of this Regulation.

Conditions for the entry of novel foods in the Community list: Members have included a broader set of conditions to prevent that unexpected drawbacks appear from the use of a novel food:

- the novel food may not be included in the list if it does not, on the basis of the scientific evidence available, and after application of the precautionary principle, **pose a safety concern to the health of the consumer and of animals**;
- a novel food that may have any adverse effects on particular groups of the population will be authorised only where specific measures preventing such adverse effects have been implemented;
- **ethical and environmental aspects** must be considered as part of the risk assessment during the authorisation procedure. These aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively;
- **foods produced with the aid of nanotechnology** may not be included in the Community list until such specific methods have been approved for use, and an adequate safety assessment on the basis of these methods has shown that the use of the respective foods is safe.

A novel food may be included in the Community list only if the competent authority has submitted an opinion establishing that the food is not harmful to health. In the event of doubt, the precautionary principle shall be applied and the food in question shall not be included in the Community list.

Information: the entry of a novel food in the Community list shall include: i) the intended use of the food; ii) where relevant, additional specific labelling requirements to inform the final consumer; iii) the date of entry of the novel food in the Union list and the date of receipt of the application; iv) the name and address of the applicant and the date and results of the last inspection; v) the fact that the entry is based on newly developed scientific evidence and/or proprietary data that are protected.

Monitoring: in order to be informed about the adverse effects from the use of a novel food, post-marketing monitoring shall be required for all novel foods. All novel foods which have been allowed on to the market shall be reviewed **after five years** and whenever more scientific evidence becomes available. In the context of this monitoring, special attention should be paid to the categories of the population with the highest dietary intakes.

Nanomaterials: Parliament calls for all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

It should be noted that the plenary rejected an amendment calling for the compulsory labelling of foodstuffs produced from animals fed with genetically modified feeding stuffs.

Traditional food from a third country: a food business operator intending to place a traditional food from a third country on the market in the Union shall notify this to the Commission, indicating the name of the food, its composition and country of origin. The notification shall be accompanied by documented data demonstrating the history of safe food use in any third country.

The Commission shall publish a list of traditional foods from third countries that may be placed on the market in the Union on a dedicated page of the Commission's website.

Obligations on the food business operators: the Commission shall impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. The Member States shall designate the competent authorities responsible for the post-marketing monitoring.

All food business operators shall notify the Commission and the competent authorities of the Member State in which they operate of any health problem of which they have been informed by consumers or consumer protection organisations. The Member State's competent authority shall report to the Commission within three months of the completion of an inspection.

European Group on Ethics and new technologies: where appropriate, on ethical questions relating to science and new technologies of major ethical importance, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies, with a view to obtaining its opinion on ethical issues. The Commission shall make this opinion available to the public.

Data protection: data from research projects partly or completely paid by the EC and/or public institutions and risk studies or data related to risk studies, like feeding studies should be published together with the application and shall be freely available for use by other applicants. In order to avoid the repetition of studies involving vertebrates, reference by a subsequent applicant to studies on vertebrates and other studies that may prevent animal testing shall be allowed. The owner of the data may claim adequate compensation for the use of the data.

Harmonised data protection: where an applicant intends a novel food to carry a health claim authorised in accordance with Regulation (EC) No 1924 /2006, and where the novel food and health claim applications are introduced at the same time and both include a request for the protection of proprietary data, at the request of the applicant the periods of data protection should start together and run concurrently.

Inspection and control measures: in order to enforce compliance with this Regulation, official controls are to be carried out in accordance with Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Penalties: in view of increasing legal certainty, Members set a clear deadline for notification (12 months) by which the Member States must announce rules for imposing sanctions for infringement of this regulation.

Privileges of Member States: a new article states that where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.

Delegated acts: the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997, in respect of the determination of whether a type of food falls within the scope of this Regulation, the adjustment and adaptation of the definition of "engineered nanomaterial" to technical and scientific progress and in line with definitions subsequently agreed at international level, rules on how to proceed in cases in which the Commission has no information about use of a food for human consumption before 15 May 1997.

Review: no later than three years and six months after the date of application of this Regulation, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and on all aspects of food produced from animals obtained by using a cloning technique and from their offspring followed, where appropriate, by any legislative proposals.

Novel foods

2008/0002(COD) - 25/03/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 658 votes to 15, with 11 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No xxx/xxxx [common procedure].

The main amendments were as follows:

Purpose: this Regulation lays down harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of protection of human life and health, animal health and welfare, the environment and the interests of consumers whilst ensuring transparency and the effective functioning of the internal market and stimulating innovation within the agri-food industry.

Scope: MEPs intend to **exclude foods derived from cloned animals and their offspring** from the scope of this Regulation. Before the date of application of this Regulation, the Commission should put forward a corresponding legislative proposal on foods derived from cloned animals and their descendants. This proposal shall be presented to the European Parliament and the Council. This Regulation shall apply to food additives, food enzymes, flavourings and certain food ingredients with flavouring properties to which is applied a new production process not used before 15 May 1997, which give rise to significant changes in the composition or structure of the food such as engineered nanomaterials. Where a novel food can have an effect on the human body comparable to that of a medicinal product, the Commission shall seek an opinion of the European Medicines Agency (EMEA) whether it falls under Regulation (EC) No 726/2004.

Definitions: MEPs have introduced the definition of “cloned animals”, “offspring of cloned animals” and “engineered nanomaterial”. In view of the various definitions of nanomaterials published by different bodies at international level and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt these definitions to technical and scientific progress and with definitions subsequently agreed at international level.

Collection of information regarding the classification of a novel food: the Commission shall collect information from the Member States and/or from food business operators or any other interested party to determine whether a food falls within the scope of this Regulation. It shall publish these data and the conclusions drawn from the data collection and the non-confidential data supporting it. It shall keep and publish the Community list on a publicly accessible page intended for that purpose on the website of the Commission.

Prohibition of non-compliant novel foods: a new provision stipulates that novel foods shall not be placed on the market if their use does not comply with the provisions of this Regulation.

Conditions for the entry of novel foods in the Community list: MEPs have included a broader set of conditions to prevent that unexpected drawbacks appear from the use of a novel food:

- the novel food may not be included in the list if it does not, on the basis of the scientific evidence available, and after application of the precautionary principle, pose a safety concern to the health of the consumer and of **animals**;
- a novel food that may have any adverse effects on **particular groups of the population** will be authorised only where specific measures preventing such adverse effects have been implemented;
- **ethnical and environmental aspects** must be considered as part of the risk assessment during the authorisation procedure. These aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively;
- **foods produced with the aid of nanotechnology** may not be included in the Community list until such specific methods have been approved for use, and an adequate safety assessment on the basis of these methods has shown that the use of the respective foods is safe.

A novel food may be included in the Community list only if the competent authority has submitted an opinion establishing that the food is not harmful to health. In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the **precautionary principle** shall be applied and the food in question shall not be included in the Community list.

Information: the entry of a novel food in the Community list shall include: a specification of the food; the intended use of the food; the conditions of use; the date of entry of the novel food in the Community list and the date of receipt of the application; the name and address of the applicant; the date and results of the last inspection.

Monitoring: in order to be informed about adverse effects from the use of a novel food, the Commission shall impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. This monitoring shall take place five years after the date of inclusion of a novel food in the Community list and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention should be paid to the categories of the population with the highest dietary intakes.

In case a novel food is a substance with a risk linked with consuming too much of it, it should get approval for use with maximum level in certain foods or food categories in order to prevent the risk of over-dosing.

Labelling: all specific data on novel foods shall be indicated and labelled to ensure proper consumer information:

- all new foods placed on the market shall be sold with **clearly distinctive, precise and easily legible labelling** indicating that they are novel foods;
- all the **characteristics or properties** of novel foods such as their composition, nutritional value and proper use, should appear clearly, precisely and in an easily legible and comprehensible manner on their packaging;
- were a novel food contains a substance which may pose a high risk to human health in the event of **excessive consumption**, the consumer must be informed of this by means of clear, precise and easily legible labelling on the packaging of the food;
- all ingredients present in the form of **nanomaterials** shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets;
- products produced from animals fed with **genetically modified feeding stuffs** must be labelled with the words “produced from animals fed with genetically modified feeding stuffs”.

Traditional food from a third country: according to the MEPs, it is important that the notification shall be accompanied by documented data demonstrating the history of safe food use in any third country.

Obligations on the food business operators: the Commission shall impose for food safety reasons and following the opinion of the Authority, a requirement for post-market monitoring. This monitoring shall take place five years after the date of inclusion of a novel food in the Community list and take into account food safety aspects as well as animal health and welfare aspects and the environmental impact. Special attention should be paid to the categories of the population with the highest dietary intakes. All food business operators shall notify the Commission and the competent authorities of the Member State in which they operate of any health problem of which they have been informed by consumers or consumer protection organisations.

In order to **avoid animal testing**, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies shall be promoted.

European Group on Ethics and new technologies: where appropriate, on ethical questions relating to science and new technologies of major ethical importance, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies, with a view to obtaining its opinion on ethical issues. The Commission shall make this opinion available to the public.

Data protection: data from research projects partly or completely paid by the EC and/or public institutions and risk studies or data related to risk studies, like feeding studies should be published together with the application and shall be freely available for use by other applicants. In order to avoid the repetition of studies involving vertebrates, reference by a subsequent applicant to studies on vertebrates and other studies that may prevent animal testing shall be allowed. The owner of the data may claim adequate compensation for the use of the data

Harmonised data protection: where an applicant intends a novel food to carry a health claim authorised in accordance with Regulation (EC) No 1924 /2006, and where the novel food and health claim applications are introduced at the same time and both include a request for the protection of proprietary data, at the request of the applicant the periods of data protection should start together and run concurrently.

Inspection and control measures: in order to enforce compliance with this Regulation, official controls are to be carried out in accordance with Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Penalties: in view of increasing legal certainty, MEPs set a clear deadline for notification (12 months) by which the Member States must announce rules for imposing sanctions for infringement of this regulation.

Privileges of Member States: a new article states that where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.

Review: no later than three years after the date of application of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation, accompanied, where appropriate, by any proposals. No later than one year after the date of entry into force of this Regulation the Commission shall forward to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a cloning technique and from their offspring followed, whereappropriate, by any legislative proposals.

Novel foods

2008/0002(COD) - 24/03/2010 - Commission communication on Council's position

The position of the Council reflects the result of the examination of the Commission's proposal taking into account the amendments voted by the European Parliament. The Council has included in its position several amendments adopted at first reading by the European Parliament and also accepted by the Commission.

The Commission has accepted all the changes introduced by the Council to its proposal **except the inclusion of the offspring (first generation) of cloned animals in the scope of the proposal** and the proposed adaptations of several **comitology** related provisions to the Lisbon Treaty. Therefore the Commission can not support the position of the Council.

Animal cloning: the Commission does not support the inclusion of food from clones' offspring within the scope and therefore can not agree with the Council's position. The Commission position is to maintain the legal status quo for the food produced with new breeding techniques such as cloning and to prepare the foreseen report by the end of the year.

The Commission considers that there is no justification to include in the scope food from clones' offspring as they are obtained through conventional breeding techniques and that the submission of food from clones' offspring to a pre-market authorisation regime would therefore be disproportionate to the objectives of the regulation, in particular food safety, and not in line with the Treaty on the Functioning of the European Union. In addition, such provision would be at variance with EU international commitments.

Adaptation to the Lisbon Treaty: following the entry into force of the Lisbon Treaty, the position of the Council was adapted to take into account Articles 290 and 291 of Treaty

on the Functioning of the European Union.

The adoption of further criteria to clarify the definitions laid down in Article 3 2) points a) (i) to (iv) related to sub-categories of novel foods, in point c) on the definition of "engineered nanomaterials" and point d) and e) related to traditional foods from third countries would be ensured through implementing acts. The Commission considers that the determination of these criteria is a measure aimed to supplement non essential elements of the Regulation which **should be adopted through delegated acts**.

As regards the adaptation of the definition of "engineered nanomaterials" to scientific and technical progress and to definitions agreed at international level, the Commission considers that the absence of a provision in the position of the Council in first reading allowing the revision of the definition to reflect the technical evolution implies the introduction of the ordinary legislative procedure for its revision. This would prevent this definition to reflect the best state of science and would have negative consequences for the innovation in the food

industry. Such adaptation is designed to amend non essential elements of this regulation and should be adopted through delegated acts.

The Commission cannot accept recital 36 as it stands concerning the consultation of experts in the preparation of delegated acts. Lastly, on the duration of the period to raise objections for delegated acts, the Commission considers that the Council did not provide enough reasons to opt for a three-month period. The Commission insists on the two-month period (which may be extended by one additional month) and cannot support this amendment of the Council.

The Commission can nevertheless support the adaptation of the following measures through implementing acts:

- the procedure for determination of the novel food status;
- the decisions whether a type of foods fall within the scope;
- the update of the list of traditional foods from third countries;
- the adoption of detailed rules for implementation of the procedure for traditional foods from third countries;
- the update of the Union list in case of data protection before the expiry of the 5 year- period of data protection;
- the adoption of implementing measures to ensure public information;
- the adoption of transitional measures for pending requests;
- the update of the Union list of authorised novel foods.

Novel foods

2008/0002(COD) - 11/10/2010 - Commission opinion on Parliament's position at 2nd reading

Out of the European's Parliament's 104 amendments to the Council's position, the Commission can accept 34 of these, either in full or in part. On the other hand, it rejects 70 amendments.

As regards the amendments accepted by the Commission, they concern in particular:

- **Nanotechnologies**: the Commission supports the principle of a regulatory definition of "**engineered nanomaterials**" in order to clarify which products would require a pre-market approval under the Novel Food Regulation. This definition, based on science, must be enforceable by food business operators and Member State control authorities. Should science provide new information about the elements to be considered in the draft definition before the final adoption of the text, the Commission will submit appropriate changes to that definition to the co-legislators. The Commission agrees with the need to adapt the regulatory definition of "engineered nanomaterials" to the scientific progress and international developments through delegated acts. As regards, the **labelling of nanomaterials** in foodstuffs, the Commission can accept the principle of a mandatory and systematic labelling of all foods and food ingredients containing nanomaterials. This labelling requirement would apply at the level of the list of ingredients and to all food ingredients containing engineered nanomaterials covered by the above mentioned definition. The Commission considers that the labelling requirement should preferably be done within the framework of the proposal

for a Regulation of the European Parliament and the Council on the provision of food information to consumers in order to provide a coherent approach to the labelling of engineered nanomaterials in all foods.

- **Precautionary principle, protection of animal welfare and environmental and ethical aspects**: the primary objective of the Novel Food Regulation is to ensure the food safety through a systematic EU risk assessment and authorisation procedure prior to getting market access and the free circulation of goods within the EU. However the Commission supports the inclusion, where applicable, of the objectives related to the protection of animal health, animal welfare, the environment and consumer protection.
- **Traditional foods from third countries**: the Commission can agree with the requirement for a 25 year period of consumption in third countries to demonstrate the history of safe food use of traditional foods from third countries. This comes in addition to the necessity to submit relevant data required to establish the safety of these foods.
- **Animal testing**: the Commission agrees that repetition of tests on vertebrates should be avoided as much as possible. Therefore, the possibility for an applicant to refer to the results of animal test studies made by a prior applicant against financial compensation can be provided, including when data protection has been granted. However, such possibility does not mean that the prior applicant has the obligation to grant access to its data in all cases.
- **Adaptation to the Lisbon Treaty**: as regards the adaptation of the definition of "engineered nanomaterials" to scientific and technical progress and to definitions agreed at international level, the Commission considers that the recourse to the "ordinary legislative procedure" for its revision would prevent this definition to reflect the best state of science and can agree with its revision through delegated acts. As regards the modalities for the delegation and revocation of power to the Commission for adopting delegated acts and for objections to delegated acts, the Commission can support the EP amendments (as regards the duration of the delegation, the modalities for the revocation of the delegation and the modalities for raising objections to delegated acts).

Amongst the amendments rejected by the Commission, the following may be highlighted:

- **Cloning**: following extensive discussions at both EP and Council levels, the Commission considers that the Novel Food Regulation is not the appropriate legal frame for addressing globally the cloning issue for food production. In particular, the production and marketing of products other than food (reproductive materials) cannot be covered by the Novel Food Regulation which deals exclusively with the pre-market authorisation of food products.
- **Nanotechnologies**: the Commission does not agree with the EP assumption that the general methodology used for the risk assessment of foodstuffs would not be applicable for that of nanomaterials in food and that, until specific test methods are developed, no food with nanomaterials should be put on the EU market. The Commission is committed to only approve the marketing of food containing nanomaterials for which the food safety has been established.
- **Data protection**: the Commission considers that, in dully justified cases concerning genuine innovative products for which data protection has been granted, these novel foods could benefit from an individual authorisation and 5-year period of exclusivity on the EU market. As only generic authorisations are granted through Article 7 of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, the authorisation procedure with data protection clearly derogates from the common authorisation procedure and shall therefore be kept separate in the Novel Food Regulation and therefore amendments the EP amendments on this issue cannot be accepted. The synchronisation of the data protection periods which may be granted both under Novel Food Regulation and under Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods would provide an improved benefit for the placing of the market of such products. However, as the data to be assessed are under both Regulations are of totally different nature and have to be examined by different EFSA panels, the matching of the periods of data protection cannot be ensured in practice and therefore amendments regarding this cannot be accepted.
- **Adaptation to the Lisbon Treaty**: the Commission considers that the possibility to adopt further criteria to clarify the definitions related to sub-categories of novel foods and to traditional foods from third countries should be kept. Its removal implies that it could be done only through the "ordinary legislative procedure". The Commission considers that the determination of these criteria is a measure aimed at supplementing non essential elements of the Regulation, which should be adopted through delegated acts.

Other issues: several amendments on other issues (such as the procedures applicable for determining the status of a food, the setting up of EU lists of authorised novel foods, the rules for the transitional period or the update of Regulation n° 1331/2008 on the common authorisation procedure) do not provide further improvements to the text and thus should be rejected.

Novel foods

2008/0002(COD) - 06/12/2010

The Council rejected the European Parliament's second-reading amendments to the draft regulation on novel foods.

This means that a conciliation procedure will be launched in accordance with article 294 of the Lisbon treaty. Once a meeting of a conciliation committee composed of representatives of both institutions has been convened, the committee has a maximum of eight weeks to find a compromise.

Novel foods

2008/0002(COD) - 14/01/2008 - Legislative proposal

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

PROPOSED ACT: Regulation of the European Parliament and of the Council.

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

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

CONTENT: the current proposal aims to:

- streamline the authorisation procedure, develop a safety assessment system that is better adjusted for traditional food from third countries, which is considered as novel food under the current Regulation;
- clarify the definition of novel food, including new technologies with an impact on food, and the scope of the novel food Regulation;
- improve the efficiency, transparency and application of the authorisation system, which also contributes to better implementation of the Regulation, and empower consumers by informing them about food;
- ensure legal clarity by making necessary changes and updating the legislation.

The main elements of the proposed Regulation are as follows:

- novel foods shall be subject to safety evaluation and approval via Community procedure. The definitions are clarified and updated following legal developments. A procedure to collect information on the novelty of a food may be laid down. It may be determined with the comitology procedure if a food falls within the scope of the Regulation;
- all novel foods and their use in food shall be evaluated for the following criteria: they should not present a danger to or mislead the consumer nor, in the case of replacement, present nutritional disadvantages for the consumer;
- all applications for the approval of novel food shall be submitted to the Commission and then directed to the European Food Safety Authority (EFSA) which will carry out the safety evaluations;
- the final decision to include a novel food in the Community list of novel foods shall be made by the Commission in accordance with the comitology procedure. The applicant-linked authorisation shall be replaced and the simplified procedure abolished by authorisation decisions addressed to the Community as a general rule. Protection of data could be granted in justified cases concerning newly developed scientific evidence and/or proprietary data in order to support innovation in the agri-food industry. The Decision on inclusion shall include, where appropriate, specific additional labelling for novel foods sold to the consumer;
- for traditional food from third countries, a safety assessment and management based on the history of safe food use in the country of origin shall be introduced. If a history of safe food use in the country of origin has been demonstrated, and the Member States and EFSA do not present reasoned safety objections, based on scientific evidence, the food could be placed on the market on basis of a notification of the food business operator intending to market the food;
- for every authorised novel food a specification, labelling, conditions of use and, where appropriate, a requirement of post-market monitoring may be laid down;
- to ensure that novel foods once authorised are kept under continuous observation and re-evaluated wherever necessary, producers of novel foods will be obliged to inform the Commission of any new information which may affect the safety assessment of the novel food;
- the Member States shall lay down rules on penalties applicable to infringements of the provisions of the proposed Regulation;
- already authorised novel foods shall continue to be marketed and included in the Community list of novel foods;
- the Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings (see COD/2006/0143) must be amended to include novel foods in the scope of the Regulation and to enable the applicant to present one single application for foods regulated under different sectoral food laws.

Novel foods

2008/0002(COD) - 22/06/2009

The Council approved a **political agreement** on a draft regulation concerning novel foods (*Council doc. 11167/09)*. The United Kingdom and Greece abstained, the Commission did not agree to all modifications made to its proposal.

Novel foods

2008/0002(COD) - 15/03/2010 - Council position

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

amendments proposed by the European Parliament. In its plenary vote on 25 March 2009, the European Parliament adopted 76 amendments to the proposal. The Council incorporated in its common position 30 amendments, of which 20 in full, 5 in part and 5 in principle.

The main modifications introduced by the Council in the proposal, with reference to European Parliament’s amendments are as follows:

Objectives of the Regulation: the Council added the protection of the environment and animal welfare.

Scope: the Council clarified that, pending the respective amendments to Regulation (EC) 1925/2006, Directive 2002/46/EC and Directive 89/398/EEC, those vitamins and minerals obtained from new sources or using a production process, which were not taken into account at the moment of their authorisation and which give rise to significant changes in the composition or structure of food which affect its nutritional value, metabolism or level of undesirable substances should be within the scope of the novel food Regulation.

Definition of novel foods: the basic criterion for assessing the novelty of the food remains whether it has been used for human consumption to a significant degree within the Union before 15 May 1997. In order to provide legal clarity, the Council agreed that further criteria for assessing human consumption to a significant degree within the Union before 15 May 1997 must be developed before the date of application of the Regulation. The adoption of these criteria has been delegated to the Commission according to Article 290 TFEU.

In order to ensure better clarity, the following changes of definition have been made: a distinction has been made between food of animal and food of plant origin; addition of the definition of "offspring" and "engineered nanomaterial"; the definition of the "traditional food from a third country" has been specified. The Council also agreed that the Commission may, through the regulatory comitology procedure, adopt further criteria to clarify definitions.

Food produced from animals obtained by non-traditional breeding techniques and their offspring: the Council agreed that foods produced from animals obtained by non-traditional breeding techniques (e.g. cloning) and their offspring shall fall within the scope of the Regulation. The Commission shall forward, within one year from the date of entry into force of this Regulation, to the European Parliament and the Council a report on all aspect of food production from cloned animals and their offspring, followed, if appropriate, by a legislative proposal. The Council considered that it was necessary to keep food produced from cloned animals within the scope of the proposed Regulation until any specific legislation has been proposed by the Commission and adopted.

Nanomaterials: the Council recognized the need for systematic safety evaluation and authorisation of foods containing or consisting of engineered nanomaterials irrespective of any changes that the nanomaterials might cause in the properties of such foods. Therefore, the Council made clear that such foods are considered to be novel and added the definition of "engineered nanomaterial". A Recital highlights the need for an internationally agreed definition of nanomaterial. The Council followed the thrust of the amendments on the necessity to have appropriate risk assessment methods for engineered nanomaterials.

Determination of the status of food: the Council agreed that the determination of the status of food to be placed on the Union market with respect to the definition of novel food would be a responsibility of food business operators, who must consult their national authority in case of doubt.

Authorisation of novel foods:the Council agreed that the authorisation of novel foods should be carried out according to the Regulation (EC) No 1331 /2008, unless there is provision for a specific derogation in the present Regulation. The Council clarified that ethical, environmental, animal welfare factors and the precautionary principle should be taken into account in authorisation of novel foods. These factors should be considered on a case-by-case basis according to the content of the application.

Authorisation of traditional foods from third countries: the Council did not accept the "notification procedure" as proposed by the Commission. In order to ensure food safety, any authorisation should be based on the EFSA opinion and subsequent authorisation adopted by the Commission through the regulatory comitology procedure. The EFSA evaluation should primarily focus on the evidence of safe food use and the information on the composition of traditional food. In order to speed up the procedure, shorter deadlines should apply - 6 months for EFSA opinion and 3 months for the draft measure submitted by the Commission to SCFCAH. A separate list of authorised traditional foods from third countries would be established.

Technical guidance: the Commission must before the date of application of the Regulation (i.e. 2 years after its entry into force) make available technical guidance and tools to interested parties, in particular food business operators and SMEs.

European Group on Ethics in Science and new Technologies – EGE: an additional provision was added on the possibility for the Commission to consult the EGE, on its initiative or at the request of a Member State, on ethical issues concerning the novel foods.

Data protection: in order to promote innovation in industry, the need for the protection of new scientific evidence and/or proprietary scientific data for the period of 5 years was accepted by the Council. Such protected data cannot be used for the benefit of another application without the agreement of the prior applicant and the authorisation is limited to the prior applicant during the period of 5 years unless a subsequent applicant obtains authorisation without reference to that proprietary data.

Information to the public: summaries of applications, findings of any consultations for determination of the status of food and lists of authorised novel foods must be made available to the public, in the latter case on the single dedicated web page.

Adaptation to the Lisbon Treaty: given the entry into force of the Treaty on the Functioning of the European Union on the 1 December 2009, the Council had to adapt the regulatory procedure with scrutiny related provisions of the Commission's proposal to the TFEU. The Council agreed that the following provisions should confer implementing powers on the Commission (Article 291(2) TFEU) for example: criteria could be adopted to clarify definitions; the update of the list of traditional foods from third countries; the update of the Union list in case of data protection before the expiry of the 5 years period for data protection; the update of the Union list of novel foods.

The Council did not accept 46 amendments. These amendments concern inter alia the following issues:

- measures aiming to avoid testing on vertebrate animals and sharing of testing results (which do not fall under the scope of this Regulation);
- exclusion of food obtained from cloned animals and their offspring from the scope of the Regulation;
- systematic specific labelling of ingredients in the form of nanomaterials;
- additional criteria for risk assessment by EFSA;
- additional conditions for authorisation of novel foods (risk management);
- precautionary principle (already laid down in Regulation (EC) No 178/2002 is still applicable);
- additional specifications for the entry of novel food in the Union list;

- post-marketing monitoring;
- labelling of novel food.