Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2013/0435(COD)
Procedure completed	

Novel foods

Repealing Regulation (EC) No 258/97 1992/0426(COD)
Amending Regulation (EU) No 1169/2011 2008/0028(COD)
Amended by 2018/0088(COD)

Subject
3.10.10 Foodstuffs, foodstuffs legislation
3.40.13 Food industry
4.60.02 Consumer information, advertising, labelling
4.60.04.04 Food safety
6.20.02 Export/import control, trade defence, trade barriers

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		14/07/2014
	ECR NICHOLSON James	
	Shadow rapporteur	
	epp AYUSO Pilar	
	S&D POC Pavel	
	PAULSEN Marit	
	STAES Bart	
	EFD EVI Eleonora	

Former committee responsible

ENVI Environment, Public Health and Food Safety

Committee for opinion	Rapporteur for opinion	Appointed
INTA International Trade		22/07/2014
	S&D KIRTON-DARLING Jude	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development		17/09/2014

	S&D SÂRBU Daciana Octavia		
	Former committee for opinion		
	INTA International Trade		
	ITRE Industry, Research and Energy		
	IMCO Internal Market and Consumer Protection		
	AGRI Agriculture and Rural Development		
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	3425	16/11/2015
European Commission	Commission DG	Commissioner	
	Health and Food Safety	ANDRIUKAITIS Vytenis Povilas	
European Economic and Social Committee			

Key events

18/12/2013	Legislative proposal published	COM(2013)0894	Summary
16/01/2014	Committee referral announced in Parliament, 1st reading		
20/10/2014	Committee referral announced in Parliament, 1st reading		
24/11/2014	Vote in committee, 1st reading		
24/11/2014	Committee decision to open interinstitutional negotiations with report adopted in committee		
02/12/2014	Committee report tabled for plenary, 1st reading	A8-0046/2014	Summary
25/06/2015	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE610.569 GEDA/A/(2015)012870	
28/10/2015	Results of vote in Parliament		
28/10/2015	Debate in Parliament		
28/10/2015	Decision by Parliament, 1st reading	T8-0380/2015	Summary
16/11/2015	Act adopted by Council after Parliament's 1st reading		
25/11/2015	Final act signed		
25/11/2015	End of procedure in Parliament		
11/12/2015	Final act published in Official Journal		

Technical information

Procedure reference	2013/0435(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)

Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Regulation (EC) No 258/97 1992/0426(COD) Amending Regulation (EU) No 1169/2011 2008/0028(COD) Amended by 2018/0088(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/00304

Documentation gateway

Legislative proposal		COM(2013)0894	18/12/2013	EC	Summary
Economic and Social Committee: opinion, report		CES0933/2014	30/04/2014	ESC	
Committee draft report		PE537.480	06/10/2014	EP	
Amendments tabled in committee		PE539.826	20/10/2014	EP	
Amendments tabled in committee		PE541.296	20/10/2014	EP	
Amendments tabled in committee		PE541.297	20/10/2014	EP	
Amendments tabled in committee		PE541.298	20/10/2014	EP	
Committee opinion	AGRI	PE537.498	10/11/2014	EP	
Committee opinion	INTA	PE537.403	17/11/2014	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0046/2014	02/12/2014	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0380/2015	28/10/2015	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2015)012870	16/11/2015	CSL	
Text agreed during interinstitutional negotiations		PE610.569	16/11/2015	EP	
Draft final act		00038/2015/LEX	25/11/2015	CSL	
Commission response to text adopted in plenary		SP(2015)750	10/12/2015	EC	

Additional information

European Commission	EUR-Lex

Final act

Regulation 2015/2283
OJ L 327 11.12.2015, p. 0001 Summary

Final legislative act with provisions for delegated acts

Novel foods

PURPOSE : 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.

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

ROLE OF THE EUROPEAN PARLIAMENT : the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND : Union rules on novel foods were set out in Regulation (EC) n° 258/97 of the European Parliament and Council and Commission Regulation (EC) n° 1852/2001. Those rules need to be updated to simplify the current authorisation procedures and to take account of recent developments in Union law.

In January 2008, the Commission adopted a proposal aiming to simplify the authorization procedure set out in Regulation (EC) 258/97 on novel foods. The legislative discussions under the ordinary legislative procedure mainly focused on the provisions applicable to: (i) nanomaterials; (ii) the cloning of animals for food production; (iii) traditional foods from third countries; (iv) the criteria to be examined for the risk assessment, and (v) 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).

However, the proposal was not adopted after the Conciliation Committee failed to reach an agreement in March 2011.

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

IMPACT ASSESSMENT : the 2008 impact assessment is still valid, and the rationale for an in-depth revision of the current legislation remains unchanged (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).

CONTENT : the proposal brings together and updates the provisions of the legislation currently in force, which will be repealed at the time of entry into application of the new legislation. It aims to streamline the authorisation procedure for novel foods, to improve its efficiency and transparency. It is limited to the safety of novel food and is based on the overall agreement achieved in conciliation.

The main points are as follows:

Subject matter, scope and definitions

- novel foods will be subject to safety evaluation and authorisation through a fully harmonised procedure;
- the definition of novel foods is clarified, bearing in mind new technologies which have an impact on food.
- a simplified procedure is created for marketing of traditional foods from third countries;
- 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.

Requirements for placing novel foods on the market within the Union:

- all novel foods and their use must 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 a system of generic authorisation;
- novel foods already authorised shall continue to be marketed and will be included in the Union list of novel foods.

Authorisation procedure for a novel food

- all applications for the authorisation of novel foods shall be submitted to the Commission which 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.

For traditional foods from third countries, a safety assessment and a risk management, based on a history of safe food use, is introduced:

- if the applicant has shown a history of safe food use in a third country for at least 25 years, 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;
- where 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.

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.

Data protection

- 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.

Penalties and committee procedure

- rules on penalties applicable to infringements of the provisions of the proposed Regulation will be laid down;
- implementation of the measures proposed in the Regulation will be mainly adopted by the Commission. This relates to the conditions of use and labelling of a novel food as well as laying down specifications and, where appropriate post-market monitoring requirements.

Transitional provisions

- transitional measures are set out to ensure a smooth transition with on-going applications and notifications, pending the entry into application of this legislation;
- 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.

BUDGETARY IMPLICATIONS : operational resources necessary for implementation of the proposal will be covered by redeployment within the contribution granted to EFSA during the annual budgetary procedure.

The estimated impact on appropriations of an administrative nature is EUR 2.750 million for the period 2014-2020.

Novel foods

The Committee on the Environment, Public Health and Food Safety adopted the report by James NICHOLSON (ECR, UK) on the proposal for a regulation of the European Parliament and of the Council on novel foods.

The committee recommended that Parliaments position adopted in first reading following the ordinary legislative procedure should amend the Commission proposal as follows :

Purpose and scope: Members stated that the primary objective of the Regulation should be to ensure a high level of protection of human health, consumers interests and of the environment and the effective functioning of the internal market.

In order to adapt the Regulation to technological progress and new kinds of food entering the Union marketplace, Members adopted amendments aiming to reintroduce food categories and introduce new categories for:

- food with a new or intentionally modified primary molecular structure;
- food containing, consisting of, or produced from microorganisms, fungi and algae;
- new foods containing, consisting of, or produced from plants or animals;
- food derived from cloned animals or their descendants ;
- food containing, consisting of, or obtained from cellular or tissue cultures.

Marketing of novel foods in the Union: food business operators shall consult the Member State in which they first intend to place the novel food. They shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of the Regulation. With a view to determining that assessment, the Member State may consult the Commission and other Member States.

Union list: the Commission shall only authorise a novel food in the Union list if: (a) it does not pose a safety risk to human health, nor to animal welfare and where applicable to the environment; (ii) its intended use, presentation and labelling do not mislead the consumer, especially when there is a significant change in the nutritional value of a food intended to replace another food; (iii) it is possible to ensure the traceability of the materials used in its manufacture.

Foods to which production processes have been applied that require specific risk assessment methods (for example, foods produced using nanotechnologies) may not be included in the Union list until such specific methods have been approved by EFSA for use.

Streamlining the authorisation procedure: Members were concerned that the Commissions proposals did not go far enough in reducing the delays applicants might face. One amendment stated that the Commission should make the application available to Member States without delay and verify the validity of the application within one month of receipt of the latter. Where the Commission requested an opinion from EFSA, it should forward a valid novel food application to EFSA within one month, rather than an unspecified period of time.

The Commission will be empowered to adopt delegated acts in order to update the list of novel foods within six months from EFSA giving its opinion.

In general, the extensions of time limits should be exceptional and appropriate. The applicant is to be the first to be informed about the extension.

Data protection: Members wanted to specify that if an applicant requested data protection on the same food both under this Regulation and Regulation (EC) 1924/2006, the Commission should endeavour to align the timing of both authorisation procedures to let the data protection periods run concurrently. In addition to this alignment of intellectual property protection periods, health claim and novel food evaluation and authorisation procedures shall, where possible, also be synchronised.

Under the Commission proposal, an applicant could obtain protection for data for five years for innovative products. Members want this period to be seven years from the date of authorisation of the novel food.

Monitoring: the Commission shall, for food safety reasons and in line with the precautionary principle impose a requirement for postmarked monitoring for all novel food, in order to ensure that the use of the authorised novel food is within safe limits.

Migration limits for constituents of food contact materials: as the Regulation deals with nanomaterials in food, Members stressed that it was important to ensure that nanoparticles that might accidentally migrate into food be taken into account.

Privileges of Member States: where a Member State had detailed grounds for considering that the use of a food complying with the Regulation endangered human health or the environment, that Member State might either temporarily restrict or suspend the trade in that food in its territory.

Cloned animals: until specific legislation on food derived from cloned animals and their descendants entered into force, this food should be accompanied by the following information for the final consumer: "Food derived from cloned animals/descendants of cloned animals."

Novel foods

The European Parliament adopted by 359 votes to 202 with 127 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on novel foods.

Parliaments position adopted in first reading following the ordinary legislative procedure amends the Commission proposal as follows:

Purpose and scope: Parliament specified that the purpose of the Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

In order to adapt the Regulation to scientific and technological developments that have occurred since 1997, Parliament adopted amendments to review, clarify and update the categories of food which constitute novel foods. These categories should include:

- food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
- food consisting of, isolated from or produced from microorganisms, fungi or algae;
- food consisting of, isolated from or produced from material of mineral origin;
- food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
- food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
- food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
- food containing engineered nanomaterials as defined in the Regulation.

In order to determine whether or not a food falls within the scope of the Regulation, Member States may consult the other Member States and the Commission.

The Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts, whether or not a particular food falls within the definition of novel food.

Union list: only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

Parliament specified that the Commission shall only authorise and include a novel food in the Union list if the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value.

Updating of the Union list may consist of, inter alia, adding, removing or changing the specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a novel food in the Union list.

With regard to the placing on the market within the Union of a traditional food from a third country, the entry in the Union list shall specify that it concerns a traditional food from a third country.

Authorisation procedure: the Commission and the Authority must respect certain time limits in order to ensure the harmonious treatment of applications for authorisation. However, in certain cases, the Commission and the Authority may extend the time limits.

The Commission shall make the application available to the Member States without delay and make the summary of the application publicly available.

The application for an authorisation shall include the name and address of the applicant; the description of the production process; the detailed composition of the novel food; and where appropriate, the analysis method(s).

Upon request by the Commission, the European Food Safety Authority shall give its opinion as to whether the update is liable to have an effect on human health.

When test methods are applied to engineered nanomaterials, the applicants shall provide an explanation of their scientific appropriateness for nanomaterials

Opinion of the Authority: where the Commission requests an opinion from the Authority, it shall forward the valid application to the Authority without delay, and not later than one month after having verified its validity. The Authority shall adopt its opinion within nine months from the date of receipt of a valid application.

Within seven months from the date of publication of the Authority's opinion, the Commission shall submit a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list

Authorisation procedure in case of a parallel application for the authorisation of a health claim: the amended text states that on request by the applicant, the Commission shall stay an authorisation procedure for a novel food started following an application, where the applicant has submitted: (i) a request for data protection; and (ii) an application for the authorisation of a health claim on the same novel food in accordance with Regulation (EC) No 1924/2006, in conjunction with a request for data protection.

The Commission shall inform the applicant about the date of effect of the stay. The authorisation procedure shall resume when the Commission has received the opinion of the Authority on the health claim. The Commission shall inform the applicant about the date of

resumption of the authorisation procedure.

Cloned animals: until specific legislation on food from animal clones enters into force, food from animal clones should fall under the scope of this Regulation as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with the Union legislation in force.

Novel foods

PURPOSE: to lay down rules for the placing of novel foods on the market within the Union while providing a high level of protection of human health.

LEGISLATIVE ACT: Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

CONTENT: this Regulation lays down rules for the placing of novel foods on the market within the Union. The purpose of this Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

Scope: novel food shall mean any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union. However, on the basis of scientific and technological developments that have occurred since 1997, the Regulation reviews, clarifies and updates the categories of food which constitute novel foods.

The following are considered as novel foods under this Regulation:

- food with a new or intentionally modified molecular structure;
- food consisting of, isolated from or produced from microorganisms, fungi or algae or from material of mineral origin, cell culture or tissue culture derived from animals;
- food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
- food consisting of engineered nanomaterials;
- 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:
- 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.

Animal clones: until specific legislation on food from animal clones enters into force, food from animal clones should fall under the scope of this Regulation as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with the Union legislation in force.

Procedure for determination of novel food status: in order to determine whether or not a food falls within the scope of this Regulation, Member States may consult the other Member States and the Commission. The Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts, whether or not a particular food falls within the definition of novel food.

Placing novel food on the market: only novel foods authorised and included in the Union list, established by the Commission, may be placed on the market within the Union. The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

- the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
- where the food 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.

Authorisation procedure: the procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list shall be efficient, time-limited and transparent. It shall start either on the Commission's initiative or following an application to the Commission by an applicant. The Commission shall make the application available to the Member States without delay.

Upon request by the Commission, the European Food Safety Authority (the Authority) shall give its opinion as to whether the update is liable to have an effect on human health.

Opinion of the Authority: the Commission and the Authority must respect certain time limits in order to ensure the harmonious treatment of applications for authorisation. However, in certain cases, the Commission and the Authority may extend the time limits.

The Commission shall forward the valid notification without delay, and not later than one month after having verified its validity, to the Member States and to the Authority.

Where the Commission requests an opinion from the Authority, it shall forward the valid application to the Authority without delay, and not later than one month after having verified its validity.

The Authority shall adopt its opinion within nine months from the date of receipt of a valid application.

Within seven months from the date of publication of the Authority's opinion, the Commission shall submit a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list.

Traditional foods from third countries: 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 demonstrated. Those foods should have been consumed in at least one third country for at least 25 years as a part of the customary diet of a significant number of people. The history of safe food use should not include non-food uses or uses not related to normal diets.

Data protection: in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation.

The Regulation stipulates that on request by the applicant, and where supported by appropriate and verifiable information included in the application, newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.

ENTRY INTO FORCE: 31.12.2015.

APPLICATION: from 01.01.2018 with the exception of certain provisions which shall apply from 31.12.2015 or from the date of application of certain implementing acts.

DELEGATED ACTS: the power to adopt delegated acts should be delegated to the Commission in respect of the adjustment and adaptation of the definition of engineered nanomaterial to technical and scientific progress or to definitions agreed at international level. It shall be conferred on the Commission for a period of five years (renewable) from 31 December 2015. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification (this period may be extended by two months). If the European Parliament or the Council objects, the delegated act shall not enter into force.