

Basic information	
1992/0426(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Novel foods and novel food ingredients Repealed by 2013/0435(COD) Amended by 2006/0144(COD) Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	

Key players			
European Parliament	Former committee responsible		Former rapporteur
	ENVI Environment, Public Health and Consumer Protection		ROTH-BEHRENDT Dagmar (PSE)
Council of the European Union	Council configuration		Appointed
			27/07/1994
Council of the European Union			

Key events			
Date	Event	Reference	Summary
07/07/1992	Legislative proposal published	COM(1992)0295 	Summary
14/09/1992	Committee referral announced in Parliament, 1st reading		
20/07/1993	Vote in committee, 1st reading		Summary
13/09/1993	Debate in Parliament		Summary
24/11/1993	Vote in committee, 1st reading		
01/12/1993	Modified legislative proposal published	COM(1993)0631 	Summary
16/06/1994	Debate in Council		
06/06/1995	Debate in Council		

23/10/1995	Council position published	09065/3/1995	Summary
16/11/1995	Committee referral announced in Parliament, 2nd reading		
21/02/1996	Vote in committee, 2nd reading		Summary
21/02/1996	Committee recommendation tabled for plenary, 2nd reading	A4-0050/1996	
12/03/1996	Debate in Parliament		Summary
15/07/1996	Parliament's amendments rejected by Council		Summary
16/10/1996	Formal meeting of Conciliation Committee		Summary
27/11/1996	Final decision by Conciliation Committee		Summary
09/12/1996	Joint text approved by Conciliation Committee co-chairs	3637/1996	
20/12/1996	Decision by Council, 3rd reading		
09/01/1997	Report tabled for plenary, 3rd reading	A4-0006/1997	
15/01/1997	Debate in Parliament		Summary
27/01/1997	Final act signed		
27/01/1997	End of procedure in Parliament		
14/02/1997	Final act published in Official Journal		

Technical information	
Procedure reference	1992/0426(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Repealed by 2013/0435(COD) Amended by 2006/0144(COD)
Legal basis	EC Treaty (before Amsterdam) E 100A
Stage reached in procedure	Procedure completed
Committee dossier	CODE/4/08075

Documentation gateway				
European Parliament				
Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A3-0244/1993 OJ C 268 04.10.1993, p. 0005	20/07/1993	
Text adopted by Parliament, 1st reading/single reading		T3-0556/1993 OJ C 315 22.11.1993, p. 0075-0139	27/10/1993	
Committee final report tabled for plenary, 1st reading /single reading		A3-0365/1993 OJ C 342 20.12.1993, p. 0003	24/11/1993	
Text adopted by Parliament confirming position adopted		T3-0683/1993		

at 1st reading		OJ C 342 20.12.1993, p. 0015-0033	02/12/1993	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0050/1996 OJ C 078 18.03.1996, p. 0004	21/02/1996	
Text adopted by Parliament, 2nd reading		T4-0112/1996 OJ C 096 01.04.1996, p. 0016-0026	12/03/1996	Summary
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A4-0006/1997 OJ C 033 03.02.1997, p. 0023	09/01/1997	
Text adopted by Parliament, 3rd reading		T4-0009/1997 OJ C 033 03.02.1997, p. 0058-0077	16/01/1997	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	09065/3/1995 OJ C 320 30.11.1995, p. 0001	23/10/1995	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1992)0295  OJ C 190 29.07.1992, p. 0003	07/07/1992	Summary
Reconsultation	COM(1993)0570 	10/11/1993	
Modified legislative proposal	COM(1993)0631  OJ C 016 19.01.1994, p. 0010	01/12/1993	Summary
Commission communication on Council's position	SEC(1995)1802 	13/11/1995	Summary
Commission opinion on Parliament's position at 2nd reading	COM(1996)0229 	23/05/1996	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0207/1993 OJ C 108 19.04.1993, p. 0008	24/02/1993	Summary
CSL/EP	Joint text approved by Conciliation Committee co-chairs	3637/1996	09/12/1996	
EU	Implementing legislative act	32004D0657 OJ L 300 25.09.2004, p. 0048-0053	19/05/2004	Summary

Additional information

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Source	Document	Date
European Commission	EUR-Lex	

Final act
Regulation 1997/0258 OJ L 043 14.02.1997, p. 0001 Summary

Novel foods and novel food ingredients

1992/0426(COD) - 24/02/1993 - Economic and Social Committee: opinion, report

Novel foods and novel food ingredients

1992/0426(COD) - 07/07/1992 - Legislative proposal

Novel foods and novel food ingredients

1992/0426(COD) - 23/10/1995

The Council adopted its common position. The Austrian, Danish, German and Swedish delegations voted against (the Danish explanation of vote is annexed). The common position will now be forwarded to the European Parliament, in the context of the codecision procedure. The Regulation will enter into force one year after its publication in the Official Journal. The Commission will be assisted in implementing these rules by the Standing Committee for Foodstuffs. Other Community legislative requirements concerning the labelling of foodstuffs obviously remain applicable. EXPLANATION OF VOTE BY THE DANISH DELEGATION: 'The Danish delegation cannot support the common position on the Regulation on novel foods and novel food ingredients. In the Danish delegation's view, the proposal does not guarantee that the consumer will be provided with sufficient information about whether foods have been produced using gene technology. Consequently, consumers will not be in a position to make their choices on a satisfactory and completely clear basis. The consumer will not therefore be free to choose. Only adequate consumer information will ensure the necessary confidence in and acceptance of new products and technologies. The Danish delegation would like this explanation of the Danish vote on the question of labelling to be forwarded to the European Parliament together with the Council's reasons'.

Novel foods and novel food ingredients

1992/0426(COD) - 16/01/1997 - Text adopted by Parliament, 3rd reading

In adopting the report by Mrs Dagmar ROTH-BEHRENDT (PSE, D), Parliament approved the joint text for a Regulation concerning novel foods and novel food ingredients. The compromise between the Council and Parliament within the Conciliation Committee gave rise to the following results: - All foodstuff labelling should inform the consumer of the characteristics or properties which, on the basis of a scientific evaluation, render a novel food or novel food ingredient different from an existing product. The label should also indicate the presence of genetically modified organisms; - exceptionally, Parliament has made a concession to the Council over supplies in bulk. This means that labelling of foodstuffs or food ingredients provided to the final consumer which may contain both genetically modified products and conventionally produced products should only indicate that such genetically modified organisms may be present. In exchange, the Council agreed to grant suppliers the right to inform the consumer that a specific foodstuff or food ingredient is not a new food and was not produced by means of the specific new-food techniques. - Parliament prevailed upon the Council to withdraw from its common position a provision to exclude from the scope of the Regulation genetic modifications limited to the agricultural characteristics of a product, e.g. where they improve a plant's resistance to rain, but where the resultant food product is not affected.

Novel foods and novel food ingredients

1992/0426(COD) - 23/10/1995 - Council position

The Council's common position took account of Parliament's wishes with regard to several important points and makes some amendments to the initial proposal. * The scope of the regulation was extended to expressly cover proteins from unicellular organisms. The following elements were also included: - all novel foods and food ingredients consisting of micro-organisms, fungi or algae or isolated from them; - novel foods and ingredients isolated from plants and animals except for those which had a history of safe food use; - all foods containing genetically modified organisms; - furthermore, the general criteria for assessing products were included in the regulation. * The procedure for placing products on the market was strengthened: - the reference to independent experts was removed and the task of carrying out an initial assessment of requests was instead allocated

to the national food assessment bodies; - wider publication of the results of the decisions taken; - clear, detailed requirements for the preparation of the dossiers to be sent to the authorities concerning products covered by the regulation; - clarification regarding cases where the Member States or the Commission could present a reasoned objection to the marketing of a product; - clarification of the procedure for the formal decision authorising the marketing of products together with the scope of such decisions; - simplified procedure for certain foods or food ingredients that did not pose any public health problems; - clarification as to the scope and allocation of tasks between the procedures provided for by the regulation on novel foods and the Community legislation on seeds, from the point of view of both assessment procedures and labelling. * As far as labelling is concerned, the common position strengthened and clarified the additional specific requirements applying to novel foods and novel food ingredients. The Council also introduced a series of rules to ensure that the consumer was systematically informed of the following points: - the differences between the characteristics or food properties of a novel food and a conventional product; in this case, the labelling should indicate the method by which the characteristics or properties in question were obtained for the consumer's information; - the presence in the product of material which was not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population (such as allergens); - the presence in the product of material which was not present in an existing equivalent foodstuff and which may give rise to ethical concerns among certain sections of the population; - the presence of a genetically modified organism. * The Council also took over Parliament's amendments concerning: - the protection of information provided in the application of procedures laid down by the regulation; - the confirmation that the general arrangements for the control of foodstuffs applied to the products in question; - the entry into force of the regulation 12 months after its publication in the OJ.

Novel foods and novel food ingredients

1992/0426(COD) - 27/01/1997 - Final act

OBJECTIVE: the regulation concerns the placing on the market in the Community of foods resulting from biotechnology. COMMUNITY MEASURE: Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients. SUBSTANCE: the regulation applies to the placing on the market of novel foods and novel food ingredients: - containing genetically modified organisms within the meaning of Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms; - products from, but not containing, genetically modified organisms; - with a new or intentionally modified primary molecular structure; - consisting of or isolated from micro-organisms, fungi or algae; - isolated from plants and from animals, except for those having a history of safe food use; - to which has been applied a production process which gives rise to significant changes in the composition or structure which affect their nutritional value, metabolism or level of undesirable substances. The regulation sets the general principle according to which the novel foods or food ingredients must not: - present a danger for the consumer, - mislead the consumer, - differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer. In order to protect public health, novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before being placed on the market within the Community. This assessment is carried out by the national authorities in cooperation with the Commission. A simplified procedure is provided for in the case of novel foods or novel food ingredients which are substantially equivalent to existing foods or food ingredients. With a view to providing adequate information to the consumer, the regulation sets specific additional requirements as regards labelling. The final customer is informed of: - any characteristic or food property (composition, nutritional value, use) which renders a novel food no longer equivalent to an existing food; - the presence in the product of substances which are not present in the existing equivalent product and which (a) may have implications for the health of certain sectors of the population (e.g. allergenic substances); (b) give rise to ethical concerns; - the presence of a genetically modified organism. The Scientific Committee for Food will be consulted on any matter falling within the scope of this Regulation. No later than five years from the date of entry into force of this Regulation the Commission will report to Parliament and the Council on the implementation of this Regulation. ENTRY INTO FORCE: 15/05/1997

Novel foods and novel food ingredients

1992/0426(COD) - 02/12/1993

In its first reading under the codecision procedure, the European Parliament confirmed its vote of 27 October 1993.

Novel foods and novel food ingredients

1992/0426(COD) - 15/07/1996

The Council had decided not to adopt the Regulation as amended by the European Parliament at its second reading. As a result, and in accordance with Article 189b of the Treaty, the Conciliation Committee would be convened to act between the Council and Parliament.

Novel foods and novel food ingredients

1992/0426(COD) - 23/05/1996 - Commission opinion on Parliament's position at 2nd reading

The Commission accepted Parliament's amendment reducing the deadline for the entry into force of the Regulation from twelve months to ninety days and amended its proposal accordingly, but was unable to accept Parliament's other amendments. However, the Commission emphasized that there was a consensus on the urgent need for a satisfactory regulatory framework at Community level for novel foods and that it would therefore cooperate constructively with the institutions during the remaining stages of the decision procedure and use every available means for resolving outstanding problems.

Novel foods and novel food ingredients

1992/0426(COD) - 01/12/1993 - Modified legislative proposal

1) CONTENT 1. Novel foods and novel food ingredients were understood to mean foods produced using processes which gave rise to significant changes in their composition and/or nutritional value and/or intended use. Examples included proteins obtained from certain algae, products similar to non-metabolisable fats or fibre, genetically modified potatoes which were immune to viruses, tomatoes which lasted longer without rotting, or more efficient yeasts which fermented more rapidly. The regulation did not apply to food additives or to other food ingredients already covered by other specific Community legislation. 2. The aim was to establish a Community assessment procedure in order to determine whether these novel foods and novel food ingredients were suitable for human consumption. 3. The regulation established a system for notifying the Commission about any novel food or other food ingredient, accompanied by a scientific expert's report. In addition, where there were serious, scientifically justified doubts or where the food was consumed in the form of a living organism, provision was made for a compulsory authorisation procedure in which the Commission referred the matter to the Standing Committee for Foodstuffs. 4. The Scientific Committee for Food had to be consulted about any decision or rule concerning a novel food or food ingredient which was likely to have an effect on public health. 5. Member States were authorised to suspend or provisionally restrict the marketing and use on their territory of a novel food or food ingredient if they considered that its use presented risks to human health. They had to inform the Commission, which would give its opinion without delay and, if necessary, launch the authorisation procedure. 2) OBJECTIVE To introduce rules on certain novel food products not previously covered by specific legislation in most Member States, in order to prevent the creation of new national technical barriers to the free movement of those products in the internal market, and at the same time to protect consumers, whilst still taking account of future prospects in the biotechnology sector in Europe. Source: European Commission - Info92 08/95

Novel foods and novel food ingredients

1992/0426(COD) - 19/05/2004 - Implementing legislative act

LEGISLATIVE ACT : Commission Decision 2004/657/EC authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation 258/97/EC of the European Parliament and of the Council.

CONTENT : This Decision provides that sweet maize from genetically modified maize line Bt11, as designated in the Annex, may be placed on the Community market as a novel food or novel food ingredient. The product shall be labelled as 'genetically modified sweet maize', in accordance with the labelling requirements laid down in Article 13 of Regulation 1829/2003/EC. The requisite information will be entered in the Community register of genetically modified food and feed.

This Decision is addressed to Syngenta Seeds BV, Westeinde 62, 1600 AA Enkhuizen, The Netherlands, representing Syngenta Seeds AG, Switzerland. It is valid for a period of 10 years.

The recitals to the Decision recount the consultation process, including validation studies.

Novel foods and novel food ingredients

1992/0426(COD) - 13/11/1995 - Commission communication on Council's position

The Commission approved the common position. While remaining faithful to the spirit of the initial proposal, the text had been considerably strengthened and clarified. The Commission regretted, however, that the entry into force of the regulation had been pushed back to 12 months after its publication instead of 6 months, but it accepted the new date. The Commission also regretted the fact that the Council had adopted a regulatory committee procedure.

Novel foods and novel food ingredients

1992/0426(COD) - 12/03/1996 - Text adopted by Parliament, 2nd reading

In adopting the report by Mrs Dagmar ROTH-BEHRENDT (PSE, D), the European Parliament amended the common position of the Council on genetically engineered foods. The EP virtually rejected all the amendments by the Committee on the Environment, which called for the labelling of all original or finished products containing genetically modified organisms. The common position, for its part, called for the labelling only of products which were rendered significantly different. The text adopted by the EP was a compromise: labelling requirements shall apply to products different from equivalent existing products. Parliament also adopted an amendment to the effect that, without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements should apply to inform the consumer of: any characteristic or food property such as composition, nutritional value or nutritional effects, intended use of the food, which rendered a novel food or food ingredient different (the common position said "significantly different") from an equivalent existing food or food ingredient.