Procedure file

Basic information

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Novel foods and novel food ingredients Amended by 2006/0144(COD) Repealed by 2013/0435(COD) Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety		

Key players

European Parliament

Former committee responsible		
ENVI Environment, Public Health and Consumer Protection	PSE ROTH-BEHRENDT Dagmar	27/07/1994

Council of the European Union

Council configuration	Meeting	Date
Fisheries	1983	20/12/1996
General Affairs	1943	15/07/1996
Education, Youth, Culture and Sport	1875	23/10/1995
Competitiveness (Internal Market, Industry, Research and Space)	1851	06/06/1995
Competitiveness (Internal Market, Industry, Research and Space)	1769	16/06/1994

Key events

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
20/07/1993	Committee report tabled for plenary, 1st reading	A3-0244/1993	
13/09/1993	Debate in Parliament		Summary
27/10/1993	Decision by Parliament, 1st reading	T3-0556/1993	
24/11/1993	Vote in committee, 1st reading		
24/11/1993	Committee report tabled for plenary confirming Parliament's position	A3-0365/1993	

01/12/1993	Modified legislative proposal published	COM(1993)0631	Summary
02/12/1993	Decision by Parliament, 1st reading	T3-0683/1993	Summary
16/06/1994	Debate in Council	1769	
06/06/1995	Debate in Council	1851	
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
12/03/1996	Decision by Parliament, 2nd reading	T4-0112/1996	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
16/01/1997	Decision by Parliament, 3rd reading	T4-0009/1997	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
	Amended by 2006/0144(COD) Repealed by 2013/0435(COD)
Legal basis	EC before Amsterdam E 100A
Stage reached in procedure	Procedure completed
Committee dossier	CODE/4/08075

Documentation gateway

Legislative proposal		COM(1992)0295 OJ C 190 29.07.1992, p. 0003	07/07/1992	EC	Summary
Economic and Social Committee: opinion, report		CES0207/1993 OJ C 108 19.04.1993, p. 0008	24/02/1993	ESC	Summary
Committee report tabled for plenary, 1st reading/single reading		A3-0244/1993 OJ C 268 04.10.1993, p. 0005	20/07/1993	EP	
Text adopted by Parliament, 1st reading/single reading		T3-0556/1993 OJ C 315 22.11.1993, p. 0075-0139	27/10/1993	EP	
Reconsultation		COM(1993)0570	10/11/1993	EC	
Committee final report tabled for plenary, 1st reading/single reading		A3-0365/1993 OJ C 342 20.12.1993, p. 0003	24/11/1993	EP	
Modified legislative proposal		COM(1993)0631 OJ C 016 19.01.1994, p. 0010	01/12/1993	EC	Summary
Text adopted by Parliament confirming position adopted at 1st reading		T3-0683/1993 OJ C 342 20.12.1993, p. 0015-0033	02/12/1993	EP	Summary
Council position		09065/3/1995 OJ C 320 30.11.1995, p. 0001	23/10/1995	CSL	Summary
Commission communication on Council's position		SEC(1995)1802	13/11/1995	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0050/1996 OJ C 078 18.03.1996, p. 0004	21/02/1996	EP	
Text adopted by Parliament, 2nd reading		T4-0112/1996 OJ C 096 01.04.1996, p. 0016-0026	12/03/1996	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(1996)0229	23/05/1996	EC	Summary
Joint text approved by Conciliation Committee co-chairs		3637/1996	09/12/1996	CSL/EP	
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	EP	
Text adopted by Parliament, 3rd reading		T4-0009/1997 OJ C 033 03.02.1997, p. 0058-0077	16/01/1997	EP	Summary
Implementing legislative act		32004D0657 OJ L 300 25.09.2004, p. 0048-0053	19/05/2004	EU	Summary

Additional information

European Commission	EUR-Lex

Final act

Regulation 1997/258
OJ L 043 14.02.1997, p. 0001 Summary

Novel foods and novel food ingredients

$summary.text

Novel foods and novel food ingredients

$summary.text

Novel foods and novel food ingredients

The report by Mrs Roth-Behrendt (PSE, D) on novel foods and novel food ingredients was the subject of a thorough debate. Although some controversial points remained unresolved, the report was adopted by a majority vote. ?

Novel foods and novel food ingredients

$summary.text

Novel foods and novel food ingredients

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

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

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

The committee adopted a draft recommendation for second reading with amendments. The Council's common position did not reflect all of Parliament's wishes, particularly from the point of view of labelling. The committee therefore adopted a series of amendments to reflect its concerns, especially as regards the protection of consumers' interests. Mrs Dagmar ROTH-BEHRENDT stated that the consumer's right to clear and unrestricted information should be guaranteed, particularly where genetically modified organisms had been used. The consumer should know that the food did not present any danger. That is why there had been many requests to ensure that foods or food ingredients constituting a potential health risk had first of all undergone a public authorisation procedure before being allowed on the market. The committee was well aware of the desire to prevent needless administrative burdens, however it wished to extend the scope of the regulation to cover more fields than provided for by the Council. The safety of a product did not depend only on the product as such, but also on the production processes involved. Therefore, new authorisation should be obligatory in the case of significant changes in the production process. The reference in the common position (Article 1(2a)) concerning the inclusion of food consisting of genetically modified organisms within the meaning of Directive 90/220/EEC considerably restricted the scope of the regulation since the legal definition of a genetically modified organism in the directive only covered organisms that could reproduce (such as tomatoes) and excluded organisms that could not reproduce (such as ketchup made from tomatoes). However, the general term "genetically modified organisms" as used by the committee applied to both organisms that could reproduce and those that could not. Thus, according to the term used by the committee, genetically modified baker's yeast came under the scope of the regulation, whilst if the wording in the common position was maintained, it would be excluded. According to Mrs ROTH-BEHRENDT's explanatory statement, it was not advisable to apply two different assessment and authorisation procedures, one of which was simplified and the other more complicated. The Council wished the simplified method to be applied to products which, although genetically modified during processing, were in the end substantially equivalent to existing foods. One example of this was sugar, which could be produced by traditional growing methods or through genetic engineering. The committee wished the rapid procedure to be significantly restricted. Given the little experience available in the field of novel foods, it felt that consumer protection was essential. It was important to eliminate where possible any potential dangers by means of a rigorous authorisation procedure involving an adequate assessment of the risks involved and the safety of the product. A simple notification procedure would not be sufficient to meet this requirement. The division of the initial assessment procedure into two sections - general (Article 4) and specific (Article 6) - with referrals from one to the other was uncoordinated from a legal standpoint. In the rapporteur's view, it was therefore essential to combine these two articles into a single, well-structured provision to define the procedure. The committee therefore decided to delete Articles 3(4), 4 and 5 and to include their content in an amended Article 6. The rapporteur referred to the concept of selective labelling advocated by the Council and pointed out that surveys carried out among consumers in various Member States clearly showed that they wanted to receive comprehensive information. Labelling should be as complete as possible. Nevertheless, the committee recognised along with the Commission that attaching a specific label to every product where the manufacturing process had involved genetic engineering at one stage or another, irrespective of the degree to which it was required, would not provide any useful information for the consumer and would be difficult to implement. As a result, its amendments concerning labelling did not cover all the possible applications of genetic engineering in the food sector. Thus, immobilised enzymes or those that were not included in the final product, such as amylases or isomerases used for the saccharification of starch, should no longer appear in the list of ingredients. However, the proposal to limit labelling to certain categories of products, for example, only final products still containing genetically modified organisms that could reproduce, did not comply with the principle of providing information that was as comprehensive as possible. ?

Novel foods and novel food ingredients

The rapporteur, Mrs Roth-Berendt (PSE, D), thought that the common position contained gaps, since it failed to provide adequate protection for the interests of consumers. She first wanted the scope of the regulation, which was restricted to foods and food ingredients produced from, but not containing, genetically modified organisms, to be extended to include enzymes. The rapporteur considered that a new authorisation was essential in cases involving a significant change in the production method being used. She also called for an approval procedure for new foods, and not just a simple notification, which might ensure a proper assessment of the risks and safety aspects of the product concerned. Finally, the consumer should be provided with adequate information (for example in the case of products produced using genetic methods); according to the rapporteur this would mean introducing a suitable system of labelling so that no essential information was concealed from the consumer. Commissioner Bangemann did not accept the main amendments being proposed by the rapporteur, as he believed this would result in a phenomenal amount of labelling. However, he agreed with Amendments Nos 17, 22 and 54 and in part with Amendments Nos 9, 29 and 44. As far as Amendment No 17 was concerned he pointed out that genetically modified food additives, flavourings and solvents were already covered by specific Directives; this also applied to transgenic organisms already authorised for use, which required no new notification. As regards the scope of the regulation the Commissioner was opposed to Amendments Nos 2, 13, 14, 15, 16 and 22. As far as the procedure was concerned he was not in favour of Amendments Nos 1, 3, 19 to 21, 23 to 28, 30, 45 to 47 and 49 to 53, and confirmed his support for a simplified procedure. Finally, on the subject of labelling the Commissioner was not in favour of Amendments Nos 32 and 55; however, he thought that it was important to know if there was a significant degree of modification, because if this was the case then the labelling would be useful in that it would enable a distinction to be drawn between a novel food or food ingredient and other equivalent products already in existence.

Novel foods and novel food ingredients

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. ?

Novel foods and novel food ingredients

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

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

Are novel foods, by which is meant genetically modified products (which could affect soybean seeds, sugar beet or tomatoes), different from traditional foodstuffs, and if so to what extent? This was the question that lay at the heart of the first exchange of views of the previous evening between delegations representing Parliament and the Council, sitting in the Conciliation Committee. Parliament wanted to see a form of foodstuffs labelling that would inform consumers of any characteristic or property that distinguished novel foods or novel food ingredients from equivalent existing foods or food ingredients. The Council took the view that this information was only justified when there was a substantial difference between the novel food and the conventional foodstuff. It intended referring back to the Conciliation Committee, under the codecision procedure, in order to obtain a compromise text for a proposal for a regulation from Parliament and the Council concerning the placing on the Community market of novel foods and novel food ingredients. On 12 March Parliament adopted at second reading six amendments to the common position that had been agreed by the Council on 23 October 1995. Compromise proposals were currently being examined and it was possible that the delegations would reach an agreement in the weeks ahead. The regulation was aimed at ensuring that novel foods and novel food ingredients posed no risk to the health of consumers or to the environment and would be subject to a detailed labelling system. It would also define the procedures to be put in place at European level in order to provide for the placing of such products on the Community market. Genetic manipulation was only to be permitted when it was designed to improve the taste, flavour or shelf life of the products concerned, or to protect them from attack by insects and herbicides.

Novel foods and novel food ingredients

The European Parliament/Council conciliation committee managed to conclude negotiations on novel foods and novel food ingredients. This agreement was described as "historic" by both delegations. Until now, the committee had only approved directives and programmes. As a result, novel foods and novel food ingredients such as genetically modified soya beans, sugar beet and tomatoes can be eaten without risk and are environmentally-friendly and correctly labelled. European procedures were adopted for marketing these products on the Community market. Without these, differences between national legislations would have hampered the free movement of these foodstuffs and constituted an obstacle to the internal market. Genetic modification is used mainly to influence taste or shelf life or to protect products against insects or pesticides. The European Parliament rapporteur, Mrs Dagmar ROTH-BEHRENDT (PSE, D) welcomed the agreement concluded last night under the codecision procedure which, she felt, would allow suitable legislation to be adopted within a reasonable period of time in the interests of European consumers. The urgency was all the greater as genetically modified foods were expected to start inundating the Community market at any moment. Under the terms of the agreement, the Council incorporated in full 3 of the 6 amendments adopted by the European Parliament at second reading of the proposal for a regulation of 12 March 1996. In doing so, the Council: - agreed that the regulation would enter into force 90 days after its publication in the Official Journal instead of the twelve months initially proposed in the common position of 23 October 1995; - agreed that novel foods which satisfied the conditions which allow them to be rapidly placed on the market (i.e. for which no further evaluation is necessary) must nonetheless comply with the labelling requirements in the regulation. A compromise was reached on the other three amendments. - 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 novel food and was not produced by means of the specific novel-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. The conciliation committee was jointly chaired by Mr Josep VERDE I ALDEA (PSE, E), vice-president of the European Parliament and Mr Jimmy DEENIHAN, Irish secretary of state (agriculture, forests and food). In the final stage of the legislative procedure, the text adopted by the conciliation committee still needs to be approved by the Council (by a qualified majority) and by the European Parliament (by a simple majority).

Novel foods and novel food ingredients

The rapporteur, Mrs Roth-Behrendt (PSE, DE), welcomed the agreement reached between Parliament and the Council on food. In particular she said that the compromise represented an important step for certain Member States which did not have detailed legislation on food labelling. Commissioner Bangemann fell in between those who felt that this was an important step and those who considered that the text would make absolutely no improvement. However, he pointed out that it would have been unreasonable to impose unlimited labelling as the protection of consumers? interests did not justify the mandatory labelling of approximately 80-90% of the ingredients used.

Novel foods and novel food ingredients

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

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

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.