COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 295 final - SYN 426

Brussels, 7 July 1992

Proposal for a

COUNCIL REGULATION (EEC)

on novel foods and novel food ingredients

(presented by the Commission)

COMMISSION OF THE EUROPEAN COMMUNITIES

CORRIGENDUM

COM(92) 295 final /2- SYN 426

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Le texte de l'article 10 du document
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(ne concerne que les versions FR, DE, EN)

Proposal for a

COUNCIL REGULATION (EEC)

on novel foods and novel food ingredients

(presented by the Commission)

Article 10

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee on Foodstuffs, set up under Decision 69/414/EEC[11] acting in an advisory capacity, hereinafter referred to as "the Committee".

2. The Chairman shall submit to the Committee a draft of measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

3. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

4. The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

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(11) OJ N° L 291 of 19.11.1969, p. 9.

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Explanatory Memorandum

1. *At the present time there is no general requirement in Member States that products offered for sale as food are subjected to a pre-marketing assessment. Companies or persons offering products for sale as food do so on their own responsibility; nevertheless, authorities have reserve powers to take action if they consider that a foodstuff is a danger for health.*

2. *Whilst this situation was acceptable when food technology and ingredients were based on a long tradition of safe use, now new raw materials for food and new processes for the production of food which lead to fundamental changes in food components are rapidly evolving from the research stage to the market place. These materials and technologies are being developed to improve nutritional qualities, to enhance the taste, smell, texture or appearance, or to render more effective the production, storage or processing of food.*

3. *These new materials may be modified food components, synthetic substances, or new or exotic raw materials that are derived from animals, plants or microorganisms. An important element of these new technologies is the application of techniques of genetic technology. These methods represent new tools that permit scientists to add desirable traits to food organisms or to remove undesirable ones more precisely than would be possible by more conventional breeding methods.*

4. *According to Community law, additives are substances not normally present in food which are added in order to achieve a technological purpose (preservatives, colourants, antioxidants, etc.) and as such are required to be assessed for their suitability for use in food by the Scientific Committee for Food and to be authorized.*

5. *Novel food components which, as nutrients, will be present in much larger quantities than additives are currently not required to be subjected to any such scientific assessment at Community level for their suitability for consumption as food and therefore the free circulation of such novel foods may be hindered by the provisions which some Member States have already developed or are in the process of laying down for assessing and in some cases authorizing novel foods.*

6. *This Regulation responds to public concern that novel foods should be examined for their safety and in some cases be subject to authorization before they can be offered for sale. It provides a schema whereby those responsible for placing foods on the market and also control authorities may identify those cases where there is a need to scientifically evaluate a food which is being offered for sale for the first time, either because it contains ingredients that have never before been consumed as food or because it has been fundamentally changed by the use of new physical, chemical or biological techniques. It further provides procedures for scientifically evaluating these "novel foods or ingredients" and in those cases where no existing assessment criteria are available for authorizing their placing on the market.*

7. *There have already been a number of requests for assessment by manufacturers to the Commission on an 'own initiative' basis of products which do not fall under the scope of the additives, solvents or flavourings directives. These products are being examined by the Scientific Committee for Food but if the result of this examination shows the products to be acceptable as food there is no legal instrument which guarantees their free circulation.*

8. *This Regulation lays a duty of care on those marketing a new product which falls in one of the categories in Annex I to carry out a scientific assessment of the food. Foods or processes with an established history of safe use will not fall under this Regulation.*

9. *Where significant new ingredients are present or changes have occurred within the meaning of this Regulation which require a scientific assessment this will first be carried out by an expert, that is a person with the appropriate expertise to evaluate any changes in the nutritional value, digestibility, stability, hygienic quality, or content of possible undesirable substances. The requirements for this assessment may vary according to the characteristics of each particular case and the evaluation will therefore be carried out on a case-by-case basis, taking into account the diversity of concerns that may arise.*

10. *Where the expert considers that the information available shows that the food can be evaluated by accepted methods with the conclusion that the food is acceptable for marketing, then the product may be marketed, with a notification sent to the Commission. However, should the Commission or a Member State consider that the safety questions have not been adequately answered they may require the product to be subjected to authorization.*

11. *In those very few cases where the expert considers that the food cannot be evaluated by accepted methods or there is a new or modified viable organism in the food, the details of the assessment are notified to the Commission and the assessment examined by the Scientific Committee for Food before authorization for the placing on the market is given.*

12. *Since "whole foods" cannot be evaluated in exactly the same way as the toxicological testing of food additives and contaminants it is anticipated that the combination of toxicological and nutritional studies needed will vary according to the nature of the product and its intended use and must be determined for each individual case. In many cases short-term physiological assessments may be needed to assess digestibility, nutritional value, anti-nutrient effects and allergenicity.*

13. *Appropriate assessment methods are being developed by researchers and by international bodies such as the Codex Alimentarius and the OECD and the Commission is participating fully in this work to ensure that these international developments are taken into account in the protocols which are being developed at Community level.*

14. *Substances that are food additives, solvents, flavours or are irradiated are excluded from the scope of this proposal since they are already assessed under the relevant Community legislation.*

15. *This proposal is a step towards the completion of Community legislation in the food sector, as announced in the Commission Communication on Food Law (COM(85)603 final).*

16. *It is also part of the regulatory framework for the development of biotechnology and was mentioned in the Commission's Communication to Parliament and the Council on "Promoting the Competitive Environment for the Industrial Activities based on Biotechnology within the Community" (SEC(91)629 final). It is coherent with the conclusions of this Communication in providing an integrated assessment procedure for foods.*

17. *A Council Regulation will be the most appropriate instrument for the assessment of novel foods and novel food ingredients in the Community. The main reasons for choosing a Regulation are as follows:*

The constraining legal nature of the proposed rules, in particular the fact that any final decision will lie with the Community, leaves only very small - if any - discretionary margin to national legislators.

It is important to ensure from the start uniform implementation of the new rules because they will represent an innovation for all Member States of the Community. Such uniformity is clearly in the interest of all socio-economic parties concerned.

Finally a Regulation will reduce substantially the implementation period of the new system since no national act is required to make it applicable. This is crucial with a view to achieving the Internal Market by the end of 1992.

Proposal for a

COUNCIL REGULATION

on novel foods and novel food ingredients

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 100a thereof,

Having regard to the proposal from the Commission(1),

In cooperation with the European Parliament(2),

Having regard to the opinion of the Economic and Social Committee(3),

Whereas, differences between national laws relating to novel foods or food ingredients could hinder the free movement of foodstuffs, whereas they may create conditions of unfair competition, thereby directly affecting the establishment or functioning of the internal market,

Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed;

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(1) ...

(2) ...

(3) ...

Whereas, also, the smooth running of the internal market requires that provisions for notification and authorization of foods or food ingredients which have not been hitherto been used for human consumption to a significant degree in the Community and/or which have been produced by food production processes that result in a significant change in their composition and/or nutritional value and/or intended use should be determined at Community level; whereas such authorization shall be of general application;

Whereas this Regulation does not affect food additives, flavourings for use in foodstuffs and extraction solvents falling within the scope of other Community provisions;

Whereas risks to the environment may be associated with food or food ingredients which contain or consist of genetically modified organisms; whereas Directive 90/220/EEC has specified that, for such products, an environmental risk assessment must always be undertaken to ensure satefy for the environment; whereas, in order to provide for a unified Community system for assessment of a product, provisions must be made under this regulation for a specific environmental risk assessment, which in accordance with the procedures of Article 10 of Directive 90/220/EEC must be similar to that laid down in that Directive, together with the assessment of the suitability of the product to be used as a food or food ingredient.

Whereas the Scientific Committee for Food has to be consulted on any decision on foods or food ingredients which have not been hitherto been used for human consumption to a significant degree in the Community and/or which have been produced by food production processes that result in a significant change in their composition and/or nutritional value and/or intended use likely to have an effect on public health;

Whereas, in respect of this Regulation, provision should be made for a procedure instituting close cooperation between Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC(4);

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(4) OJ No L 291, 19.11.1969, p. 9.

HAS ADOPTED THIS REGULATION

Article 1

This Regulation lays down provisions for the placing on the market of foods or food ingredients which have not hitherto been used for human consumption to a significant degree and/or which have been produced by processes that result in a significant change in their composition and/or nutritional value and/or intended use. The categories of products falling within the scope of this Regulation are listed in Annex I.

Article 2

This Regulation shall not apply to:

(a) food additives falling within the scope of Council Directive 89/107/EEC(5);

(b) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC(6).

(c) extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC(7).

(d) foods and food ingredients treated with ionizing radiation, falling withing the scope of Council Directive .../../EEC(8)

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(5) OJ No L 40, 11. 2.1989, p. 27.
(6) OJ No L 184, 15. 7.1988, p. 61.
(7) OJ No L 157, 24. 6.1988, p. 28.
(8) OJ No .....

Article 3

1. Member States shall establish a list of independent experts with scientific experience qualified to carry out the examinations referred to in article 5.

2. The list and subsequent modifications shall be notified to the Commission. The Commission shall compile the consolidated list of experts from the notifications and shall ensure its publication.

3. Criteria for the selection of the experts mentioned in paragraph 1 may be adopted in accordance with the procedure laid down in Article 10.

Article 4

1. A food or food ingredient falling under the scope of this Regulation shall be placed on the market for the first time in accordance with the procedure stipulated in Articles 5; however, where the food is consumed as a viable organism or where generally accepted scientific data are not available to demonstrate its safety it is submitted to the procedure of Article 6.

Article 5

1. Where on the basis of generally accepted scientific data, in the opinion of one or more of the qualified experts from the list mentioned in article 3, there is evidence that the product to be used as a food or food ingredient complies with the general criteria mentioned in Annex II, the person legally responsible shall notify the Commission a summary of the evidence together with the opinion of the expert.

   The Commission shall immediately send the notification to the Member States.

2. The food or food ingredient concerned may be placed on the market only three months after the notification received by the Commission and provided the Commission has not delivered a negative opinion within the period of three months at its own initiative or at the duly motivated request from a Member State.

   In the event of a negative opinion, the procedure in article 6 is to be followed.

3. For the purposes of control, where necessary, the competent authority shall be empowered to require the person legally responsible for placing the product on the market to produce the scientific work and the data establishing the product's compliance with the general criteria mentioned in Annex II and with the procedure laid down in paragraph 2. If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

4. Detailed rules for implementing paragraphs 1 and 2 may be adopted in accordance with the procedure laid down in Article 10.

Article 6

1. When the procedure laid down in this article is to be followed the person legally responsible for placing the product in the market on the Community shall submit a request for authorization to the Commission comprising the necessary information to assure the compliance with the criteria mentioned in Annex II. The Commission shall inform the Member States accordingly. The Member States may send to the Commission observations including pertinent scientific information.

2. A decision shall be taken on the authorization for the marketing of the food or food ingredient according to the procedure laid down in Article 10.

3. The decision mentioned in paragraph 2 may establish the conditions of use of the food or food ingredient when appropriate. It may also establish the name of the food or food ingredient and any indications concerning the labelling, as the case may be, as laid down in Article 5 of Council Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (9).

4. The Commission shall communicate to the applicant the decision taken with respect to his request.

5. The Commission shall inform Member States of any decision adopted pursuant to paragraph 2.

6. Detailed rules for implementing this article may be adopted in accordance with the procedure laid down in Article 10.

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(9) OJ No L 33 of 8.2.1979, p.1

Article 7

1. *Where the food or food ingredient falling under the scope of this Regulation contains or consists of a genetically modified organism within the meaning of Article 2 paragraphs 1 and 2 of Council Directive 90/220/EEC(10) on the deliberate release of genetically modified organisms, the information required in the request for authorization mentioned in Article 6 shall be accompanied by :*

   - *a copy of the written consent, from the competent authority, to the deliberate release of the genetically modified organisms for research and develoment purposes provided for in Article 6(4) of Directive 90/220/EEC, together with the results of the release(s) with respect to any risk to human health and the environment;*

   - *the complete technical dossier supplying the information requested in Annexes II and III of Directive 90/220/EEC and the environmental risk assessment resulting from this information.*

   Articles 11 to 18 of Directive 90/220/EEC(10) shall not apply to food or food ingredients falling under the scope of article 6 which contain or consist of a genetically modified organism.

2. *In the case of food or food ingredients falling under the scope of this Regulation containing or consisting of a genetically modified organism, the decision mentioned in article 6 paragraph 2 shall take account of the environmental safety requirements laid down by Directive 90/220/EEC.*

3. *Detailed rules for implementing this article may be adopted in accordance with the procedure laid down in Article 10.*

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(10) OJ No L 117 of 8.5.1990, p.15

Article 8

Any decision or provision regarding a food or food ingredient falling under the scope of Article 1 likely to have an effect on public health shall be adopted by the Commission after consultation with the Scientific Committee for Food, either on its own initiative or at the request of a Member State.

Article 9

1. Where a Member State has detailed grounds for considering that the use of a food or a food ingredient falling under the scope of Article 1, although it complies with this Regulation, endangers human health, that Member State may temporarily suspend or restrict the trade 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 and give reasons for its decision.

2. The Commission shall examine the grounds given by the Member State referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures following the procedure laid down in Article 10.

3. If the Commission considers that the national measure must be dispensed with or modified, it shall initiate the procedure laid down in Article 10 for the adoption of the appropriate measures.

Article 10

1. *Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee for Foodstuffs, set up under Decision 69/414/EEC (11), hereinafter referred to as the Committee.*

2. *The Chairman shall refer the matter to the Committee either on his own initiative or at the request of the representative of a Member State.*

3. *The Commission representative shall submit to the Committee a draft of measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148(2) of the Treaty. The Chairman shall not vote.*

4. *(a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion.*

(b) Where the intended measures are not in accordance with the opinion of the Committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measure, the Commission shall adopt the proposed measures.

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(11) OJ No L 291 of 19.11.1969, p.9

Article 11

This Regulation shall enter into force on 1st. January 1993.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at: ..... For the Council

The President

ANNEX I

Categories of products falling within the scope of this Regulation:

- *a product consisting of or containing a modified food molecular entity, or a molecular entity with no established history of food use;*

- *a product produced from or consisting of, or containing an organism or part of an organism with no established history of food use;*

- *a product produced from or consisting of, or containing an organism or part of an organism currently used in food production which has been modified by gene technology;*

- *a product to which has been applied a process not currently used for food manufacture or which, although subjected to such a process, has not previously been placed on the market and where such a process gives rise to significant changes in the composition or structure of the end product which affect its nutritional value and/or its digestibility and/or its metabolism and/or the level of undesirable substances in the food.*

ANNEX II

GENERAL CRITERIA FOR THE PLACING ON THE MARKET OF FOODS AND FOOD INGREDIENTS FALLING UNDER THE SCOPE OF ARTICLE 1

Foods and food ingredients falling under the scope of article 1 may be placed on the market provided that :

1. *they are safe for the consumer when consumed as food at the intended levels of use;*

2. *they do not mislead the consumer;*

3. *they do not differ from similar foods or food ingredients that they may replace in the diet in such a way that their normal consumption would be nutritionally disadvantageous for the consumer.*

IMPACT ASSESSMENT FORM
THE IMPACT OF THE PROPOSAL ON BUSINESS
with special reference to small and medium sized enterprises

Title of proposal:

Proposal for a Council Regulation on novel foods and novel food ingredients

Document reference number:

III/3562/89

The proposal

1. *Taking account of the principal of subsidiarity, why is Community legislation necessary in this area and what are its main aims?*

"Novel foods" are being produced by synthesis, chemical or physical treatment of existing foods, or by genetic modification of food microorganisms, plants or animals. Examples of such products are low calorie fat replacers, microorganisms to produce proteins which have never been used as food, or fruit genetically modified to improve taste, flavour, or keeping qualities.

Community legislation exists for assessing and authorizing food additives, which are present normally in very small amounts in foods, whereas "novel foods", which are used in relatively large quantities in products or even sold as a complete food, are subject to national assessment and authorization procedures.

Some Member States have adopted legislation on novel foods, whilst others have preferred to wait for the adoption of the regulation, in the interim dealing with individual products on an ad hoc basis using the general safety provisions of food law.

The proposal provides a schema to guide those responsible for the importing, manufacturing and placing on the market of food which is being offered for sale for the first time and control authorities as to when scientific assessment is needed and providing a framework for assessment and authorization.

The impact on business

2. Who will be affected by the proposal?

All firms placing food on the market will be affected by the proposal; however, the impact on them will be positive since the proposal will give guidance as to their responsibilities and how, if necessary, a safety question can be dealt with.

The number of novel foods requiring authorisation would be very limited and the firms involved in authorisations will either be large manufacturers or technologically orientated SMEs who will have generated the data required for assessment as a matter of course in research and development on the food.

A very large number of SMEs may use "novel foods" which have already been authorised as ingredients in developing ranges of specialist foods, e.g. low fat patisserie based on low calorie fat replacers or vegetarian dishes based on meat simulated mycoprotein. These firms will enjoy the benefits offered by a Community authorization of a "novel food" ingredient in that their composite foods containing the ingredient will not require authorisation.

Such businesses can be found throughout the Community.

Importers of food will also be affected buy similar procedures are in place or being developed in third countries and at international level (see below).

The authorisation, where necessary, of the marketing of "novel foods" produced from genetically modified plants and animals will allow farmers to use improved varieties once they have been appropriately registered.

3. What will businesses have to do to comply with the proposal?

Any firm producing foods containing a "novel food" as an ingredient will have to take cognisance of the fact and record this. It should be recalled that ingredient listing of foods is already required by the labelling directive and the keeping and inspection of records is required by the control directive so that no new tasks are imposed. The regulation then lays down how a "novel food" is identified and the criteria which may be necessary if authorization is required.

Firms or importers placing a novel food on the market for the first time will have to follow the full procedure which may require a submission to be made for authorisation. The procedure proposed for authorisation is similar to that already in place for food additives and as such is familiar to the industry. However, it is much more rapid once the SCF has given its opinion on safety.

SMEs processing ingredients into composite foods will simply have to ensure by asking their supplier that a "novel food" ingredient has, where necessary, received the proper authorisation.

4. *What economic effect is the proposal likely to have?*

The impact on business will be positive both in respect of offering innovators the potential of a Community-wide market and also in respect of facilitating international trade.

The WHO/FAO Codex Alimentarius has produced a document on the strategy for assessing the safety of foods produced by biotechnology and the OECD is working on a similar document. Similar initiatives to the regulation have been undertaken in Japan and the USA and regular discussions on these questions are held with the appropriate USA and Japanese agencies.

The existence of a Community-wide system for novel foods will be a distinct advantage to those wishing to develop new products for export to these markets.

5. *Does the proposal contain measures to take account of the specific situation of small and medium sized firms (reduced or different requirements, etc)?*

The proposal does not provide for derogations for small firms, nor would it be appropriate to do so since the fundamental question is one of food safety. The proposal will, however, by its nature have little direct impact on firms who are not the primary producers or importers of novel foods, the users of novel foods as ingredients being required to obtain the appropriate assurances from their suppliers.

Consultation

6. *List the organisations which have been consulted about the proposal and outline their main views.*

An earlier draft proposal was discussed in the Food Advisory Committee on 5-6 June 1990 on which the economic operators (industry, commerce, agricultural sector, consumers, workers) are represented. Industry and commerce expressed some concern about the possibility of creating a too bureaucratic burden/ Commerce expressed certain concerns about the obligation to provide guarantees about the manufacturing process for imported products. It has been pointed out that similar obligations already exist where safety considerations are important, eg food additives. The need to clearly identify safety questions has been taken in the development of the proposal by clarifying the scope of the proposal (eliminating the reference to processes) and establishing a decision tree to lead to three different procedures whose requirements are relevant to the absence or the need for safety clearance (no further action needed; notification; authorisation).

Following these revisions an informal meeting has been held with interested parties to explain the modified text. They appear to be satisfied with the modified provisions and accept that where "novel foods" are being imported the appropriate procedures will have to be followed.

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