II

(Preparatory Acts)

COMMISSION

Proposal for a Council Regulation (EEC) on novel foods and novel food ingredients

(92/C 190/04)

COM(92) 295 final — SYN 426

(Presented by the Commission on 7 July 1992)

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,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

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;

Whereas, also, the smooth running of the internal market requires that provisions for notification and authorization of foods or food ingredients which have not 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 safety 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 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 [1],

[1] 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 (1);

(b) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC (2);

(c) extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC (3)

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

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 within the scope of this Regulation shall be placed on the market for the first time in accordance with the procedure stipulated in Article 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 with 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 on the market in 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.

(1) OJ No L 40, 11. 2. 1989, p. 27.
(2) OJ No L 184, 15. 7. 1988, p. 61.
(3) OJ No L 157, 24. 6. 1988, p. 28.

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 (1).

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.

Article 7

1. Where the food or food ingredient falling within the scope of this Regulation contains or consists of a genetically modified organism within the meaning of Article 2 (1) and (2) of Council Directive 90/220/EEC (2) 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 development 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 shall not apply to food or food ingredients falling within the scope of Article 6 which contain or consist of a genetically modified organism.

2. In the case of food or food ingredients falling within the scope of this Regulation containing or consisting of a genetically modified organism, the decision mentioned in Article 6 (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.

Article 8

Any decision or provision regarding a food or food ingredient falling within 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 within 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 fort with 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 on Foodstuffs, set up pursuant to Decision 69/414/EEC (3) 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

(1) OJ No L 33, 8. 2. 1979, p. 1.

(2) OJ No L 117, 8. 5. 1990, p. 15.

(3) OJ No L 291, 19. 11. 1969, p. 9.

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.

Article 11

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

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

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 level of undesirable substances in the food.

ANNEX II

General criteria for the placing on the market of foods and food ingredients falling within 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.