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REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1997 concerning novel foods and novel food ingredients

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3) in the light of the joint text approved by the Conciliation Committee on 9 December 1996,

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

(2) Whereas, in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community; whereas in the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients a simplified procedure should be provided for;

(3) Whereas food additives, flavourings for use in foodstuffs and extraction solvents are covered by other Community legislation and should therefore be excluded from the scope of this Regulation;

(4) Whereas appropriate arrangements should be made for the placing on the market of novel foods and novel food ingredients derived from plant varieties subject to Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species (4) and Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed (5);

(5) Whereas risks to the environment may be associated with novel foods or novel food ingredients which contain or consist of genetically modified organisms; whereas Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (6) stipulates that, for such products, an environmental risk assessment must always be undertaken to ensure environmental safety; whereas, in order to establish a unified Community system for assessment of such products, provision must be made under this Regulation for a specific environmental risk assessment, which in accordance with the procedure provided for in Article 10 of Directive 90/220/EEC must be similar to that laid down in that Directive, but must also include the assessment of the suitability of the product to be used as a food or food ingredient;

(6) Whereas the Scientific Committee for Food set up by Decision 74/234/EEC (7) should be consulted on any question relating to this Regulation which may have an effect on public health;

(7) Whereas Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (8) and Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (9) apply to novel foods or food ingredients;

(8) Whereas, without prejudice to the other requirements in Community legislation relating to the labelling of foodstuffs, additional specific requirements on labelling should be laid down; whereas these requirements must be subject to precise provisions in order to ensure that the necessary information is available to the consumer; whereas defined population groups associated with well established practices regarding food should be informed when the presence in a novel food of material which is not present in the existing equivalent foodstuff gives rise to ethical concerns as regards those groups; whereas foods and food ingredients which contain genetically modified organisms and which are placed on the market must be safe for human health; whereas this assurance is provided for through compliance with the authorization procedure contained in Directive 90/220/EEC and/or by the single assessment procedure laid down in this Regulation; whereas insofar as an organism is defined by Community law, with respect to labelling, information to the consumer on the presence of an organism which has been genetically modified constitutes an additional requirement applicable to the foods and food ingredients referred to in this Regulation;

(9) Whereas, in respect of foods and food ingredients which are intended to be placed on the market to be supplied to the final consumer, and which may contain both genetically modified and conventional produce, and without prejudice to the other labelling requirements of this Regulation, information for the consumer on the possibility that genetically modified organisms may be present in the foods and food ingredients concerned is deemed - by way of exception, in particular as regards bulk consignments - to fulfil the requirements of Article 8;

(10) Whereas nothing shall prevent a supplier from informing the consumer on the labelling of a food or food ingredient that the product in question is not a novel food within the meaning of this Regulation or that the techniques used to obtain novel foods indicated in Article 1 (2) were not used in the production of that food or food ingredient;

(11) Whereas, under 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 Decision 69/414/EEC (10);

(12) Whereas a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was concluded on 20 December 1994 (11),

HAVE ADOPTED THIS REGULATION:

Article 1

1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

3. Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls within the scope of paragraph 2 of this Article.

Article 2

1. This Regulation shall not apply to:

(a) food additives falling within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (12);

(b) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (13);

(c) extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (14).

2. The exclusions from the scope of this Regulation referred to in paragraph 1, indents (a) to (c) shall only apply for so long as the safety levels laid down in Directives 89/107/EEC, 88/388/EEC and 88/344/EEC correspond to the safety level of this Regulation.

3. With due regard for Article 11 the Commission shall ensure that the safety levels laid down in the above Directives, as well as in the implementing measures for these Directives and this Regulation, correspond to the safety level of this Regulation.

Article 3

1. Foods and food ingredients falling within the scope of this Regulation 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.

2. For the purpose of placing the foods and food ingredients falling within the scope of this Regulation on the market within the Community, the procedures laid down in Articles 4, 6, 7 and 8 shall apply on the basis of the criteria defined in paragraph 1 of this Article and the other relevant factors referred to in those Articles.

However, in the case of foods or food ingredients referred to in this Regulation derived from plant varieties subject to Directives 70/457/EEC and 70/458/EEC, the authorization decision referred to in Article 7 of this Regulation shall be taken in accordance with the procedures provided for in those Directives, provided they take account of the assessment principles laid down in this Regulation and the criteria set out in paragraph 1 of this Article, with the exception of the provisions relating to the

labelling of such foods or food ingredients, which shall be established, pursuant to Article 8, in accordance with the procedure laid down in Article 13.

3. Paragraph 2 shall not apply to the foods and food ingredients referred to in Article 1 (2) (b) where the genetically modified organism used in the production of the food or food ingredient has been placed on the market in accordance with this Regulation.

4. By way of derogation from paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1 (2) (b), (d) and (e) which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4 (3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls under this paragraph.

Article 4

1. The person responsible for placing on the Community market (hereinafter 'the applicant`) shall submit a request to the Member State in which the product is to be placed on the market for the first time. At the same time, he shall forward a copy of the request to the Commission.

2. An initial assessment as provided for in Article 6 shall be carried out.

Following the procedure referred to in Article 6 (4), the Member State referred to in paragraph 1 shall inform the applicant without delay:

- that he may place the food or food ingredient on the market, where the additional assessment referred to in Article 6 (3) is not required, and that no reasoned objection has been presented in accordance with Article 6 (4), or

- that, in accordance with Article 7, an authorization decision is required.

3. Each Member State shall notify to the Commission the name and address of the food assessment bodies responsible in its territory for preparing the initial assessment reports referred to in Article 6 (2).

4. Before the date of entry into force of this Regulation, the Commission shall publish recommendations concerning the scientific aspects of:

- the information necessary to support an application and the presentation of such information,

- the preparation of the initial assessment reports provided for in Article 6.

5. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 5

In the case of the foods or food ingredients referred to in Article 3 (4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the relevant details provided for in Article 3 (4). The Commission shall forward to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the 'C` series of the Official Journal of the European Communities.

With respect to labelling, the provisions of Article 8 shall apply.

Article 6

1. The request referred to in Article 4 (1) shall contain the necessary information, including a copy of the studies which have been carried out and any other material which is available to demonstrate that the food or food ingredient complies with the criteria laid down in Article 3 (1), as well as an appropriate proposal for the presentation and labelling, in accordance with the requirements of Article 8, of the food or food ingredient. In addition, the request shall be accompanied by a summary of the dossier.

2. Upon receipt of the request, the Member State referred to in Article 4 (1) shall ensure that an initial assessment is carried out. To that end, it shall notify the Commission of the name of the competent food assessment body responsible for preparing the initial assessment report, or ask the Commission to arrange with another Member State for one of the competent food assessment bodies referred to in Article 4 (3) to prepare such a report.

The Commission shall forward to the Member States without delay a copy of the summary provided by the applicant and the name of the competent body responsible for carrying out the initial assessment.

3. The initial assessment report shall be drawn up within a period of three months from receipt of a request meeting the conditions laid down in paragraph 1, in accordance with the recommendations referred to in Article 4 (4), and shall decide whether or not the food or food ingredient requires additional assessment in accordance with Article 7.

4. The Member State concerned shall without delay forward the report of the competent food assessment body to the Commission, which shall forward it to the other Member States. Within a period of 60 days from the date of circulation of the report by the Commission, a Member State or the Commission may make comments or present a reasoned objection to the marketing of the food or food ingredient concerned. The comments or objections may also concern the presentation or labelling of the food or food ingredient.

Comments or objections shall be forwarded to the Commission, which shall circulate them to Member States within the period of 60 days referred to in the first subparagraph.

The applicant shall, where a Member State so requests, provide a copy of any pertinent information appearing in the request.

Article 7

1. Where an additional assessment is required in accordance with Article 6 (3) or an objection is raised in accordance with Article 6 (4), an authorization decision shall be taken in accordance with the procedure laid down in Article 13.

2. The decision shall define the scope of the authorization and shall establish, where appropriate:

- the conditions of use of the food or food ingredient,

- the designation of the food or food ingredient, and its specification,

- specific labelling requirements as referred to in Article 8.

3. The Commission shall without delay inform the applicant of the decision taken. Decisions shall be published in the Official Journal of the European Communities.

Article 8

1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:

(a) any characteristic or food property such as:

- composition,

- nutritional value or nutritional effects,

- intended use of the food,

which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient.

A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.

In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained;

(b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

(c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;

(d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex I A, Part 1 of Directive 90/220/EEC.

2. In the absence of an existing equivalent food or food ingredient, appropriate provisions shall be adopted where necessary in order to ensure that consumers are adequately informed of the nature of the food or food ingredient.

3. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 9

1. Where a 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 Directive 90/220/EEC, the information required in the request for placing on the market referred to in Article 6 (1) shall be accompanied by:

- a copy of the written consent, if any, 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 relevant information requested in Article 11 of Directive 90/220/EEC and the environmental risk assessment based on this information, the results of any studies carried out for the purposes of research and development or, where appropriate, the decision authorizing the placing on the market provided for in part C of Directive 90/220/EEC.

Articles 11 to 18 of Directive 90/220/EEC shall not apply to foods or food ingredients which contain or consist of genetically modified organisms.

2. In the case of foods or food ingredients falling within the scope of this Regulation containing or consisting of genetically modified organisms, the decision referred to in Article 7 shall respect the environmental safety requirements laid down by Directive 90/220/EEC to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the

Commission or the Member States with the bodies set up by the Community or the Member States in accordance with Directive 90/220/EEC.

Article 10

Detailed rules for the protection of the information provided by the applicant shall be adopted in accordance with the procedure laid down in Article 13.

Article 11

The Scientific Committee for Food shall be consulted on any matter falling within the scope of this Regulation likely to have an effect on public health.

Article 12

1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in 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, giving the grounds for its decision.

2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.

Article 13

1. Where the procedure defined in this Article is to be implemented, the Commission shall be assisted by the Standing Committee for Foodstuffs, hereinafter referred to as the 'Committee`.

2. Matters shall be referred to the Committee by the Chairman either on his own initiative or at the request of the representative of a Member State.

3. The representative of the Commission shall submit to the Committee a draft of the 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 majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14

1. No later than five years from the date of entry into force of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation accompanied, where appropriate, by any suitable proposal.

2. Notwithstanding the review provided for in paragraph 1, the Commission shall monitor the application of this Regulation and its impact on health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 15

This Regulation shall enter into force 90 days following its publication in the Official Journal of the European Communities.

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

Done at Brussels, 27 January 1997.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

G. ZALM

(1) OJ No C 190, 29. 7. 1992, p. 3

and OJ No C 16, 19. 1. 1994, p. 10.

(2) OJ No C 108, 19. 4. 1993, p. 8.

(3) Opinion of the European Parliament of 27 October 1993 (OJ No C 315, 22. 11. 1993, p. 139). Council Common Position of 23 October 1995 (OJ No C 320, 30. 11. 1995, p. 1) and Decision of the European Parliament of 12 March 1996 (OJ No C 96, 1. 4. 1996, p. 26). Decision of the Council of 19 December 1996 and Decision of the European Parliament of 16 January 1997.

(4) OJ No L 225, 12. 10. 1970, p. 1. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

(5) OJ No L 225, 12. 10. 1970, p. 7. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

(6) OJ No L 117, 8. 5. 1990, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).

(7) OJ No L 136, 20. 5. 1974, p. 1.

(8) OJ No L 186, 30. 6. 1989, p. 23. Directive as last amended by Directive 93/99/EEC (OJ No L 290, 24. 11. 1993, p. 14).

(9) OJ No L 290, 24. 11. 1993, p. 14.

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

(11) OJ No C 102, 4. 4. 1996, p. 1.

(12) OJ No L 40, 11. 2. 1989, p. 27. Directive as last amended by Directive 94/34/EC (OJ No L 237, 10. 9. 1994, p. 1).

(13) OJ No L 184, 15. 7. 1988, p. 61. Directive as last amended by Directive 91/71/EEC (OJ No L 42, 15. 2. 1991, p. 25).

(14) OJ No L 157, 24. 6. 1988, p. 28. Directive as last amended by Directive 92/115/EEC (OJ No L 409, 31. 12. 1992, p. 31).

COMMISSION STATEMENT - AD ARTICLE 2

The Commission confirms that should it appear, in the light of experience, that there are gaps in the system of protection of public health provided for by the existing legal framework, in particular in respect of processing aids, it will formulate appropriate proposals in order to fill those gaps.