

EUROPEAN PARLIAMENT

2004



2009

Committee on the Environment, Public Health and Food Safety

2008/0002(COD)

26.6.2008

*****I**

DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure]
(COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Kartika Tamara Liotard

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	33

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure] (COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0872),
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0027/2008),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Agriculture and Rural Development (A6-0000/2008),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Amendment 1

Proposal for a regulation – amending act
Recital 1

Text proposed by the Commission

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as to their social and economic interests. Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of novel foods may hinder their free movement, thereby creating unfair

Amendment

(1) In implementing Community policy and having regard to the Treaty establishing the European Community, a high level of protection of human health and consumer protection should be guaranteed and also a high level of animal welfare and environmental protection. At all times, moreover, the precautionary principle as referred in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the

competition conditions.

general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹ should be applied.

¹ OJ L 31, 1.2.2002, p. 1.

Or. nl

Justification

The emphasis should be on food safety and consumer protection. Account should also be taken of protection of animal health and the environment. Lastly, the precautionary principle is of the utmost importance.

Amendment 2

**Proposal for a regulation – amending act
Recital 2**

Text proposed by the Commission

(2) A high level of human health protection should be assured in the pursuit of Community policies.

Amendment

(2) This regulation guarantees a high level of human health and also protects the social and economic interests of consumers. At the same time, differences between national provisions relating to assessment of the safety of novel foods and their authorisation may not only constitute an obstacle to the free movement of these products, thus giving rise to unfair competition, but may also create a risk to the health and wellbeing of the public.

Or. nl

Justification

The emphasis should be on food safety and consumer protection. Harmonisation of national provisions is necessary in order to ensure that differences in regulation do not adversely affect the health and wellbeing of the public.

Amendment 3

Proposal for a regulation – amending act Recital 6

Text proposed by the Commission

(6) It should also be clarified that a food should be considered as novel when it is applied a production technology which was not previously used. ***In particular, emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from plants and animals, produced by non-traditional breeding techniques, and foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.***

Amendment

(6) It should also be clarified that a food should be considered as novel when it is applied a production technology which was not previously used. ***It must be clear that if a food is changed by a new production process, such as nanotechnology and nanoscience - about which not enough is yet known to carry out a risk assessment - the food must only be placed on the market if it has been assessed as safe by means of a valid risk assessment.***

Or. nl

Justification

This regulation should make it clear when a food is to be regarded as novel.

Amendment 4

Proposal for a regulation – amending act Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) Cloning of animals is incompatible with Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes¹, Annex, point 20. Point 20 states that natural or artificial breeding procedures which cause or are likely to cause

suffering or injury to any of the animals concerned must not be practised. Food from cloned animals or their descendants must therefore not be placed on the Community list.

¹ OJ L 221, 8.8.1998, p. 23

Or. nl

Justification

A wide range of scientific research and the Opinion of the European Group on Ethics show that cloning leads to serious health and welfare problems for both the cloned animals and their surrogate mothers. Cloned foetuses are often larger than normal; this leads to difficult births and to many deliveries being by caesarean section. Many clones die during pregnancy or in the early weeks of life from immune deficiencies, cardiovascular failure, respiratory problems and kidney abnormalities.

The animal health and welfare problems caused by cloning mean that this process is incompatible with paragraph 20 of the Annex to Council Directive 98/58/EC.

Amendment 5

Proposal for a regulation – amending act Recital 7

Text proposed by the Commission

(7) ***If necessary***, implementing measures should be adopted to provide for criteria in order to facilitate the assessment of whether a food has been used for human consumption ***to a significant degree*** within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior that date, it can be placed on the market after that date for the same use without being considered as a novel food. ***However, that use as or in a food supplement should not be taken into account for the assessment whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other***

Amendment

(7) Implementing measures should be adopted to provide for criteria in order to facilitate the assessment of whether a food has been used for human consumption within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior that date, it can be placed on the market after that date for the same use without being considered as a novel food.

than food supplement uses, have to be authorised in accordance with this Regulation.

Or. nl

Justification

Clarification and simplification of the Commission proposal.

Amendment 6

**Proposal for a regulation – amending act
Recital 13**

Text proposed by the Commission

(13) Whether a food was used for human consumption to a significant degree before 15 May 1997, should be based on information available in the Member States. Where the Commission does not have information on human consumption before 15 May 1997, a simple and transparent procedure for collecting that information should be established involving the Member States and any interested parties.

Amendment

(13) The Commission should establish a simple and transparent procedure for cases in which it does not have information on human consumption before 15 May 1997; the Member States should be involved in this procedure. The procedure should be adopted no later than six months after the entry into force of this Regulation.

Or. nl

Justification

Clarification and simplification of the Commission proposal. It must be clear what responsibilities are being assigned to the Commission when this Regulation enters into force.

Amendment 7

**Proposal for a regulation – amending act
Recital 15**

Text proposed by the Commission

(15) It is necessary to apply a harmonised centralised procedure for safety

Amendment

(15) It is necessary to apply a procedure for safety assessment and authorisation that is

assessment and authorisation that is efficient, time-limited and transparent. ***With a view to further harmonising different authorisation procedures of food***, the safety assessment of novel foods and their inclusion in the Community list should be carried out in accordance with the procedure laid down in ***Regulation (EC) No [..] of the European Parliament and of the Council of [date] establishing a common authorisation procedure for the food additives, food enzymes and flavourings***.

efficient, time-limited and transparent. The safety assessment of novel foods and their inclusion in the Community list should be carried out in accordance with the procedure laid down in ***this Regulation***.

Or. nl

Justification

The European Parliament has not yet taken a democratic decision on the uniform authorisation procedure.

Amendment 8

Proposal for a regulation – amending act Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) Ethical and environmental aspects must be considered as part of the risk assessment during the authorisation procedure. These aspects should be assessed by the European Group on Ethics in Science and New Technologies and the European Environment Agency respectively.

Or. nl

Justification

Apart from the aspects of protection of health, the interests of consumers and animal health, the risk assessment should also include consideration of ethical and environmental aspects.

Amendment 9

Proposal for a regulation – amending act Recital 17

Text proposed by the Commission

(17) In order to simplify procedures, applicants should be allowed to present a single application for foods regulated under different sectoral food laws. **Regulation EC No [common procedure] should therefore be amended accordingly.**

Amendment

(17) In order to simplify procedures, applicants should be allowed to present a single application for foods regulated under different sectoral food laws. **The Commission should determine the sectoral food law under which the application falls.**

Or. nl

Justification

It should be made easier for manufacturers to submit applications, irrespective of which sectoral food law is applicable to the application.

Amendment 10

Proposal for a regulation – amending act Recital 18

Text proposed by the Commission

(18) **Where appropriate and based on** the conclusions of the safety assessment, post-market monitoring requirements for the use of novel foods **for human consumption** should be introduced.

Amendment

(18) **On the basis of** the conclusions of the safety assessment, **any** post-market monitoring requirements for the use of novel foods should be introduced.

Or. nl

Justification

Clarification and simplification of the Commission proposal.

Amendment 11

Proposal for a regulation – amending act Recital 20

Text proposed by the Commission

(20) ***Under specific circumstances*** in order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Community list ***should not be used to the benefit of another applicant during a limited period of time, without the agreement of the first applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Community list of novel foods on the basis of their own scientific data.***

Amendment

(20) In order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Community list ***may be treated as confidential in accordance with the provisions of this Regulation. At the same time the Commission should draw up guidelines as to how the transparency of the procedure relating to the confidentiality of new scientific evidence and proprietary data can be ensured for consumers.***

Or. nl

Justification

Where necessary, new scientific evidence and proprietary data which are provided in support of an application for inclusion of a novel food in the Community list should be treated as confidential.

Amendment 12

Proposal for a regulation – amending act Recital 21

Text proposed by the Commission

(21) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs. In certain cases it might be necessary to

Amendment

(21) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs. In certain cases it might be necessary to

provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore, the inclusion of a novel food in the Community list *may* impose specific conditions of use or labelling obligations.

provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore, the inclusion of a novel food in the Community list *will* impose specific conditions of use or labelling obligations *in those cases*.

Or. nl

Justification

Linguistic adjustment.

Amendment 13

Proposal for a regulation – amending act Recital 23

Text proposed by the Commission

(23) As regards the safety assessment and management of traditional food from third countries, their history of safe use in the third country of origin should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets. If Member States *and* the Authority have not presented any reasoned safety objections, based on scientific evidence, for example information on adverse health effects, it *should* be permissible to place the food on the Community market after notification of the intention to do so.

Amendment

(23) As regards the safety assessment and management of traditional food from third countries, their history of safe use in the third country of origin should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets. If Member States *and/or* the Authority have not presented any reasoned safety objections, based on scientific evidence, for example information on adverse health effects, it *will* be permissible to place the food on the Community market after notification of the intention to do so *provided that there are no ethical objections*.

Or. nl

Justification

It must be clear that Member States and/or the Authority can comment. Even if a product is safe, there may be ethical objections.

Amendment 14

Proposal for a regulation – amending act Recital 24

Text proposed by the Commission

(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 **may** be consulted, where appropriate, with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.

Amendment

(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 **will** be consulted, where appropriate, with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods. ***The Eurobarometer can be used, where necessary, to carry out an opinion poll concerning the ethical perception of novel foods by the European general public.***

Or. nl

Justification

Account should be taken of whether a society regards a novel food as inedible on ethical grounds.

Amendment 15

Proposal for a regulation – amending act Article 1 – paragraph 1

Text proposed by the Commission

1. This Regulation ***lays down harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring*** a high level of ***human health and consumers'*** protection, whilst ensuring the effective functioning of the internal market.

Amendment

1. This Regulation ***has the aim of creating a basis for guaranteeing*** a high level of protection ***of human life and health, animal health and welfare, the environment and the interests of consumers,*** whilst ensuring the effective functioning of the internal market.

Or. nl

Justification

A high level of protection of human health, the environment, animal welfare and the interests

of consumers have the highest priority.

Amendment 16

Proposal for a regulation – amending act Article 2 – paragraph 2 –point b a (new)

Text proposed by the Commission

Amendment

(ba) foods derive from cloned animals and their descendants. The Commission shall publish a report before the date of entry into force referred to in Article 20 assessing the situation with regard to cloned animals. The report shall be forwarded to the European Parliament and the Council, accompanied by a legislative proposal if necessary.

Or. nl

Justification

The decision as to whether or not to place foods from cloned animals and their descendants on the market must not be left to the committee procedure but should be taken by means of a specific regulation of the European Parliament and of the Council under codecision.

Amendment 17

Proposal for a regulation – amending act Article 2 – paragraph 3

Text proposed by the Commission

Amendment

3. Where necessary, it may be determined in accordance with the procedure referred to in **Article 14(2)** whether a type of food falls within the scope of this Regulation.

3. Where necessary, it may be determined in accordance with the procedure referred to in **Article 14(3)** whether a type of food falls within the scope of this Regulation.

Or. nl

Justification

The European Parliament must retain the right to decide to which foods this Regulation does and does not apply.

Amendment 18

Proposal for a regulation – amending act Article 3 – paragraph 2 – introductory part

Text proposed by the Commission

2. The following definitions shall **also** apply:

Amendment

2. The following definitions shall apply **to foods placed on the market in the Community from 15 May 1997:**

Or. nl

Justification

Clarification and simplification of the Commission proposal.

Amendment 19

Proposal for a regulation – amending act Article 3 – paragraph 2 – point a – point i

Text proposed by the Commission

(i) **food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;**

The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, which are designed to amend non-essential elements of this Regulation,

Amendment

(i) ***a food, including one or more micro-organisms, whose history of safe food use within the Community has not yet been ascertained;***

inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Or. nl

Justification

The emphasis should be on the safe use of foods placed on the market since 15 May 1997.

Amendment 20

**Proposal for a regulation – amending act
Article 3 – paragraph 2 – point a – point ii**

Text proposed by the Commission

(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique ***not used before 15 May 1997; and***

Amendment

(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique, ***with the exception of foods derived from cloned animals and their descendants;***

Or. nl

Justification

The decision as to whether or not to place foods from cloned animals and their descendants on the market must not be left to the comitology procedure but should be taken by means of a specific regulation of the European Parliament and of the Council under codecision.

Amendment 21

**Proposal for a regulation – amending act
Article 3 – paragraph 2 – point a – point iii**

Text proposed by the Commission

(iii) food to which is applied a new production process, ***not used before 15 May 1997***, where that production process gives rise to ***significant*** changes in the composition or structure of the food which affect its nutritional value,

Amendment

(iii) food to which is applied a new production process - ***including, but not confined to, foods produced with the aid of nanotechnology*** - where that production process gives rise to changes in the composition or structure of the food which

metabolism or level of undesirable substances.

affect its nutritional value, metabolism or level of undesirable substances.

Or. nl

Justification

In order to be regarded as a novel food, it is sufficient that a novel production process should affect the nutritional value, the metabolism or the undesirable substance content.

Amendment 22

**Proposal for a regulation – amending act
Article 3 – paragraph 2 – point b**

Text proposed by the Commission

(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least **one generation** in a large part of the population of the country;

Amendment

(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least **50 years** in a large part of the population of the country;

Or. nl

Justification

Clarification of the definitions.

Amendment 23

**Proposal for a regulation – amending act
Article 3 – paragraph 2 – point c**

Text proposed by the Commission

(c) "history of safe food use" means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use in the normal diet of a large part of the population **of a country**.

Amendment

(c) "history of safe food use" means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use in the normal diet of a large part of the population.

Justification

Clarification of the definitions.

Amendment 24

**Proposal for a regulation – amending act
Article 3 – paragraph 2 – point c a (new)**

Text proposed by the Commission

Amendment

(ca) “cloned animals”: animals produced by means of an asexual, artificial method of reproduction with the aim of producing a genetically identically or nearly identical copy of an individual animal;

Or. nl

Justification

Clarification of the definitions.

Amendment 25

**Proposal for a regulation – amending act
Article 3 – paragraph 2 – point c b (new)**

Text proposed by the Commission

Amendment

(cb) “descendants of cloned animals”: animals produced by means of sexual reproduction, in cases in which at least one of the parents is a cloned animal;

Or. nl

Justification

Clarification of the definitions.

Amendment 26

Proposal for a regulation – amending act Article 3 – paragraph 2 – point c c (new)

Text proposed by the Commission

Amendment

(cc) “produced with the aid of nanotechnology”: a product which contains, consists of or is produced with the aid of synthetic substances not larger than 100 nm in length, breadth or height.

Or. nl

Justification

Clarification of the definitions.

Amendment 27

Proposal for a regulation – amending act Article 4 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission ***may*** collect information from the Member States and/or from food business operators to determine to what extent a food ***has been used for human consumption within the Community before 15 May 1997.***

1. The Commission ***shall*** collect information from the Member States and/or from food business operators to determine to what extent a food ***falls within the scope of this Regulation.***

Or. nl

Justification

Clarification and simplification of the Commission proposal. It must be clear what responsibilities are being assigned to the Commission upon the entry into force of this Regulation.

Amendment 28

Proposal for a regulation – amending act Article 4 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In cases in which the Commission has no information about use for human consumption before 15 May 1997, it shall decide a procedure not later than six months after the entry into force of this Regulation.

Or. nl

Amendment 29

Proposal for a regulation – amending act Article 5 – paragraph 1

Text proposed by the Commission

Amendment

Only novel foods included in the Community list of novel foods (hereinafter "the Community list") may be placed on the market.

1. Only novel foods included in the Community list of novel foods (hereinafter "the Community list") may be placed on the market. The Commission shall keep and publish the Community list on a publicly accessible page intended for the purpose on the website of the Commission.

Or. nl

Justification

The provision of information to consumers, manufacturers and other interested parties is a priority.

Amendment 30

Proposal for a regulation – amending act Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Foods from cloned animals or their descendants shall not be placed on the Community list.

Or. nl

Justification

The decision as to whether or not to place foods from cloned animals and their descendants on the market must not be left to the committee procedure but should be taken by means of a specific regulation of the European Parliament and of the Council under codecision.

Amendment 31

Proposal for a regulation – amending act Article 6 – point a

Text proposed by the Commission

Amendment

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer under normal consumption conditions;

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer ***and of animals*** under normal consumption conditions;

Or. nl

Justification

Animal health is also relevant here.

Amendment 32

Proposal for a regulation – amending act Article 6 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the opinion of the European Environment Agency concerning the extent to which the production process and normal consumption have a harmful impact on the environment shall be taken into account in the assessment;

Or. nl

Justification

It is important also to take account of environmental aspects as part of the conditions for inclusion in the Community list.

Amendment 33

Proposal for a regulation – amending act Article 6 – point c b (new)

Text proposed by the Commission

Amendment

(cb) the opinion of the European Group on Ethics in Science and New Technologies concerning the extent to which there are ethical objections shall be taken into account in the assessment.

Or. nl

Justification

It is important also to take account of ethical aspects as part of the conditions for inclusion in the Community list.

Amendment 34

Proposal for a regulation – amending act Article 7 – paragraph 1

Text proposed by the Commission

1. The Community list shall be updated in accordance with the procedure laid down in **Regulation (EC) No [common procedure]**.

Amendment

1. The Community list shall be updated in accordance with the procedure laid down in **this Regulation**.

Or. nl

Justification

As no democratic decision has yet been taken on the uniform authorisation procedure, it is not clear whether this procedure is ultimately the most appropriate procedure for novel foods.

Amendment 35

Proposal for a regulation – amending act Article 7 – paragraph 3

Text proposed by the Commission

3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure referred to in Article 14(2) in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.

Amendment

deleted

Or. nl

Justification

As Article 12 of the Commission proposal is being amended, Article 7(3) of the Commission proposal must be deleted.

Amendment 36

Proposal for a regulation – amending act Article 7 – paragraph 4

Text proposed by the Commission

Amendment

4. Before the expiry of the period referred to in Article 12, the Community list shall be updated to amend non-essential elements of this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 14(3) laid down in Regulation (EC) No [common procedure] so that, provided that the authorised food still meets the condition laid down in this Regulation, the specific indications referred to in paragraph 3, second subparagraph of this Article, are no longer included. *deleted*

Or. nl

Justification

As Article 12 of the Commission proposal is being amended, Article 7(4) of the Commission proposal must be deleted.

Amendment 37

Proposal for a regulation – amending act Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7 a

Authorisation procedure

- 1. The applicant shall supply the following particulars to the Commission:**
 - (a) the name and address of the applicant;**
 - (b) the designation of the food, and its specification, including the production process used;**

(c) particulars concerning the physical and chemical properties of the novel food or the novel food ingredient;

(d) particulars of the impurity profile for a normal preparation;

(e) a specification of the identity and purity of a novel food ingredient;

(f) a detailed description of the production method and the manufacture;

(g) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 6;

(h) an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics;

(i) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

(j) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;

(k) a summary of the dossier in a standardised form.

2. The Commission shall forward the application to the authority within 14 days of receiving it. The authority shall deliver an opinion to the Commission within nine months of receiving the application.

3. The Commission shall ultimately determine whether a food is included in the Community list. The procedure for updating the Community list shall be determined by means of the procedure referred to in Article 14(2).

Justification

As no democratic decision has yet been taken on the uniform authorisation procedure, it is not clear whether this procedure is ultimately the most appropriate procedure for novel foods. The proposed procedure is closely modelled on the procedure provided for in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, which was carefully drafted with a view to consumer protection and environmental protection, and also closely resembles the most recently devised specific procedure for novel foods.

Amendment 38**Proposal for a regulation – amending act
Article 8 – paragraph 3 - subparagraph 2***Text proposed by the Commission*

In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. ***The notification as referred to in paragraph 1 shall be considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common procedure].***

Amendment

In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply.

Justification

This article is amended in accordance with Article 7a.

Amendment 39**Proposal for a regulation – amending act
Article 9***Text proposed by the Commission*

The Commission shall, where appropriate, in close cooperation with the Authority, make available technical guidance and tools to assist food business operators and especially small and medium-sized

Amendment

The Commission shall, where appropriate, in close cooperation with the Authority, make available technical guidance and tools to assist food business operators and especially small and medium-sized

enterprises in preparing and submitting applications under this Regulation.

enterprises in preparing and submitting applications under this Regulation. ***The technical guidance and tools shall be published, not more than six months after the date of entry into force of this Regulation, on a publicly accessible page intended for the purpose on the website of the Commission.***

Or. nl

Justification

SMEs should receive assistance and support from the Commission in preparing and submitting applications under this Regulation.

Amendment 40

Proposal for a regulation – amending act Article 10

Text proposed by the Commission

In assessing the safety of novel foods, the Authority shall:

- (a) compare, where appropriate, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;
- (b) take into account for traditional food from a third country, the history of safe food use.

Amendment

In assessing the safety of novel foods, the Authority shall:

- (a) compare, where appropriate, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;
- (b) take into account:
 - (i) for traditional food from a third country, the history of safe food use;***
 - (ii) the composition of the novel food, particularly the levels of anti-nutrients and naturally occurring toxins;***
 - (iii) the method of preparation and specifications of a novel food ingredient;***
 - (iv) the potential for allergenicity of the novel food;***

(v) metabolism/toxicokinetic studies on the novel food ingredient;

(vi) animal toxicity studies on the novel food ingredient;

(vii) human toleration studies on the novel food ingredient.

Or. xm

Justification

When assessing the safety of novel foods, the authority should also consider such aspects as the composition, allergenicity and toxicity of novel foods.

Amendment 41

Proposal for a regulation – amending act Article 12 – title

Text proposed by the Commission

Amendment

Data protection

Confidential data

Or. nl

Amendment 42

Proposal for a regulation – amending act Article 12

Text proposed by the Commission

Amendment

*On request by the applicant, supported by appropriate and verifiable information included in the application dossier, **newly developed scientific evidence and proprietary scientific data provided to support the applications, may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant.***

1. On request by the applicant, supported by appropriate and verifiable information included in the application dossier, **details of manufacture may be treated as confidential. In this case a verifiable justification shall be provided.**

2. The Commission shall determine after consultation with the applicant what details of manufacture are to be treated as confidential.

3. After receiving the opinion of the authority, the Commission shall publish the following particulars:

(a) the name and address of the applicant;

(b) description allowing the identification of the food or food ingredient;

(c) intended use of the food or food ingredient;

(d) summary of the dossier, except for those parts which are of a confidential character;

(e) the date of receipt of a complete application.

Or. nl

Justification

Measures must be included in this Regulation which currently form part of Regulation (EC) No 1852/2001, which will lapse when this Regulation enters into force.

Amendment 43

Proposal for a regulation – amending act Article 19

Text proposed by the Commission

Amendment

*Amendments to Regulation (EC) No
[common procedure]*

deleted

*Regulation (EC) No [common procedure]
is amended as follows:*

(1) The title is replaced by the following:

*"Regulation (EC) No XXX/XXXX of the
European Parliament and of the Council
of [date] establishing a common
authorisation procedure for food
additives, food enzymes, food flavourings*

and novel foods"

(2) In Article 1, paragraph 1, first subparagraph is replaced by the following:

"1. This Regulation lays down a common assessment and authorisation procedure (hereinafter referred to as the "common procedure") for food additives, food enzymes, food flavourings and sources of food flavourings used or intended for use in or on foodstuffs and novel foods (hereinafter referred to as the "substances or products"), which contributes to the free movement of foods within the Community and to a high level of protection of human health and protection of consumers' interests."

(3) In Article 1, paragraph 2 is replaced by the following:

"2. The common procedure shall set the procedural arrangements for updating the lists of substances and products the marketing of which is authorised in the Community pursuant to Regulation (EC) No AAA/2007, Regulation (EC) No BBB/2007, Regulation (EC) No CCC/2007, Regulation (EC) No DDD/DDDD (hereinafter referred to as the "sectoral food laws")."

(4) In Article 1 paragraph 3, Article 2 paragraphs 1 and 2, Article 9 paragraph 2, Article 12 paragraph 1 and Article 13 the word 'substance' or 'substances' is replaced by 'substance or product' or 'substances or products'.

(5) The title of Article 2 is replaced by the following:

"Community list of substances or products"

(6) In Article 4 the following paragraph 3 is added:

"3. A single application relating to a substance or product may be made to update the different Community lists regulated under the different sectoral food

laws in so far as the application complies with the requirements of each of the sectoral food laws."

(7) The following sentence is added at the beginning of Article 6, paragraph 1:

"In the case of scientific grounds for safety concerns, additional information concerning risk assessment, shall be identified and requested from the applicant."

Or. nl

Justification

Article 19 of the Commission proposal is deleted in accordance with Article 7a.

EXPLANATORY STATEMENT

The purpose of the Commission proposal is to amend Regulation (EC) No 258/97 on novel foods, with the aim of simplifying and centralising the procedures for authorising novel foods and placing them on the market. Thus it has been decided that new regulation is necessary. The rapporteur considers that if it is decided to adopt regulations, it must be very clear what their purpose is.

In the rapporteur's view, the objectives of the new regulation on novel foods are to attain a high level of food safety, consumer protection, environmental protection and protection of animal health while at all times the precautionary principle as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹ must be observed. All other objectives are of secondary importance.

Novel foods must not endanger or mislead consumers, either. Where novel foods serve to replace another food, the novel foods must not be nutritionally inferior from the consumer's point of view.

The Commission proposal seeks to clarify the definition of novel foods and the associated definitions. The rapporteur endorses this aim, but considers that the Commission has negligently fallen short in achieving it. Its proposal did not include clear definitions, and the rapporteur has therefore clarified the existing definitions and where necessary supplemented them with new ones. These include, for example, a definition of foods derived from cloned animals and foods produced using nanotechnology.

The rapporteur considers it very important that foods derived from cloned animals should be excluded from the scope of the Regulation on novel foods. As no democratic agreement has yet been reached on the desirability of these foods, particularly from the point of view of animal health and welfare, the decision as to whether or not to place on the market foods derived from cloned animals and their descendants cannot be left to the committee procedure. It must be resolved by means of a specific regulation of the European Parliament and of the Council under the codecision procedure. Lastly, account must also be taken of whether a society regards a novel food as inedible on ethical grounds.

All applications for authorisation of novel foods will be submitted to the Commission and must comply with the criteria laid down in this Regulation; they will then be forwarded for consideration to the European Food Safety Authority (EFSA), which will assess the foods' safety. This assessment must also take account of ethical and environmental aspects. Consequently the opinions of the European Group on Ethics in Science and New Technologies and the European Environment Agency must be involved in the safety assessment. At present, the Commission is promising consumers and citizens that it will take responsibility for environmental and animal welfare aspects, inter alia in view of the problems

¹ OJ L 31, 1.2.2002, pp. 1-24.

of climate change and animal welfare, and European policy must therefore be comprehensive and sound with reference to all relevant fields of legislation and therefore also to the Regulation on novel foods.

The Commission proposal seeks to make the authorisation procedure more effective and transparent and to implement it better. This will contribute to better implementation of the Regulation and give consumers greater power and more options because they will have more information at their disposal. Here too, the Commission has got ahead of itself by taking the view that the Regulation on novel foods should be governed, inter alia, by the Regulation establishing a common authorisation procedure for food additives, food enzymes and flavourings. The European Parliament and the Council have not yet taken a democratic decision on the uniform authorisation procedure. The rapporteur has therefore opted to propose an authorisation procedure based on the procedure laid down in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed¹, which was carefully drafted with a view to consumer protection and environmental protection, and also the most recently devised specific procedure for novel foods.

For traditional foods from third countries, the Commission proposes a simpler authorisation procedure, under which safety would be assessed in the light of the history of safe use in the country of origin. It is important that it should be precisely established what period of safe use of such traditional foods from third countries is long enough to guarantee the safety of the product, and the rapporteur proposes a period of 50 years for this, rather than the 'one generation' proposed by the Commission, which is difficult to define.

The Commission proposal aims to achieve a certain level of data protection for a five-year period for applications under this Regulation. This surprises the rapporteur, as the Commission adduced a completely different line of argument during the consideration of the uniform authorisation procedure in the European Parliament. The Commission claimed there that a data protection system would result in an increase in regulation and would render monitoring systems and administrative procedures more complex. In addition, a data protection system would constitute an obstacle to free movement of goods which are safe and meet the criteria of the relevant legislation, which is contrary to the purposes of a measure adopted under Article 95 of the EC Treaty.

This inconsistency in the Commission's legislative proposals is highly unsatisfactory. The rapporteur therefore proposes retaining the system of confidentiality of manufacturing data laid down in Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97².

The Commission proposal envisages Member States being required to impose penalties on those who violate the provisions of the regulation on novel foods. The rapporteur strongly emphasises that the criminal law is always a matter for Member States. It is highly desirable

¹ OJ L 268, 18.10.2003, pp. 1-23.

² OJ L 253, 21.9.2001, pp. 17-18.

that Member States should be able to decide freely whether a penalty is to be imposed under the criminal law or whether it should be administrative or of some other nature. So long as a Member State takes adequate action against violations of the Regulation on novel foods, it will be fulfilling its obligations under Community law.

The rapporteur supports all measures to lessen administrative burdens and improve transparency and efficiency. However, they must never be allowed to detract from the overriding aim of the Regulation on novel foods, namely food safety and consumer protection.