



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 2 March 2010

**Interinstitutional File:
2008/0002 (COD)**

**11261/09
ADD 1 REV 1**

**DENLEG 51
CODEC 893**

DRAFT STATEMENT OF THE COUNCIL'S REASONS

Subject : Council position at first reading with a view to adopting a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001

DRAFT STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 15 January 2008, the Commission submitted a proposal¹ for a Regulation on novel foods and amending Regulation (EC) No 1331/2008 of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. The proposal was based on Article 95 of the Treaty establishing the European Community.

Acting in accordance with Article 251 of the Treaty establishing the European Community, the European Parliament adopted its first reading Opinion on 25 March 2009².

The Economic and Social Committee adopted its opinion on 29 May 2008³.

In accordance with Article 294(5) of the Treaty on the Functioning of the European Union (TFEU), the Council adopted its position at first reading by unanimity on

II. OBJECTIVE OF THE PROPOSED REGULATION

The Commission announced already in the White Paper on Food Safety adopted on 12 January 2000⁴ its intentions to examine the application of the novel food legislation and to make the necessary adaptations to the existing Regulation (EC) No 258/97 on novel foods and novel food ingredients.

The proposal aims at updating and clarifying the regulatory framework for authorisation and placing on the market of novel foods while ensuring food safety, protection of human health and consumer interests and the effective functioning of the internal market. It repeals the current Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

¹ 5431/08.

² 7990/09.

³ OJ C 224, 30.8.2008, p. 81.

⁴ 5761/00, COM (1999)719 final

The proposal keeps the date of 15 May 1997 as the threshold date for determination of the novelty of the food and clarifies that the novel food definitions include foods to which new technologies are applied or foods originating from plants or animals to which non-traditional breeding techniques are applied.

The Commission proposed that the placing on the market of novel foods would be subject to a centralised procedure at the Community level in accordance with Regulation (EC) No 1331/2008 establishing the common authorisation procedure that would replace the current system of risk assessment by national authorities. The risk assessment would be carried out by the European Food Safety Authority (EFSA). The inclusion of a novel food in the Community list of novel foods would be considered by the Commission on the basis of the opinion from EFSA. The Commission would be assisted by the Standing Committee on the Food Chain and Animal Health (SCFCAH). The final decision to update the list of novel foods would be made by the Commission via the comitology with scrutiny procedure.

The applicant-linked authorisation would be replaced and the simplified procedure abolished by authorisation decisions addressed to the Community as a general rule. Protection of data could be granted in justified cases concerning newly developed scientific evidence and proprietary data in order to support innovation in the agri-food industry.

The proposal introduced a definition of "traditional food from a third country", as a category of novel food that should be subject to notification if no reasoned safety objections are presented by EFSA or Member States.

Already authorised novel foods would continue to be marketed and included in the Community list of novel foods.

III. ANALYSIS OF THE COUNCIL POSITION

1. Introductory remarks

The Council position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced several changes in the text, some of them inspired by the amendments proposed by the European Parliament.

The Commission has accepted all the changes introduced by the Council to its proposal, except the introduction of the definition of offspring of cloned animals in Article 3(2)(b) and the inclusion of offspring in Article 3(2)(a)(i).

2. The amendments of the European Parliament

In its plenary vote on 25 March 2009, the European Parliament adopted 76 amendments to the proposal⁵. The Council incorporated in its common position 30 amendments, of which 20 in full (amendments **7, 15, 16, 20, 35, 41, 42, 44, 45, 53, 63, 65, 67, 68, 69, 76, 77, 88, 89, 93**), 5 in part (amendments **1, 30, 40, 91, 92**) and 5 in principle (amendments **3, 6, 11, 25, 64**).

⁵ 7990/09 (P6_TA(2009)0171)

2.1. The main modifications introduced by the Council in the proposal, with reference to EP amendments ⁶

- a) Objectives of the Regulation (Article 1 and recitals 1 and 2) - the Council added the protection of the environment and animal welfare. This partly covers amendments **1** and **30** and reflects the spirit of amendment **3**.
- b) Scope (Article 2(2)(a)(v) and recitals 13 and 14) - the Council clarified that, pending the respective amendments to Regulation (EC) 1925/2006, Directive 2002/46/EC and Directive 89/398/EEC, those vitamins and minerals obtained from new sources or using a production process, which were not taken into account at the moment of their authorisation and which give rise to significant changes in the composition or structure of food which affect its nutritional value, metabolism or level of undesirable substances should be within the scope of the novel food Regulation. This is in line with the first part of amendment **91**.
- c) Definition of novel foods (Article 3 and recitals 6, 8, 10, 11) - the basic criterion for assessing the novelty of the food remains whether it has been used for human consumption to a significant degree within the Union before 15 May 1997. In order to provide legal clarity, the Council agreed that further criteria for assessing human consumption to a significant degree within the Union before 15 May 1997 must be developed before the date of application of the Regulation. The adoption of these criteria has been delegated to the Commission according to Article 290 TFEU. This was coupled with delaying the date of application until 24 months after the date of publication of the Regulation.

⁶ The numbering of recitals and Articles refers to the text of the Council position at first reading.

In order to ensure better clarity, the following changes of definition have been made:

- § a distinction has been made between food of animal and food of plant origin. Food of plant origin falls under the scope of this Regulation only if a non-traditional breeding technique applied to the plant gives rise to significant changes in the composition or structure of the food;
- § addition of the definition of "offspring" and "engineered nanomaterial" (see also points d) and e) below);
- § ingredients used in food supplements before 15 May 1997 fall under the definition, and consequently require authorisation, only if they are to be used in foods other than food supplements;
- § definition of the "traditional food from a third country" cover food that is derived only from primary production and for which the history of safe food use has been proven in any third country for a continuous period of 25 years in the customary diet of a large part of the population ;
- § it has been noted that the level of harmonisation for medicinal products makes it possible that a Member State may, if it establishes in accordance with Directive 2001/83/EC that a substance is a medicinal product, restrict the placing on the market of such product in accordance with Union law, even if the same product has been authorized as a novel food under the present Regulation.

The Council also agreed that the Commission may, through the regulatory comitology procedure, adopt further criteria to clarify definitions in sub-points (i) to (iv) of point (a) and points (c), (d) and (e) of Article 3(2) in order to ensure their harmonised implementation by the Member States.

These changes cover amendment **15, 16, 35, 63** and most of amendment **92**.

- d) Food produced from animals obtained by non-traditional breeding techniques and their offspring (Article 3(2)(a)(i) and recitals 6 and 7) - the Council agreed that foods produced from animals obtained by non-traditional breeding techniques (e.g. cloning) and their offspring shall fall within the scope of the Regulation. At the same time, the Council is of the opinion that this Regulation cannot adequately manage all aspects of cloning and that the Commission should study the subject further. To this end, the Commission shall forward, within one year from the date of entry into force of this Regulation, to the European Parliament and the Council a report on all aspect of food production from cloned animals and their offspring, followed, if appropriate, by legislative proposal (Article 20(2)). This is in line with amendment **93**. The Council considered that it was necessary to keep food produced from cloned animals within the scope of the proposed Regulation until any specific legislation has been proposed by the Commission and adopted. This solution avoids a legal vacuum that would be created by excluding such a food from the Regulation as proposed by the European Parliament in the absence of any legislation regulating food production from cloned animals.
- e) Nanomaterials - the Council recognized the need for systematic safety evaluation and authorisation of foods containing or consisting of engineered nanomaterials irrespective of any changes that the nanomaterials might cause in the properties of such foods. Therefore, the Council made clear that such foods are considered to be novel (Article 3(2)(a)(iv)) and added the definition of "engineered nanomaterial" (Article 3(2)(c)). The Council thus closed the gap that might have been created if the use of nanotechnologies would have not given rise to significant changes in the composition or structure of the food as defined by Article 3(2)(a)(iii), but the food would have still contained engineered nanomaterials. Recital 9 highlights the need for an internationally agreed definition of nanomaterial. If a different definition is agreed at international level, the adaptation of the definition in this Regulation would be done through the ordinary legislative procedure. The Commission expressed its reservation as it argued that this adaptation should have been delegated to the Commission according to Article 290 TFEU. The Council thus accepted a part of amendment **92**.

The Council followed the thrust of amendments **6** and **11** on the necessity to have appropriate risk assessment methods for engineered nanomaterials, which is reflected in recital 20.

- f) Determination of the status of food (Article 4 and recital 16) - the Council agreed that the determination of the status of food to be placed on the Union market with respect to the definition of novel food would be a responsibility of food business operators, who must consult their national authority in case of doubt.

- g) Authorisation of novel foods (Article 9 and recital 18) – the Council agreed that the authorisation of novel foods should be carried out according to the Regulation (EC) No 1331/2008, unless there is provision for a specific derogation in the present Regulation. The Council clarified that ethical, environmental, animal welfare factors and the precautionary principle should be taken into account in authorisation of novel foods. These factors should be considered on a case-by-case basis according to the content of the application. This covers amendment **20**.

- h) Authorisation of traditional foods from third countries (Article 11 and recital 22) - the Council did not accept the "notification procedure" as proposed by the Commission. In order to ensure food safety, any authorisation should be based on the EFSA opinion and subsequent authorisation adopted by the Commission through the regulatory comitology procedure. The EFSA evaluation should primarily focus on the evidence of safe food use and the information on the composition of traditional food. In order to speed up the procedure, shorter deadlines should apply - 6 months for EFSA opinion and 3 months for the draft measure submitted by the Commission to SCFCAH. A separate list of authorised traditional foods from third countries would be established (Article 7(2)). The new Council approach nevertheless covers amendments **65** and **68**.

- i) Technical guidance (Article 12) – the Commission must before the date of application of the Regulation (i.e. 2 years after its publication) make available technical guidance and tools to interested parties, in particular food business operators and SMEs. It is self-evident that the Commission Recommendation 97/618/EC will be applicable until the repeal of the of Regulation (EC) 258/1997. This is in line with amendment **69**.

- j) European Group on Ethics in Science and new Technologies - EGE (Article 15 and recital 28) - an additional provision was added on the possibility for the Commission to consult the EGE, on its initiative or at the request of a Member State, on ethical issues concerning the novel foods. This corresponds to amendment **76**. If consulted, its opinion will be taken into account at the risk management stage.

- k) Data protection (Article 16 and recital 25) - in order to promote innovation in industry, the need for the protection of new scientific evidence and/or proprietary scientific data for the period of 5 years was accepted by the Council. Such protected data cannot be used for the benefit of another application without the agreement of the prior applicant and the authorisation is limited to the prior applicant during the period of 5 years unless a subsequent applicant obtains authorisation without reference to that proprietary data. This fully covers amendment **77**. Though amendment **25** was not accepted as such, its spirit is covered by Article 16.

- l) Information to the public (Article 17) - summaries of applications, findings of any consultations for determination of the status of food and lists of authorised novel foods must be made available to the public, in the latter case on the single dedicated web page. This is in line with amendments **41**, **53** and **67**, part of amendment **40** and covers in principle amendment **64**.

- m) Transitional measures (Article 23 and recital 29) – pending application submitted according to Article 4 of the Regulation (EC) No 258/97 shall be processed under that Regulation only if the initial assessment report has been provided under Article 6(3) and neither additional assessment was required, nor were any objections raised by Member States. This is in line with amendments **88** and **89**.

In addition to the amendments mentioned above, the common position incorporates amendments 7, 42, 44, 45, which are of technical/editorial nature and aim at improving the clarity of the text.

Given the entry into force of the Treaty on the Functioning of the European Union on the 1 December 2009, the Council had to adapt the regulatory procedure with scrutiny related provisions of the Commission's proposal to the TFEU. The Council agreed that the following provisions should confer implementing powers on the Commission (Article 291(2) TFEU):

- § Article 3(4): the adoption of further criteria to clarify definitions in sub-points (i) to (iv) of point (a) and points (c), (d) and (e) of Article 3(2) that may be adopted;
- § Article 11(5): the update of the list of traditional foods from third countries;
- § Article 16(5): the update of the Union list in case of data protection before the expiry of the 5 years period for data protection;
- § Article 27 (2): the transitional measures for the application of Article 27(1) that may be adopted;
- § Article 9: the update of the Union list of novel foods. The Regulation (EC) 1331/2008 would need to be amended for that purpose (see Article 28 of the Council position).

As already mentioned in point c) above, the Council agreed that the adoption of criteria for assessing whether a food has been used for human consumption to a significant degree within the Union before 15 May 1997 by the date of application of this regulation (i.e. 24 months after the entry into force) should be delegated to the Commission according to Article 290 TFEU.

2.2. The European Parliament's amendments not accepted

The Council did not accept 46 amendments listed on the following grounds:

- i) **Amd 2:** high level of protection of human health and consumers' interests in relation to food and effective functioning of the internal market are two main goals of Union law on foodstuffs (Article 1 of Regulation (EC) No 178/2002). These two aspects are covered by recitals 1 and 2.
- ii) **Amd 9:** as explained in point c) above, the basic criterion for assessing the novelty of the food remains its use for human consumption to a significant degree within the Union before 15 May 1997. Modified primary molecular structure, micro-organisms, fungi, algae, new strains of micro-organisms and concentrates of substances still fall under this definition and do not need to be listed separately
- iii) **Amd 22:** EFSA cooperates with Member States when preparing its opinions and may use a network as provided for by Article 36 of Regulation (EC) No178/2002 and Commission Regulation (EC) No 2230/2004.
- iv) Animal testing (amds **21, 87**) - the issue of animal testing, in particular avoidance of testing on vertebrate animals and sharing of testing results, does not fall under the scope of this Regulation. According to Article 9(2) of the Regulation (EC) No 1331/2008 (Common authorisation procedure), EFSA shall present a proposal concerning the data required for risk assessment of novel foods and these should recognise the need to avoid unnecessary animal testing.

- v) Prohibition of food production, placing on the market and imports of cloned animals and their offspring (amds **5, 10, 12, 14, 91 (point 2(ba)), 92 (point 2(a)(ii) and 2(ca)), 51 (second part)**) - the Council cannot agree with the immediate exclusion of food obtained from cloned animals and their offspring from the scope of the Regulation (see point d) above). It should also be noted that the Commission has a right of initiative in proposing EU legislation and cannot be obliged to make a legislative proposal by a legislative act.
- vi) Nanomaterials
- a. amd **13**: does not fall under the scope of novel foods Regulation; Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food applies.
 - b. amd **90**: systematic specific labelling of ingredients in the form of nanomaterials is excessive; there is a requirement to consider specific labelling requirements on a case-by-case basis according to Article 9(2).
 - c. amd **50**: in case of doubt concerning the safety of foods containing nanomaterials the precautionary principle would apply. In addition, the date of application of the Regulation has been prolonged to 24 months, thus leaving additional time for the development of risk assessment methods for engineered nanomaterials.
- vii) Determination of the status of food (amd **18** and part of amd **40**): the amendments are not compatible with the approach agreed by the Council (see point d) above).

viii) Additional criteria for risk assessment by EFSA

- d. amd **70**: reference to Article 6 (Article 8 in the Common position) is not appropriate as it concerns conditions to be considered at risk management stage, not risk assessment conducted by EFSA.
- e. amd **71**: interferes with EFSA internal procedures; in assessing safety of food, EFSA may consider also other aspects than harmful or toxic effects to human health.
- f. amd **74**: does not belong to the risk assessment stage; the opinion of the European Group on Ethics in Science and New Technologies (EGE) could be sought at the request of a Member State and would then be considered at the risk management stage.

ix) Additional conditions for authorisation of novel foods (risk management)

- g. amd **23**: ethical aspects may be considered at the risk management stage; assessment by European Environment Agency (EEA) is not applicable.
- h. amd **43**: not necessary, aspects covered by this amendment are taken into account by EFSA at the risk assessment stage.
- i. amd **47**: not applicable; it is neither necessary nor possible to ask a opinion of the EEA for every application for novel food authorisation.
- j. amd **48**: the opinion of EGE cannot be requested for every application for novel food authorisation. If it is requested as provided for in Article 15, it will be taken into account at the risk management stage.
- k. amd **49**: aspects covered by this amendment are taken into account by EFSA at risk assessment stage and may be covered by conditions of use and additional specific labelling requirements according to Article 9(2).

- x) Precautionary principle (amds **1(second part), 19, 52**) - the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002 is always applicable. There is a reference to this principle in recital 18. Therefore, there is no need to repeat it in other recitals and as an additional condition for authorisations.

- xi) Additional specifications for the entry of novel food in the Union list:
- l. **amd 54:** all points raised are already covered by the Regulation, except point (f), which is not clear as monitoring requirements and inspections according to Regulation No. 882/2004 on official controls are two different issues.
 - m. **amd 57:** according to Article 9(2), the presence of undesirable substances in the novel food is already controlled by specifications of the food and limitation of exposure to substances present in novel foods will be covered under “conditions of use” and may be introduced following the EFSA opinion.
- xii) Post-marketing monitoring (amd 55 and 75) - systematic post market monitoring and revision of authorisations after five years for all novel foods placed on the market is disproportionate. It would place an administrative burden on food business operators and authorities of Member States. Article 14 provides for a possibility to impose post market monitoring on a case-by-case basis. Producers are obliged to inform the Commission of any new scientific or technical information which might influence the safety evaluation in use of novel food already placed on Union market.
- xiii) Labelling of novel food (amd 60 and 62) - the systematic labelling of all novel foods (amd 62) is disproportionate and would create an administrative burden. Specific labelling requirements are possible according to Article 9(2). Labelling of products from animals fed with genetically modified feeding stuff (amd 60) does not fall under the scope of this Regulation (Regulation (EC) 1829/2003 is clearly excluded).
- xiv) Traditional foods from third countries (amds 28, 64 and 66): the Council agreed a different procedure for authorisation of these foods than that proposed by the Commission (see point h) above).

- xv) Consultation of the EGE (amd **29**): the Council wording of recital 28 better correspond to the content of Article 15 concerning consultations of the EGE (see point j) above).
- xvi) Alignment of deadlines for authorisation of health claim and novel food in the case of data protection (amd **27, 80**) - such an alignment may be desirable, but would be difficult to ensure in practice as evaluations proceed according to different time schedules and the two decisions are taken separately.
- xvii) Amd **61**: updates of the Union list in the case of data protection are to be decided in accordance with the regulatory procedure as these are individual authorisations and not measures of general scope.
- xviii) Amd 56 and 91 (subparagraph (2a)): authorisation of food additives, food enzymes and food flavourings, to which a new production process is applied, which gives rise to significant changes is already covered by sectoral legislation on additives (Art. 12 and Recital 11 of Regulation (EC) No 1333/2008), enzymes (Art. 14 and Recital 12 of Regulation (EC) No 1332/2008) and flavourings (Art. 19 of Regulation (EC) No 1334/2008). The common authorization procedure applies to such authorizations.
- xix) Amd **78**: the Council did not consider the issue of research projects financed from EU and/or public sources.
- xx) Amd **81**: Regulation (EC) 882/2004 on official controls to ensure compliance with feed and food law (including novel foods Regulation) is applicable and does not need to be repeated.
- xxi) Amd **82**: the Council agreed to postpone the date of application of the Regulation until 24 months after the date of its publication. The same deadline was given to Member States to notify provisions concerning penalties.

xxii) Amd **83**: Not necessary; duplication of provisions applicable according to the Articles 53 and 54 of Regulation 178/2002.

The Council did not accept amds **8** and **85** as they are unclear and amds **4, 17, 51 (first part)**, whose content is self-evident and they do not bring any added value.

IV. Conclusions

The Council believes that its position at first reading represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation ensuring a high level of human health and consumer protection.

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