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EUROPEAN COMMISSION

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OPINION OF THE COMMISSION

**pursuant to Article 294, paragraph 7, point (c) of the Treaty on the Functioning of the
European Union,
on the European Parliament's amendments
to the Council's position regarding the
proposal for a**

**REGULATION OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL**

**on novel foods, amending Regulation (EC) N° 1331/2008 and repealing Regulation (EC)
N° 258/97 and Commission Regulation (EC) N° 1852/2001**

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1. INTRODUCTION

Article 294 (7) (c) of the Treaty on the Functioning of the European Union provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out its opinion below on the 104 amendments proposed by the Parliament.

2. BACKGROUND

Date on which the proposal was sent to Parliament and Council: 14 January 2008

Doc COM (2007)872 final -2008/0002 (COD)

Date of the opinion of the European Economic and social Committee: 29 May 2008

Date of Parliament's opinion at first reading: 25 March 2009

Date on which the amended proposal was sent to Parliament and Council: none

Date of political agreement on the Council position: 22 June 2009

Date of formal adoption of the Council position: 11 March 2010

Date of Parliament's opinion at second reading: 7 July 2010

Date of transmission of Parliament's opinion at second reading: 9 August 2010

3. PURPOSE OF THE PROPOSAL

Authorisation and use of novel foods are regulated at E.U. level since 1997 when Council Regulation (EC) n° 258/97 was adopted. The aim of the draft Regulation is to update and clarify the regulatory framework for the authorisation and placing on

the market of novel foods while ensuring food safety, the protection of public health and of consumer interests and the functioning of the internal market. It repeals Regulation (EC) n° 258/97 and Commission regulation (EC) n° 1852/2001.

This proposal aims to streamline and centralize at Union level the authorisation procedure in accordance with Regulation (EC) n° 1331/2008 establishing the common authorisation procedure. It develops a specific authorisation procedure for traditional foods from third countries and clarifies the definition of novel foods, including new technologies with an impact on food.

The current procedure for extensions of use is abolished and applicant-linked authorisations are replaced by generic authorisation decisions except when protection of data is granted for innovative food products.

The proposal also confirms the "status quo" for food derived from animals obtained by non conventional breeding techniques (e.g. clones) by explicitly requiring a pre-market authorisation while food derived from animals obtained by conventional breeding techniques (e.g. offspring of clones) is not considered as being novel.

4. OPINION OF THE COMMISSION ON THE AMENDMENTS BY THE EUROPEAN PARLIAMENT

4.1. Summary of the Commission's opinion

The Parliament has adopted 104 amendments to Council's position. The Commission can accept 34 amendments, either in full or in part.

The Commission can accept 16 amendments as they stand (n° 3, 8, 12, 17, 27, 44, 56, 57, 75, 90, 91, 93, 99, 111, 114, 117) and can accept 18 amendments in part or subject to rewording (n° 1, 16, 26, 34, 35, 45, 47, 49, 50, 52, 82, 94, 95, 96, 97, 106, 109, 110).

The Commission cannot support 70 amendments (n° 2, 4, 5, 6, 9, 10, 11, 13, 14, 15, 20, 21, 22, 23, 25, 28, 29, 30, 32, 33, 37, 39, 40, 41, 42, 43, 46, 51, 53, 54, 55, 58, 59, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 74, 77, 78, 80, 81, 84, 85, 87, 88, 89, 92, 98, 100, 101, 102, 103, 104, 105, 107, 108, 113, 115, 116, 118, 120).

4.2. Amendments accepted by the Commission

4.2.1 Nanotechnologies

The Commission supports the principle of a regulatory definition of "engineered nanomaterials" in order to clarify which products would require a pre-market approval under the Novel Food Regulation (amendment 16). This definition, based on science, must be enforceable by food business operators and Member State control authorities.

Should science provide new information about the elements to be considered in the draft definition before the final adoption of the text, the Commission will submit appropriate changes to that definition to the co-legislators.

The Commission agrees with the need to adapt the regulatory definition of "engineered nanomaterials" to the scientific progress and international developments through delegated acts (amendments 34 and 49).

As regards, the labelling of nanomaterials in foodstuffs, the Commission can accept the principle of a mandatory and systematic labelling of all foods and food ingredients containing nanomaterials (amendment 75). This labelling requirement would apply at the level of the list of ingredients and to all food ingredients containing engineered nanomaterials covered by the above mentioned definition.

The Commission considers that the labelling requirement should preferably be done within the framework of the proposal for a Regulation of the European Parliament and the Council on the provision of food information to consumers in order to provide a coherent approach to the labelling of engineered nanomaterials in all foods.

4.2.2 Precautionary principle, protection of animal welfare and environmental and ethical aspects

The primary objective of the Novel Food Regulation is to ensure the food safety through a systematic EU risk assessment and authorisation procedure prior to getting market access and the free circulation of goods within the EU.

However the Commission supports the inclusion, where applicable, of the objectives related to the protection of animal health, animal welfare, the environment and consumer protection (amendments 1, 3 and 35).

4.2.3 Traditional foods from third countries

The Commission can agree with the requirement for a 25 year period of consumption in third countries to demonstrate the history of safe food use of traditional foods from third countries (amendment 47). This comes in addition to the necessity to submit relevant data required to establish the safety of these foods.

4.2.4 Animal testing

The Commission agrees that repetition of tests on vertebrates should be avoided as much as possible. Therefore, the possibility for an applicant to refer to the results of animal test studies made by a prior applicant against financial compensation can be provided, including when data protection has been granted. However, such possibility does not mean that the prior applicant has the obligation to grant access to its data in all cases. Therefore amendment 99 can be accepted provided rewriting to clarify this aspect.

4.2.5 Adaptation to the Lisbon Treaty

As regards the adaptation of the definition of "engineered nanomaterials" to scientific and technical progress and to definitions agreed at international level, the Commission considers that the recourse to the "ordinary legislative procedure" for its revision would prevent this definition to reflect the best state of science and can agree with its revision through delegated acts (amendment 49).

As regards the modalities for the delegation and revocation of power to the Commission for adopting delegated acts and for objections to delegated acts, the Commission can support the EP amendments (amendment 109 as regards the duration of the delegation, amendment 110 as regards the modalities for the revocation of the delegation and amendment 111 as regards the modalities for raising objections to delegated acts).

4.3. Amendments rejected by the Commission

4.3.1. Cloning

The EP requests a legislative proposal to prohibit food from clones and their offspring of all generations within 6 months after the entry into force of the Regulation (amendment 5). The EP also requests a moratorium on the placing of such products on the market until the proposal is adopted (amendment 14) and a report dealing with all aspects of cloning within 3.5 years after the entry into force of the Novel Food Regulation, accompanied if necessary by any legislative proposal (amendment 113).

Following extensive discussions at both EP and Council levels, the Commission considers that the Novel Food Regulation is not the appropriate legal frame for addressing globally the cloning issue for food production. In particular, the production and marketing of products other than food (reproductive materials) cannot be covered by the Novel Food Regulation which deals exclusively with the pre-market authorisation of food products.

The Commission will also adopt by mid November at the latest a report on all aspects of the use of the cloning technique for food production. This report will serve as a basis for further discussions on this issue between the EU Institutions. The Commission is open to find a consensus and is considering the options for a future legal frame.

4.3.2. Nanotechnologies

The Commission does not agree with the EP assumption that the general methodology used for the risk assessment of foodstuffs would not be applicable for that of nanomaterials in food (amendment 6) and that, until specific test methods are developed, no food with nanomaterials should be put on the EU market (amendment 120).

In line with the EFSA opinion of 10 February 2010, the Commission acknowledges that additional safety tests and control tools need to be developed but that the methodology used for the risk assessment of foodstuffs remains valid (amendments 6, 10, 13 and 23). Therefore amendments 6, 10, 13, 23 and 120 cannot be accepted.

The Commission is committed to only approve the marketing of food containing nanomaterials for which the food safety has been established.

4.3.3. Traditional foods from third countries

The Commission considers that traditional foods from third countries should cover foods derived from primary production, including some processed foods provided they have not undergone extensive or innovative food processes and is not in favour of a restriction to "natural non engineered novel foods " (amendment 47– partial rejection).

The Commission has agreed with a systematic risk assessment by EFSA followed by an authorisation at EU level with shorter deadlines as laid down in the position of the Council.

However, as amendment 81 refers to the notification procedure provided by the original Commission proposal and would facilitate the trade of traditional foodstuffs from third countries without undermining the food safety, the Commission considers it would be appropriate to reintroduce the concept of the notification procedure.

4.3.4. Data protection

The Commission considers that, in dully justified cases concerning genuine innovative products for which data protection has been granted, these novel foods could benefit from an individual authorisation and 5-year period of exclusivity on the EU market.

As only generic authorisations are granted through Article 7 of Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings, the authorisation procedure with data protection clearly derogates from the common authorisation procedure and shall therefore be kept separate in the Novel Food Regulation and therefore amendments 100, 101 and 102 cannot be accepted.

The synchronisation of the data protection periods which may be granted both under Novel Food Regulation and under Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods would provide an improved benefit for the placing of the market of such products.

However, as the data to be assessed are under both Regulations are of totally different nature and have to be examined by different EFSA panels, the matching of the periods of data protection cannot be ensured in practice and therefore amendments 28 and 103 cannot be accepted.

4.3.5. Adaptation to the Lisbon Treaty

The possibility to adopt further criteria to clarify the definitions laid down in Article 3 2) points a) (i) to (iv) related to sub-categories of novel foods, and point d) and e) related to traditional foods from third countries should be kept. Its removal implies that it could be done only through the "ordinary legislative procedure" (amendment 33). The Commission considers that the determination of these criteria is a measure aimed at supplementing non essential elements of the Regulation, which should be adopted through delegated acts.

The Commission also considers that the adaptation of the following measures should be done through implementing acts:

- The procedure for determination of the novel food status in Article 4(4);
- The decisions whether a type of foods fall within the scope in Article 5;
- The update of the list of traditional foods from third countries and the adoption of detailed rules for implementation of the procedure for traditional foods from third countries in Article 11(5) and (7); -
- The adoption of implementing measures to ensure public information in Article 17;
- The update of the Union list in case of data protection before the expiry of the 5 year period of data protection in Article 16(5);
- The adoption of transitional measures for pending requests in Article 27(2);
- The update of the Union list of authorised novel foods in Article 28(8).

Therefore amendments 32, 34, 54, 55, 70, 81 100, 101 102, 104, 108, 115 and 118 cannot be accepted.

4.3.5. Other issues

Several amendments on other issues (such as the procedures applicable for determining the status of a food, the setting up of EU lists of authorised novel foods, the rules for the transitional period or the update of Regulation n° 1331/2008 on the common authorisation procedure) do not provide further improvements to the text and thus should be rejected.