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EUROPEAN COMMISSION

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**COMMUNICATION FROM THE COMMISSION  
TO THE EUROPEAN PARLIAMENT**

**pursuant to Article 294(6) of the Treaty on the Functioning of the European Union**

**concerning the**

**position of the Council on the adoption of a Regulation of the European Parliament and  
of the Council on novel foods, amending Commission Regulation (EC) No 1331/2008  
and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No  
1852/2001**

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**1. BACKGROUND**

Date of transmission of the proposal to the European Parliament and to the Council [14 January 2008]  
(document COM(2007)872 final – 2008/0002COD):

Date of the opinion of the European Economic and Social Committee: [29 May 2008]

Date of the opinion of the European Parliament, first reading: [25 March 2009]

Date of transmission of the amended proposal: [\*...]

Date of adoption of the position of the Council: [15 March 2010]

\* Taking into account the developments in Council at the time of the European Parliament first reading, the Commission did not find necessary to prepare a revised proposal but expressed its views on the Parliament amendments within the document SP(2009)3060 sent to the European Parliament on 11 September 2009.

**2. OBJECTIVE OF THE COMMISSION PROPOSAL**

1. 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 consumer interests and the functioning of the internal market. It repeals Regulation (EC) n° 258/97 and Commission regulation (EC) n° 1852/2001.
2. 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.

3. 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.

### **3. COMMENTS ON THE POSITION OF THE COUNCIL**

#### **3.1. GENERAL REMARKS**

The position of the Council reflects the result of the examination of the Commission's proposal taking into account the amendments voted by the European Parliament.

The Commission has accepted all the changes introduced by the Council to its proposal except the inclusion of the offspring (first generation) of cloned animals in the scope of the proposal and some modifications introduced following the entry into force of the Treaty on the functioning of the European Union.

#### **3.2. MAIN AMENDMENTS INTRODUCED BY THE POSITION OF THE COUNCIL**

The Council has included in its position several amendments adopted at first reading by the European Parliament and also accepted by the Commission.

##### **a) Objectives of the Regulation**

The position of the Council (Article 1 and recitals 1 and 2) has extended the objectives of the Regulation, on the basis of European Parliament amendments, to the protection of the environment and animal welfare. These objectives are in line with other specific food legislations which have been updated and can be supported by the Commission.

##### **b) Traditional foods from third countries**

The Commission proposal laid down a simplified procedure based on a notification by any interested party, before the placing on the European Union market, of traditional foods from third countries which can demonstrate a history of safe food use.

The Council has rejected this procedure as it would like the European Food Safety Authority to deliver a scientific opinion and the Member States to be consulted on the authorisation for the placing on the EU market of traditional foods from third countries. However a specific procedure (Article 11(3) and 11(5)) with shorter deadlines (9 months instead of 18 months) has been agreed by the Council. The Commission can support this compromise.

**c) Nanotechnologies**

With regard to nanotechnologies, the European Parliament called for the introduction of a legal definition of nanomaterials and for the mandatory labelling of these products.

Concerning labelling, the Council considers that the labelling rules should, as appropriate, be imposed by the authorisation decision on a case by case basis.

The position of the Council (Article 3(2) a) iv) and 3(2) c)) provides for a definition of "engineered nanomaterials" and a systematic evaluation and pre-marketing authorisation of all food ingredients which contain those nanomaterials.

These amendments can be supported by the Commission.

**d) Animal Cloning**

On cloning, positions between the Council and the European Parliament differ significantly. The amendments of the European Parliament are in favour of the removal of products from clones and their offspring from the scope and of a ban of the use of food from clones and their offspring or, as a fall back, a moratorium until a specific legislation is in place. Such exclusion from the scope, pending the adoption of a specific legislation on cloning, would lead to situation where there will be no E.U. harmonised legislation applicable after the repeal of current novel food Regulation.

The Council considers that a specific legislation on cloning would be desirable to address the various aspects of the cloning issue. However, the Council agrees that the novel food Regulation should continue to apply in order to cover food from cloned animals until a specific legislation is in place. In addition, the Council has agreed by unanimity to include food from first generation of clones' offspring in the definition of novel food which implies that such food would be subject to a marketing authorisation before it is placed on the market.

The position of the Council (Article 24(2)) also introduces the obligation for the Commission to submit to the European Parliament and the Council a report on all aspects of food produced from cloned animals and their offspring followed, where appropriate, by any legislative proposal.

The Commission does not support the inclusion of food from clones' offspring within the scope and therefore can not agree with the position of the Council (Article 3(2) b)). The Commission position is to maintain the legal status quo for the food produced with new breeding techniques such as cloning and to prepare the foreseen report by the end of the year.

The current and revised novel food definition covers all foods (including meat and milk) derived from animals obtained by new reproductive techniques (such as cloning), but not the food derived from animals

obtained by conventional reproductive techniques (i.e. techniques used before the entry into force of Regulation (EC) 258/97).

The Commission considers that there is no justification to include in the scope food from clones' offspring as they are obtained through conventional breeding techniques and that the submission of food from clones' offspring to a pre-market authorisation regime would therefore be disproportionate to the objectives of the regulation, in particular food safety, and not in line with the Treaty on the Functioning of the European Union. In addition, such provision would be at variance with EU international commitments.

**e) Data protection**

In order to promote innovation in the food industry, the Commission proposal introduced the possibility to protect newly developed scientific evidence and proprietary scientific data. The position of the Council supports and reinforces these measures (Article 16(1) and 16(4)) by defining eligibility criteria for data protection and providing an applicant linked authorisation for a 5 year period. The Commission can support these amendments.

**f) Adaptation to the Lisbon Treaty**

Following the entry into force of the Lisbon Treaty, the position of the Council was adapted to take into account Articles 290 and 291 of Treaty on the Functioning of the European Union.

The adoption of further criteria to clarify the definitions laid down in Article 3 2) points a) (i) to (iv) related to sub-categories of novel foods, in point c) on the definition of "engineered nanomaterials" and point d) and e) related to traditional foods from third countries would be ensured through implementing acts. The Commission considers that the determination of these criteria is a measure aimed to supplement non essential elements of the Regulation which should be adopted through delegated acts.

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 absence of a provision in the position of the Council in first reading allowing the revision of the definition to reflect the technical evolution implies the introduction of the ordinary legislative procedure for its revision. This would prevent this definition to reflect the best state of science and would have negative consequences for the innovation in the food industry. Such adaptation is designed to amend non essential elements of this regulation and should be adopted through delegated acts.<sup>1</sup>

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<sup>1</sup> Statement by the Commission at the Council of 15 March 2010.

For the above reasons, the Commission opposes to the above mentioned provisions of the position of the Council.

The Commission cannot accept recital 36 as it stands concerning the consultation of experts in the preparation of delegated acts. The Commission has made a political commitment in its Communication of 9 December 2009 on Art.290 of the TFEU to systematically consult experts from the national Authorities of the Member States except in cases where this preparatory work does not require any new expertise. However, given that the Treaty does not foresee expert groups, they cannot have a formal institutional role. Therefore, provisions as regards the involvement of experts in the preparation of delegated acts should not be included in the basic acts.

Finally, on the duration of the period to raise objections for delegated acts, the Commission considers that the Council did not provide enough reasons to opt for a three-month period. The Commission insists on the two-month period (which may be extended by one additional month) and cannot support this amendment of the Council.

The Commission can nevertheless support the adaptation of the following measures through implementing acts:

- The procedure for determination of the novel food status (Article 4, paragraph 4);
- The decisions whether a type of foods fall within the scope (Article 5);
- The update of the list of traditional foods from third countries in Article 11(5),
- The adoption of detailed rules for implementation of the procedure for traditional foods from third countries (Article 11(7));
- 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 implementing measures to ensure public information (Article 17);
- 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),

#### **4. CONCLUSION**

The Commission has accepted all the changes introduced by the Council to its proposal except the inclusion of the offspring (first generation) of cloned animals in the scope of the proposal and the proposed adaptations of several comitology related provisions to the Lisbon Treaty. Therefore the Commission can not support the position of the Council.

## **ANNEX**

### **Statement by the Commission**

The Council's political agreement of June 2009 considered that the adaptation of the definition of engineered nanomaterials to the scientific and technical progress and to the definitions subsequently agreed at international level should be made in accordance to the regulatory procedure with scrutiny. In the current Council's position at first reading the adaptation of this definition is limited to the adoption of further criteria to clarify it.

First, this modification implies that any adaptation of the definition itself would only be possible through the ordinary legislative procedure. The Commission opposes to this limitation as it would prevent this definition to reflect the best state of science and would have negative consequences for the innovation in the food industry.

In addition, the Commission opposes the adoption of further criteria to clarify definitions through implementing acts pursuant to Article 291 TFEU. The Commission considers that the adoption of these criteria implies supplementing non essential elements of the Regulation and thus they should be adopted through delegated acts pursuant to Article 290 TFEU. This applies to definitions laid down in Article 3(2)(a)(i) to (iv) on sub-categories of novel foods, to Article 3(2)(c) on engineered nanomaterials, and to Article 3(2)(d) and (e) related to traditional foods from third countries.