

SUMMARY
of
**Nano-Specific Amendments to the *Novel Foods* Regulation,
proposed by the European Parliament**

(Plenary Vote, 7th July 2010)

[excerpts of full *European Parliament legislative resolution of 7 July 2010 on the Council position at first reading for 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 (11261/3/2009 – C7-0078/2010 – [2008/0002\(COD\)](#))*]

NOTE:

The below document lists the different amendments in relation to nanotechnology which have been voted in plenary session by the EP during second reading on 7th July 2010.¹

How to read the table below:

- In the case only 1 column is given: this is an amending act proposed by the EP, it is an addition to the Council position.
- In case 2 columns are given: the first column represents the Council position (adopted on March 15) and the second column the EP position (voted on 7 July 2010).

¹ For all amendments, please see: [European Parliament legislative resolution of 7 July 2010 on the Council position at first reading for 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 \(11261/3/2009 – C7-0078/2010 – \[2008/0002\\(COD\\)\]\(#\)\)](#).

Amendment 6
Council position – amending act
Recital 2 d (new)

(2d) The Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted on 28-29 September 2005 an opinion which concluded that there were "major gaps in the knowledge necessary for risk assessment. These include nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate, and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles". Furthermore, the SCENIHR opinion concluded that "existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles".

Amendment 10
Council position – amending act
Recital 6

(6) It should also be clarified that a food ***is to*** be considered as novel when a production technology which was not previously used for ***food production in the Union*** is applied to that food. 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 animals produced by non-traditional breeding techniques and ***from their offspring, foods derived from plants produced by non-traditional breeding techniques, foods produced by new production processes which might have an impact on food, and foods containing or consisting of engineered nanomaterials.*** Foods derived from new plant varieties or animal breeds produced by traditional breeding techniques should not be considered as novel foods. ***Furthermore, it should be clarified that foods from third countries which are novel in the***

(6) It should also be clarified that a food ***should*** be considered as novel when a production technology which was not previously used for ***the production of foods to be marketed and consumed*** is applied to that food. 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. Foods derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.

Union can be considered as traditional only when they are derived from primary production as defined in Regulation (EC) No 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should neither include foods produced from animals or plants to which a non-traditional breeding technique was applied or foods produced from the offspring of such animals, nor foods to which a new production process is applied.

Amendment 13
Council position – amending act
Recital 7 a (new)

(7a) Only nanomaterials entered in a list of approved substances should be present in food packaging, accompanied by a limit on migration into or onto the food products contained in such packaging.

Amendment 16
Council position – amending act
Recital 9

(9) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, ***free movement of goods and legal certainty for manufacturers***, it is necessary to develop a uniform definition for engineered ***nanomaterial at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of engineered nanomaterial in this Regulation should be adapted accordingly***

(9) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, it is necessary to develop a uniform definition for engineered ***nanomaterials***

Amendment 23
Council position – amending act

Recital 20

(20) ***At present, there is inadequate information on the risks associated with engineered nanomaterials. In order to better assess their safety the Commission, in cooperation with the Authority, should develop test methodologies which take into account specific characteristics of engineered nanomaterials.***

(20) ***Test methods currently available are not adequate for assessing the risks associated with nanomaterials. Non-animal test methods for testing nanomaterials should be developed as a matter of urgency.***

Amendment 33 Council position – amending act Recital 35

(35) ***In particular, the Commission should be empowered to clarify certain definitions in order to ensure a harmonised implementation of these provisions by the Member States on the basis of relevant criteria, including the definition of "engineered nanomaterial", taking into account the technical and scientific developments, and the non-traditional animal breeding technique that includes techniques used for asexual reproduction of genetically identical animals not used for food production within the Union before 15 May 1997. Furthermore, the Commission should be empowered to adopt any appropriate transitional measures and to update the list of traditional foods from third countries and the Union list.***

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Amendment 34 Council position – amending act Recital 36

(36) ***In addition, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997. It is of particular importance that the Commission consult experts in the preparatory phase in accordance with the commitment of the Commission undertaken in the Communication of 9 December 2009***

(36) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997, ***in respect of the determination of whether a type of food falls within the scope of this Regulation, the adjustment and adaptation of the definition of "engineered nanomaterial" to***

***on the implementation of Article 290
of the Treaty on the Functioning of
the European Union.***

***technical and scientific progress and
in line with definitions subsequently
agreed at international level, rules
on how to proceed in cases in which
the Commission has no information
about use of a food for human
consumption before 15 May 1997, as
well as in respect of rules for the
application of Article 4(1) and Article
11 and the update of the Union list.***

***It is of particular importance that the
Commission **carry out appropriate
consultations during its preparatory
work, including at expert level.*****

Amendment 49
Council position – amending act
Article 3 – paragraph 3

***3. The Commission may adopt
further criteria to clarify the
definitions in sub-points (i) to
(iv) of point (a), and in points
(c), (d) and (e) of paragraph 2 of
this Article in accordance with
the regulatory procedure
referred to in Article 19(2).***

***3. In view of the various definitions of
nanomaterials published by different
bodies at international level and the
constant technical and scientific
developments in the field of
nanotechnologies, the Commission shall
adjust and adapt point (c) of paragraph 2
of this Article to technical and scientific
progress, and in line with definitions
subsequently agreed at international level,
by means of delegated acts in accordance
with Article 21 and subject to the
conditions of Articles 22 and 23.***

Amendment 120
Council position – amending act
Article 8 - paragraph 1 a (new)

***1a. Foods to which production processes have been applied that require
specific risk assessment methods (for example, foods produced using
nanotechnologies) may not be included in the Union list until such specific
methods have been approved by the Authority for use, and an adequate
safety assessment on the basis of those methods has shown that the use of
the respective foods is safe.***

Amendment 68

Council position – amending act
Article 8 - paragraph 1 b (new)

1b. A novel food may be included in the Union list only if the competent authority has submitted an opinion establishing that the food is not harmful to health.

Amendment 69
Council position – amending act
Article 8 - paragraph 1 c (new)

1c. In the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the precautionary principle shall be applied and the food in question shall not be included in the Union list.

Amendment 75
Council position – amending act
Article 9 - paragraph 2 c (new)

2c. All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.