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COMMISSION DELEGATED REGULATION (EU) No .../..

of **XXX**

**amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council
on the provision of food information to consumers as regards the definition of
'engineered nanomaterials'**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 1169/2011 of the European Parliament and of the¹ establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information, while providing sufficient flexibility to respond to future developments and new information requirements.

In order to inform consumers of the presence of engineered nanomaterials in food, Article 18(3) of Regulation (EU) No 1169/2011 provides that all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients and the names of such ingredients must be followed by the word 'nano' in brackets. In addition, it provides a definition of engineered nanomaterials, which shall be adjusted and adapted to technical and scientific progress or to definitions agreed at international level, by means of delegated acts, for the purposes of achieving the objectives of the Regulation.

On 18 October 2011, the Commission adopted Recommendation 2011/696/EU as regards the definition of nanomaterial². According to the Commission Communication to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials³, the Commission intends to use the definition of 'nanomaterial' set out in the Commission Recommendation 2011/696/EU in Union legislation and instruments of implementation, where appropriate. Where other definitions are used in Union legislation, provisions will be adapted in order to ensure a consistent approach, although sector specific solutions may remain necessary.

On 12 December 2013, the Commission adopted a Delegated Regulation amending Regulation (EU) No 1169/2011 as regards the definition of 'engineered nanomaterials'. The proposed definition, amongst others, excluded food additives set out in the Union lists referred to in Article 4 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁴ by Commission Regulations (EU) No 1129/2011⁵ and (EU) No 1130/2011⁶.

On 12 March 2014, the European Parliament objected to the Commission Delegated Regulation, by means of Resolution P7_TA-PROV(2014)0218, as it excluded certain food additives from the definition of 'engineered nanomaterials'. The European

¹ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p. 18).

² Commission Recommendation 2011/696/EU on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

³ COM (2012)572 final, dated 3.10.2012.

⁴ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

⁵ Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (OJ L 295, 12.11.2011, p. 1).

⁶ Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients (OJ L 295, 12.11.2011, p. 178).

Parliament called the Commission to adopt a new delegated act taking into account the position of the European Parliament.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Expert Group on Regulation (EU) No 1169/2011 on the provision of food information to consumers was consulted on 23 June 2014 on a revised draft Commission Regulation, which takes into account the position of the European Parliament.

Exchange of views with stakeholders took place on 4 July 2014 in the context of the Advisory Group of the Food Chain, Animal and Plant Health.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for this Delegated Regulation is Article 18(5) of Regulation (EU) No 1169/2011 on the provision of food information to consumers. According to the latter provision, for the purposes of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts, adjust and adapt the definition of engineered nanomaterials to technical and scientific progress or to definitions agreed at international level. This Delegated Regulation adapts the definition of 'engineered nanomaterials' laid down in Article 2(2)(t) of Regulation (EU) No 1169/2011 to the Commission Recommendation 2011/696/EU, taking into account the position of the European Parliament in its Resolution P7_TA-PROV(2014)0218.

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers⁷, and in particular Article 18(5) thereof,

Whereas:

- (1) Article 18(3) of Regulation (EU) No 1169/2011 provides that all food ingredients present in the form of engineered nanomaterials have to be clearly indicated in the list of food ingredients to ensure consumer information. In addition, the names of food ingredients present in the form of engineered nanomaterials have to be followed by the word 'nano' in brackets. Accordingly, point (t) of Article 2(2) of Regulation (EU) No 1169/2011 provides for a definition of 'engineered nanomaterials').
- (2) Article 18(5) of Regulation (EU) No 1169/2011 empowers the Commission to adjust and adapt the definition of 'engineered nanomaterials' referred therein to technical and scientific progress or to definitions agreed at international level, by means of delegated acts, for the purposes of achieving the objectives of that Regulation.
- (3) On 18 October 2011, Commission Recommendation 2011/696/EU⁸ was adopted, responding to a request from the European Parliament for the introduction of a comprehensive science-based definition of nanomaterials in the Union legislation. The definition set out in that Recommendation is based solely on the size of the constituent particles of a material and covers natural, incidental and manufactured materials. It takes into account the European Commission Joint Research Centre's Reference Report 'Considerations on a Definition of Nanomaterial for Regulatory purposes'⁹, the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concerning the 'Scientific basis for the definition of the term "Nanomaterial"¹⁰ and the definition of 'nanomaterial' developed by the International Organization for Standardization (ISO)¹¹.

⁷ OJ L 304, 22.11.2011, p. 18.

⁸ Commission Recommendation of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

⁹ EUR 24403 EN, June 2010.

¹⁰ http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf.

¹¹ <http://cdb.iso.org>.

- (4) Commission Recommendation 2011/696/EU set out that the definition of 'nanomaterial' neither prejudices, nor reflects the scope of application of other Union acts.
- (5) In a Communication to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials¹², the Commission expressed its intent to apply the definition of 'nanomaterial' as set out in Recommendation 2011/696/EU to Union legislation. Where other definitions are used in Union legislation, provisions should be adapted in order to ensure a consistent approach, although sector specific solutions may remain necessary.
- (6) It is therefore appropriate to adapt the definition of 'engineered nanomaterials' laid down in Regulation (EU) No 1169/2011, for the purposes of providing a high level of human health and consumers' interests, to that provided in Recommendation 2011/696/EU, which reflects technical and scientific progress to date.
- (7) Since the definition laid down in Regulation (EU) No 1169/2011 refers to 'engineered nanomaterials' and not to 'nanomaterials' in general, natural and incidental nanomaterials should not be included in the definition.
- (8) Moreover, it is appropriate to link the definition of 'engineered nanomaterials' to intentionally manufactured material, which should be explicitly defined. This definition should take into account the definition adopted by ISO, according to which 'engineered nanomaterial' is 'nanomaterial designed for a specific purpose or function'¹³. The notion of 'specific function or purpose' should encompass any function or purpose and not be limited to a new or nano-specific function or purpose.
- (9) The number based particle size distribution threshold of 50% should be reviewed with the view to assess whether it should be replaced by a threshold between 1% and 50% in the future in light of technological developments concerning detection and quantification methods and where warranted by concerns for health and safety.
- (10) In order to enable food business operators to adapt the labelling of their products to the requirements introduced by this Regulation, it is important to provide for an appropriate transitional period.
- (11) Therefore, Regulation (EU) No 1169/2011 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Point (t) of Article 2(2) of Regulation (EU) No 1169/2011 is replaced by the following:

- "(t) 'engineered nanomaterial' means any intentionally manufactured material, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm to 100 nm.

By way of derogation, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as engineered nanomaterials.

¹² COM (2012)572 final, dated 3.10.2012.

¹³ <http://cdb.iso.org>.

For the purposes of the definition set out in the first paragraph:

- (i) "particle" means a minute piece of matter with defined physical boundaries;
- (ii) "agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
- (iii) "aggregate" means a particle comprising of strongly bound or fused particles;
- (iv) "intentionally manufactured" means that the material is manufactured to perform/fulfil a specific function or purpose;"

Article 2

1. Foods placed on the market or labelled before 1 April 2016 which do not comply with the requirements of this Regulation may be marketed until the stocks of the foods are exhausted.
2. Foods labelled in accordance with this Regulation may be placed on the market before 1 April 2016.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2016, with the exception of Article 2(2) which shall apply from the entry into force of this Regulation.

It shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER