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DRAFT

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of engineered nanomaterial

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001¹, and in particular Articles 31 and 32 thereof,

Whereas:

- (1) Article 3(2)(f) of Regulation (EU) No 2015/2283 provides for a definition of engineered nanomaterial. Article 2(1)(h) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council² on the provision of food information to consumers, also provides for that same definition.
- (2) For the purposes of achieving the objectives of that Regulation by means of delegated acts, Article 32 of that Regulation empower the Commission to adjust and adapt the definition of engineered nanomaterial referred to therein to technical and scientific progress or to definitions agreed at international level.
- (3) On 10 June 2022, Commission Recommendation 2022/C 229/01³ was adopted, updating the nanomaterial definition set out in Commission Recommendation 2011/696/EU⁴, in light of experience and of technical and scientific progress. It takes into account the European Commission Joint Research Centre's Science and Policy Reports "Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 1⁵, 2⁶, and 3⁷ on the experience of stakeholders with the

¹ OJ L 327, 11.12.2015, p. 1.

² 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, amending Regulation (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p.18).

³ Commission Recommendation C(2022)3689 of 10 June 2022 on the definition of nanomaterial (OJ C 229, 14.6.2022, p.1).

⁴ Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

⁵ Towards a review of the EC Recommendation for a definition of the term "nanomaterial; Part 1: Compilation of information concerning the experience with the definition; EUR 26567 EN; doi: 10.2788/36237 (2014).

implementation of the definition and with the identification of possible points of revision, and two reports providing guidance on the implementation of the definition^{8,9} including relevant developments in standardisation by the International Organization for Standardization (ISO) and the European Committee for Standardisation (CEN), results of the NanoDefine project of the Commission's 7th Framework Programme for Research, and 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.

- (4) According to Recommendation 2022/C 229/01, the definition of nanomaterial set out therein does not affect nor reflect the scope of application of any piece of Union legislation, but it may serve different policy, legislative, and research purposes when addressing materials or issues concerning products of nanotechnologies or be used in another act providing a definition of nanomaterial for policy and legislative use adopted by the Commission.
- (5) It may in some cases be considered necessary to either exclude certain materials from the scope of application of specific legislation or legislative provisions even if they are nanomaterials according to Recommendation 2022/C 229/01 or to develop regulatory requirements for additional materials not falling under the definition of the present Recommendation, in the scope of application of specific Union legislation or legislative provisions targeting nanomaterials. Such legislation should, however, aim to differentiate between a nanomaterial and a member of such subgroup as to maintain consistency with the definition and consequently other legislation.
- (6) It is therefore, appropriate to adapt the definition of engineered nanomaterial laid down in Regulation (EU) 2015/2283 taking into consideration Recommendation 2022/C 229/01, which reflects technical and scientific progress to date.
- (7) Experience with the current definition of engineered nanomaterial laid down in Regulation (EU) 2015/2283 has shown difficulties in its implementation for both food business operators and enforcement authorities due to elements of subjectivity in the interpretation of the intentionality in the manufacture of the engineered nanomaterial in order to acquire specific functional properties or to deliver specific functions. Additional elements of subjectivity that hindered the implementation of the current definition were also introduced by the lack of a default threshold value of particles with external dimensions in the nanoscale. It is therefore, appropriate that the definition is adapted to include a default threshold of particles in the number-based size distribution with external dimensions in the nanoscale present in a manufactured material above which the material would be considered to have acquired specific functional properties due to the presence of particles in the nanoscale and would therefore be considered as an engineered nanomaterial.

⁶ Towards a review of the EC Recommendation for a definition of the term "nanomaterial; Part 2: Assessment of collected information concerning the experience with the definition; EUR 26744 EN; doi: 10.2787/97286 (2014).

⁷ Towards a review of the EC Recommendation for a definition of the term "nanomaterial; Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation; EUR 27240 EN; doi:10.2788/770401 (2015).

⁸ An overview of concepts and terms used in the European Commission's definition of nanomaterial; EUR 29647 EN; doi:10.2760/459136 (2019).

⁹ Identification of nanomaterials through measurements; EUR 29942 EN; doi:10.2760/053982 (2019).

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

- (8) The technical and scientific elements underpinning the nanomaterial definition of Recommendation 2022/C 229/01 did not identify scientific evidence that the default threshold of 50% of particles with external dimensions at the nanoscale of the definition of Commission Recommendation 2011/696/EU should be changed. It is therefore, appropriate that this default threshold is also included in the definition of engineered nanomaterial to ensure regulatory consistency and coherence, to avoid that a specific material is considered a nanomaterial under one regulatory framework but not under another, and to provide objectivity and clarity in the implementation of the definition of engineered nanomaterial for economic operators, consumers and regulators.
- (9) Since the definition laid down in Regulation (EU) 2015/2283 refers to engineered nanomaterials and not to nanomaterials in general, only manufactured materials consisting of at least 50% of particles in the nanoscale, should therefore be included in the definition. Natural materials or manufactured materials which incidentally may contain a minor fraction of particles in the nanoscale, should not be included in the definition.
- (10) Materials whether natural or manufactured which incidentally may contain a minor fraction of particles in the nanoscale, and which are not included in the definition of engineered nanomaterial, may still be within the scope of Regulation (EU) 2015/2283 if they are not used for human consumption to a significant degree within the Union before 15 May 1997 and fall within at least one of the categories referred to in Article 3(2)(a) of that Regulation. The risk assessment of these materials should take into account material properties at the nanoscale.
- (11) For the purpose of the definition of engineered nanomaterial of this Regulation, the term 'manufactured' shall be defined to refer to materials intentionally produced, synthesised or generated from physical, biological and/or chemical processing, formulation and/or transformation of raw and/or starting materials.
- (12) The definition should be based on the relative fraction of particles in a defined range within the particle number-based distribution of the external dimension of the constituent particles of a material.
- (13) The definition and its core terms should, where applicable, be based on existing scientifically defined and standardised terms adopted by the international communities (ISO, CEN). The core terms used in the definition should remain sufficiently specific and should enable practical implementation of the definition within the context of Regulation (EU) 2015/2283. Implementation should be supported, where applicable, by guidance that is to be developed by the European Commission Joint Research Centre ('JRC') in the context of the implementation of the definition of Recommendation 2022/C 229/01 and by guidance developed by the European Food Safety Authority ('the Authority') on the risk assessment of the application of nanoscience and nanotechnologies in food and feed, and kept updated with evolving science and technical progress, listing recommended measurement methods and best practice tools.
- (14) The definition should cover both particles on their own and identifiable constituent particles in agglomerates or aggregates. The identification and measurement of constituent particles in agglomerates or aggregates can be very challenging. Thus, the qualifier 'identifiable' is bound by practical considerations pertaining to their identification. These considerations may be further elaborated in guidance documents developed by the JRC to support the implementation of the nanomaterial definition of

Recommendation 2022/C 229/01 and/or by the Authority on the risk assessment of nanomaterials in the food and feed chain.

- (15) The term 'particle' should be defined as a minute piece of matter with defined physical boundaries, thus pursuant to the definition of 'particle' adopted in ISO 26824:2022. Any technical aspects of the definition of particle may be clarified in the JRC and/or the Authority guidance documents.
- (16) A single molecule, including a macromolecule such as a protein that may be larger than 1 nm, should not be considered as a particle. In very specific cases, the distinction may depend on a precise understanding of the term 'single molecule'. Illustrative cases and explanations may be presented in the JRC and/or the Authority guidance documents.
- (17) Commission Recommendation 2022/C 229/01 refers only to materials consisting of particles in solid state. However, in its opinion of 30 June 2021 on Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health¹¹, the Authority considered that materials should be also considered on the basis of their solubility and/or dissolution/degradation properties and not solely on the basis of their physical state. In that Guidance the Authority noted that materials with high solubility and/or dissolution/degradation rate values would either dissolve in food or in the gastrointestinal tract of consumers when they ingest foods containing them. The Authority also identified approaches, and the technical conditions that allow for a proper evaluation of the solubility and/or dissolution/degradation properties of materials and defined cut-off values for these parameters. Materials with respective values for these properties below these thresholds would fall within the scope of the Guidance, regardless of their physical form. It is therefore, appropriate that these properties, measured according to the approach and technical elements set out in the Authority Guidance, are included in the definition of engineered nanomaterial.
- (18) In its opinion of 30 June 2021 on Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles¹², the Authority noted that the materials that are not engineered nanomaterials but contain a fraction of small particles with one or more external dimensions smaller than 500 nm, either on their own or as identifiable constituent particles in aggregates or agglomerates, of which those smaller than 250 nm exceed 10% in the number-based size distribution, would require specific risk assessment, taking into account material properties at the nanoscale.
- (19) In order to limit the administrative burden and to provide business operators with sufficient time to adjust their practices to comply with the requirements of this Regulation, transitional periods should be laid down to cover foods which have been placed on the market or dispatched from third countries for the Union before the date of entry into force of this Regulation, and materials lawfully placed on the market which will fall within the scope Regulation (EU) 2015/2283 as of the date of entry into force of this Regulation as regards the definition of engineered nanomaterial.
- (20) Therefore, Regulation (EU) 2015/2283 should be amended accordingly,

¹¹ Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768.

¹² Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769.

HAS ADOPTED THIS REGULATION:

Article 1

Point (f) of Article 3(2) of Regulation (EU) 2015/2283 is replaced by the following:

1. 'Engineered nanomaterial' means a manufactured material consisting of particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:
 - a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;
 - b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
 - c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm;

In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.

2. For the purposes of point 1, the following definitions apply:
 - i. 'manufactured material' means a material intentionally produced, synthesised or generated from physical, biological and/or chemical processing, formulation and/or transformation of raw and/or starting materials.
 - ii. 'particle' means a minute piece of matter with defined physical boundaries; single molecules are not considered 'particles';
 - iii. 'aggregate' means a particle comprising of strongly bound or fused particles;
 - iv. '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.
3. A material with a specific surface area by volume of $< 6 \text{ m}^2/\text{cm}^3$ and/or with high solubility and/or dissolution/degradation rate values in water as determined using the thresholds, methodologies, and media identified by the Authority to be appropriate for the risk assessment of nanomaterials and/or for the determination of the presence of small particles including nanoparticles, shall not be considered an engineered nanomaterial.

Article 2

1. Foods falling within the scope of the definition of engineered nanomaterial of Article 3(2)(f) of Regulation (EU) 2015/2283 before the entry into force of this Regulation, which are lawfully placed on the market and which will not fall within the scope Regulation (EU) 2015/2283 as of the date of entry into force of this Regulation as regards the definition of engineered nanomaterial may be placed on the market until *(12 months following the entry into force of this Regulation)* and may remain on the market until exhaustion of stocks.
2. Foods not falling within the scope of the definition of engineered nanomaterials of Article 3(2)(f) of Regulation (EU) 2015/2283, which are lawfully placed on the market by *(date of entry into force of this Regulation)* and which will fall within the scope Regulation (EU) 2015/2283 as of the date of entry into force of this Regulation as regards the definition of engineered nanomaterial, may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 of Regulation (EU) 2015/2283 following an application for authorisation of a novel food submitted no later than *(18 months following the date of entry into force of this Regulation)*.

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*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN