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[...] (2023) **XXX** 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 nanomaterials’

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

According to Article 31 of Regulation (EU) 2015/2283 of the European Parliament and Council on novel foods¹, the Commission is empowered to adopt a delegated act to adjust and adapt the definition of engineered nanomaterials established in point (f) of Article 3(2) in line with technical and scientific progress or with definitions agreed at international level.

This Delegated Regulation adapts the definition of ‘engineered nanomaterial’ set out in Regulation (EU) 2015/2283 by transposing the main technical elements of the general definition of nanomaterial established in Commission Recommendation 2022/C 229/01² which was elaborated based on the state-of-the-art technical and scientific developments.

Therefore, the definition of nanomaterials set out in Commission Recommendation 2022/C 229/01 and the technical and scientific elements underpinning it have served as basis for the revision of the definition of ‘engineered nanomaterials’ set out in Regulation (EU) 2015/2283.

The amended definition of ‘engineered nanomaterial’ aims at ensuring the regulatory coherence of the nanomaterials definition used in EU legal framework, and at addressing implementation issues related to the current definition of ‘engineered nanomaterials’.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has carried out consultations in preparing this Delegated Act.

Notably, the Commission consulted the national experts, which were invited to expert meetings to discuss the draft delegated act. The consultations took place at the meetings of the expert group on ‘Nanomaterials in Food’ held on 13 October and 1 December 2022, and on 23 February and 18 April 2023.

The European Parliament and the Council were also duly informed.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation will adapt the definition of ‘engineered nanomaterial’ contained in Regulation (EU) 2015/2283, by transposing the technical elements of the general definition of nanomaterial definition set out in Commission Recommendation 2022/C 229/01 to include in its scope the size limit (< 100 nm), applicability (external dimension and shape of the material), the exclusion from the definition of materials with a surface to volume ratio above a certain value, the definitions of ‘particle’, ‘aggregate’ and ‘agglomerate’, and the default threshold value of 50% of particles being at the nanoscale for a material to be considered a nanomaterial.

At the same time, the adapted definition of ‘engineered nanomaterial’ will keep some elements of the existing definition. It will include manufactured materials only in line

¹ OJ L 327, 11.12.2015, p. 1.

² Commission Recommendation of 10 June 2022 on the definition of nanomaterial (2022/C 229/01) (OJ C 229, 14.6.2022, p. 1)]

with the concept of ‘engineered nanomaterial’, which entails the making of such materials as opposed to natural or incidental materials. It will also encompass only materials in solid state to exclude particles with highly dynamic external dimensions such as micelles, liposomes, or nanoscale droplets in emulsions. A definition of what is a ‘manufactured’ material will also be included in the scope of this definition, in order to capture the notion of intentionality (manufacturing implies that a material is purposely made). This, combined with the inclusion of the 50% threshold, will provide for objective elements in the definition of an engineered nanomaterial.

In addition, using technical elements from the EFSA risk assessment guidance documents on nanotechnology^{3,4}, it will be possible to include or exclude materials from the scope of the definition, on the basis of their solubility.

The delegated act has no implications for the Union budget.

The delegated act concerns a matter relating to the European Economic Area (EEA) and its application should therefore extend to the EEA.

DRAFT

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³ 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).

⁴ 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).

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

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

(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 Article 31 thereof,

Whereas:

- DRAFT**
- (1) Article 3(2), point (f), of Regulation (EU) 2015/2283 provides for a definition of engineered nanomaterial. Article 2(1), point (h), of Regulation (EU) No 1169/2011 of the European Parliament and of the Council² refers to the definition of ‘engineered nanomaterials’ as established by point (f) of Article 3(2) of Regulation (EU) 2015/2283.
 - (2) On 10 June 2022, Commission Recommendation 2022/C 229/01³ was adopted, updating the definition of nanomaterial set out in Commission Recommendation 2011/696/EU⁴, in light of experience and technical and scientific progress. Recommendation 2022/C 229/01 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” Parts 1⁵, 2⁶, and 3⁷ on 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 Regulations (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 of 10 June 2022 on the definition of nanomaterial 2022/C 229/01 (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).

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).

experience of stakeholders with the 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}. It also takes into account of relevant developments in standardisation by the International Organization for Standardization (ISO) and the European Committee for Standardisation (CEN), of the results of the NanoDefine project of the Commission's 7th Framework Programme for Research¹⁰, and of 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"'¹¹.

- (3) 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 the latest technical and scientific updates in this area.
- (4) Experience with the current definition of engineered nanomaterial has shown difficulties in its implementation for both food business operators and enforcement authorities, as it allows for different interpretations as to whether a material is intentionally produced to be an engineered nanomaterial. The implementation of the current definition was hindered also by the lack of a default threshold value of particles with external dimensions in the nanoscale. It is therefore appropriate that the definition of engineered nanomaterial 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 and would therefore be considered as an engineered nanomaterial.
- (5) The technical and scientific elements underpinning the nanomaterial definition contained in Recommendation 2022/C 229/01 did not provide scientific evidence that the default threshold of 50% of particles with external dimensions at the nanoscale pursuant to Recommendation 2011/696/EU should be changed. It is therefore appropriate that this default threshold is included in the definition of engineered nanomaterial to ensure regulatory consistency and coherence, to avoid the possibility that a specific material could be 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 the economic operators, consumers, and enforcement authorities.
- (6) Since the definition laid down in Regulation (EU) 2015/2283 refers to engineered nanomaterials and not to natural and/or incidental nanomaterials, only manufactured materials consisting of at least 50% of particles in the nanoscale should be included in that definition.
- (7) For the purposes of defining engineered nanomaterials, and to address the inherent subjectivity of the current definition in interpreting whether a material is intentionally produced to be an engineered nanomaterial or not, the term 'manufactured' should be included in the definition to refer to materials produced, synthesised or generated from physical/mechanical, and/or biological, and/or chemical processing, formulation and/or transformation of raw and/or starting materials.

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 The NanoDefine Methods Manual; EUR 29876 EN; doi:10.2760/79490 (2020).

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- (8) 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 the practical implementation of the definition within the context of Regulation (EU) 2015/2283. Its implementation should be supported, where applicable, by the guidance prepared by the European Commission Joint Research Centre ('JRC') in the context of the implementation of the definition of Recommendation 2022/C 229/01¹², and by the guidance of the European Food Safety Authority ('the Authority') on the risk assessment of the application of nanoscience and nanotechnologies in food and feed: human and animal health¹³. These guidance documents may be further updated as a result of the evolving scientific and technical progress.
- (9) The definition of 'engineered nanomaterial' 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 'identifiable' qualifier is bound by practical considerations pertaining to their identification.
- (10) The term 'particle' should be defined as a minute piece of matter with defined physical boundaries in line with the definition of 'particle' adopted in ISO 26824:2022.
- (11) As the external dimension of the constituent particles of a material is the only common feature of all nanomaterials, the definition of engineered nanomaterial 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.
- (12) 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'.
- (13) Recommendation 2022/C 229/01 refers to materials consisting of particles in solid state. It is therefore appropriate that the definition of engineered nanomaterial would also refer to materials consisting of particles in solid state to exclude particles with highly dynamic external dimensions such as micelles, liposomes, or nanoscale droplets in emulsions.
- (14) The NanoDefine¹⁴ project demonstrated that, in a broad range of materials tested, there were no inconsistencies in classification of non-nanomaterials, based on the median value determined from the particle number-based size distributions and on the volume specific surface area being less than $6 \text{ m}^2/\text{cm}^3$ (even if particle shape is unknown), respectively. Therefore, a material with a volume specific surface area less than $6 \text{ m}^2/\text{cm}^3$ should not be considered an engineered nanomaterial.
- (15) In its guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health, the Authority stated that materials should be also considered on the basis of their solubility and/or dissolution/degradation properties

¹² Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial EUR 31452 EN, doi.org/10.2760/143118.

¹³ 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).

¹⁴ NanoDefine, "Evaluation report on the applicability ranges of the volume specific surface area (VSSA) method and the quantitative relation to particle number-based size distribution for real world samples, Deliverable number 3.5, 2015 and Reliable nanomaterial classification of powders using volume-specific surface area method", J. Nanopart. Res. 19, 61 (2017); DOI: 10.1007/s11051-017-3741-x.

and not solely on the basis of their physical form. 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 thresholds above which materials should not be considered to be nanomaterials. It is therefore appropriate that materials which exhibit solubility and/or dissolution/degradation properties, measured according to the approach and technical elements set out by the Authority Guidance, below the thresholds established by the Authority, should not be considered engineered nanomaterials.

- (16) Transitional measures should be laid down with regard to the definition of engineered nanomaterial set out in this Regulation, in order to limit the administrative burden and to provide business operators with sufficient time to comply with the requirements of this Regulation.
- (17) Regulation (EU) 2015/2283 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

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

‘(f)

(1) ‘Engineered nanomaterial’ means a manufactured material consisting of solid 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 shall not be considered.

- (2) For the purposes of point (1), the following apply:
- (a) ‘manufactured material’ means a material produced, synthesised or generated from physical/mechanical, and/or biological and/or chemical processing, and/or formulation, and/or transformation, of raw and/or starting materials;
 - (b) ‘particle’ means a minute piece of matter with defined physical boundaries. Single molecules are not considered ‘particles’;
 - (c) ‘aggregate’ means a particle comprising of strongly bound or fused particles;
 - (d) ‘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 shall not be considered an engineered nanomaterial.’

Article 2

Foods falling within the scope of the definition of engineered nanomaterials, as amended by this Regulation that were lawfully placed on the market before entry into force of this Regulation, may continue to be placed on the market until [18 months following the entry of this Regulation] and may remain on the market until their date of minimum durability or use by date.

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