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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 14.3.2024 amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of 'engineered nanomaterials'

Delegations will find attached document C(2024) 1612.

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COMMISSION DELEGATED REGULATION (EU) …/...

of 14.3.2024

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 3(2)(f) of Regulation (EU) 2015/2283 of the European Parliament and Council on novel foods[1], provides for a definition of engineered nanomaterials, taking into account the possibility of food consisting of engineered nanomaterials being a novel food. This definition is also referred to in Article 2(1), point (h), of Regulation (EU) No 1169/2011 of the European Parliament and of the Council[2] on the provision of food information to consumers, as it is appropriate to inform consumers of the presence of engineered nanomaterials in food. Article 18 of that Regulation requires that all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

According to Article 31 of Regulation (EU) 2015/2283 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 229/01[3] 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 the 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 and assist in the preparation of the 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.

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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)]

The European Parliament and the Council were duly informed.

The Commission also consulted stakeholders and the public during a 6-week period between 30 November 2023 and 12 January 2024, via the feedback/consultation mechanism foreseen under the better regulation for delegated acts.

In total, the Commission received 2.503 contributions. Of these, 2.417 contributions came from private citizens and 86 contributions from professional associations, consumer organisations, non-governmental organisations, companies, labour unions, entities from non-EU states, and public authorities.

The citizen responses referred to the use of nanomaterials in food in general. They called for the inclusion in the scope of the definition of all materials that may contain particles in the nanoscale and to apply the precautionary principle in the management of nanomaterials so as to limit or even outright prohibit their use in foods.

The reflections and work on the revision of the current definition of 'engineered nanomaterial' of Regulation EU 2015/2283 of the Commission and of the Member State Expert Group that assisted in the work and preparation of this Delegated Regulation, distinguished, on one hand, the need to provide for a definition on the basis of physical/chemical characteristics of a given material, and on the other, the need to ensure that all materials, both those that are defined as engineered nanomaterials and those that are not but may contain small particles including nanoparticles, are properly and fully assessed for safety, and any identified risks are managed accordingly and taking into account, when necessary, the precautionary principle. Thus, although the definition of a material as an 'engineered nanomaterial' is ultimately linked to its risk assessment and management, risk assessment and management elements cannot be included in the definition itself.

The positions of stakeholders other than private citizens can be roughly divided into two groups.

One group comprising mainly of non-government consumer and environmental organisations, labour unions, academic organisations, and public authorities, while recognising that the revision is a step in the right direction, advocated for a definition that would include all materials, be they manufactured, incidental or natural, and a default threshold of 10% or more of particles in the number-based size distribution with external dimensions in the nanoscale (less than 100 nanometres) for it to be defined as an engineered nanomaterial, as opposed to only manufactured materials consisting of 50% of more of particles in the number-based size distribution with external dimensions in the nanoscale (less than 100 nanometres) proposed in the definition of this Delegated Regulation.

There are regulatory, technical, and scientific reasons supporting the inclusion in the revised engineered nanomaterials definition of only 'manufactured' materials and of the default threshold value of 50% or more particles in the number-based size distribution with external dimensions in the nanoscale. Regulation (EU) 2015/2283 clearly refers to 'engineered nanomaterials', a term that inherently pre-supposes the manufacturing of a material by human activities and excludes naturally or incidentally occurring materials. Thus, it is not possible in the context of the 'engineered nanomaterial' definition of Regulation (EU) 2015/2283 to include naturally or incidentally occurring nanomaterials.

Concerning the setting of a default threshold in the content of particles with external dimensions in the nanoscale for a material to be defined as an 'engineered

nanomaterial', the setting of a default threshold of 50% or more of particles in the number-based size distribution with external dimensions in the nanoscale, not only entails that the majority of the particles must be in the nanoscale in order for a material to be defined as an 'engineered nanomaterial' but is also pertinent from the analytical and enforcement point of view.

According to the technical experts from the Member States who assisted the Commission in the preparation of this Delegated Regulation, the analytical identification and characterisation of materials consisting of 50% or more of particles in the number-based size distribution with external dimensions in the nanoscale is routinely feasible. On the other hand, in their view, the analytical identification and characterisation of materials containing 10% or more of particles in the number-based size distribution with external dimensions below 100 nm, is not always possible with today's methodologies, and in those rare situations that analyses are possible, they are cumbersome and may deliver dubious and equivocal results.

In addition, aligning to the extent possible the definition of 'engineered nanomaterials of Regulation (EU) 2015/2283 with the general definition of nanomaterials of Commission Recommendation 2022/C 229/01 will help ensure regulatory consistency and coherence, will avoid the possibility that a specific material could be considered a nanomaterial under one regulatory framework but not under another, and will provide objectivity and clarity in the implementation of the definition of engineered nanomaterial for the economic operators, consumers, and enforcement authorities.

The second group of stakeholders other than private citizens, comprising of industry associations and individual companies, that contributed to the feedback/consultation, while recognising that the revised definition is indeed a step towards regulatory consistency, voiced concerns as to the implications of the revised definition and its effect on the definition of novel foods, in particular by the removal from the definition of the 'intentionally produced' element.

The revised definition addresses the issue of subjectivity in determining the 'intentionality' in the manufacturing of nanomaterials of the current definition by combining the inclusion of only manufactured materials, with a definition of what constitutes manufactured material, which presupposes that the material was intentionally produced, and with default threshold value of 50% or more of particles in the number-based size distribution with external dimensions in the nanoscale. Thus, the definition is effectively introducing objective elements to determine whether a material is an intentionally manufactured 'engineered nanomaterial' as it becomes technically and scientifically difficult, if not impossible, to argue that a manufactured material consisting of more than 50% nanoparticles in the number-based size distribution is not a 'engineered nanomaterial'.

In addition, this second group of stakeholders considered that the removal of the 'intentionally manufactured' in the revised definition has a wider scope and alters the novel food definition of Article 3(2)(a) of Regulation (EU) 2015/2283 and as a result, a number of materials currently placed on the market will be defined as 'engineered nanomaterials' and this automatically will also define them as novel foods requiring a novel food authorisation under Regulation (EU) 2015/2283.

The Commission clarifies that Article 3(2)(a) of the Regulation (EU) 2015/2283 lays down cumulative conditions for a food to qualify as 'novel food'. First, the food was not used for human consumption to a significant degree within the Union before 15

May 1997 and, in addition, food must fall under at least one of the categories set out in points (i) to (x) of that Article. Therefore, amending the definition of engineered nanomaterial laid down in Regulation (EU) 2015/2283 will not affect the novelty of foods placed on the market before 15 May 1997.

The relevant stakeholders did not offer concrete examples in support of their claims that currently legally marketed non-novel foods would be affected by the new definition laid down in this Regulation and will therefore require an authorisation to be marketed upon the application of this Regulation. However, to pro-actively address such cases should they arise, appropriate transitional measures laid down in this Regulation also cover any affected foods that are currently legally marketed.

Finally, that group of stakeholders also considered that in addition to high solubility and/or dissolution/degradation rate values in water used in this Regulation to exclude materials from the definition of engineered nanomaterials, solubility and/or dissolution/degradation rates in simulated gastric juices should also be included in the definition for the same purpose. According to the views of the technical experts from the Member States who assisted the Commission in the preparation of this Delegated Regulation, the methods for water solubility and/or dissolution/degradation rates of materials are straightforward, standardised, and objective and therefore suitable for the proper implementation and enforcement of the definition of this Regulation, whereas the methods to measure solubility and/or dissolution/degradation rates in simulated gastric juices and/or other media pose technical and analytical challenges with dubious and ambiguous results that would hinder the proper implementation and enforcement of the definition of this Regulation.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is adopted pursuant to Article 31 of Regulation (EU) 2015/2283 which empowers the Commission to adjust and adapt the definition of engineered nanomaterials referred to in point (f) of Article 3(2) to technical and scientific progress or to definitions agreed at international level.

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 Commission Recommendation 2022/C 229/01 which was underpinned by the European Commission Joint Research Centre's Science for Policy Reports "Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Parts 1, 2, and 3 on the 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, 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[4], 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.

In this respect the definition of 'engineered nanomaterial' of this Delegated Regulation includes adaptations in line with technical and scientific progress as

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

regards the size limit (< 100 nm) below which a material would be considered as a nanomaterial, the provisions on its applicability taking into account the external dimension and shape of the material, the exclusion from the definition of single molecules and materials with a surface to volume ratio below a certain value, the definitions of 'particle', 'aggregate' and 'agglomerate', the inclusion of only materials in solid state to exclude particles with highly dynamic external dimensions such as micelles, liposomes, or nanoscale droplets in emulsions, and the default threshold value of 50% of particles being at the nanoscale for a material to be considered a nanomaterial.

In addition, using technical elements from the EFSA risk assessment guidance documents on nanotechnology[5,6], it will be possible in line with technical and scientific progress to include or exclude materials from the scope of the definition, on the basis of their water solubility and/or dissolution/degradation properties.

At the same time, the adapted definition of 'engineered nanomaterial' will keep elements of the existing definition. It will include manufactured materials only in line with the concept of 'engineered nanomaterial', which entails the making of such materials as opposed to natural or incidental materials. 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.

The possible consequence for foods currently lawfully placed on the market that will fall within the scope of revised definition of 'engineered nanomaterial' of Regulation EU 2015/2283, will be that they will need to be labelled as 'nano' according to the provisions of Article 18 of Regulation (EU) 1169/2011. Regulation (EU) 1169/2011 applies to both, novel foods and foods that have been consumed to a significant degree by humans in the Union before 15 May 1997. In order to ensure a smooth transition to the rules of this Regulation, the Commission provides in the delegated act appropriate transitional measures in this respect and in respect of, any non-novel foods that are currently lawfully placed on the market, of authorised novel foods or of foods for which the authorisation procedures under the Regulation (EU) 2015/2283 will not be concluded before the application of this Regulation, and which will fall under the new definition of nanomaterials.

Besides the fact that this Regulation is not included in the Commission Work Programme, is it is not expected to have significant economic, environmental or social impacts to have warranted an impact assessment. Information available to the Commission of the situation in the marketplace[7,8,9,10,11] has indicated that the number of materials used in foods that may contain a certain fraction of nanoparticles is

5 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).

6 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).

7 Nanomatériaux dans les produits destinés à l'alimentation. Avis de l'Anses – Rapport d'expertise collective. Mai 2020 https://www.anses.fr/fr/system/files/ERCA2016SA0226Ra.pdf.

8 Résultats détaillés tests de produits (veillenanos.fr).

9 Nanoparticelle di additivi negli alimenti. Chiediamo il bando dell'E171 | Altroconsumo.

10 Nanoparticules dissimulées - 9 plaintes de l'UFC-Que Choisir contre des fabricants de produits alimentaires et de cosmétiques - Action UFC-Que Choisir - UFC-Que Choisir.

11 Testsanté 151. Nanomatériaux: partout sans qu'on le sache. June 2019.

limited and most if not all of these are materials are not novel. Thus, the main consequence of the revised definition of this Regulation might be that several more foods would need to be labelled according to the provisions of Regulation (EU) 1169/2011 if they are manufactured to consist of 50% nanoparticles in in the number-based size distribution. Similarly, with the exception of one material that was authorised as an 'engineered nanomaterial' novel food in 2022[12], few, if any, recently authorised foods and few foods for which applications for their authorisation have been submitted are manufactured solid materials that contain a fraction of particles in the nanoscale.

The potential impacts of the delegated act will therefore only concern a very limited number of materials and therefore a limited number of food business operators. In view of that, the impact assessment in this regard would only cause undue delay in the adaptation of the definition of engineered nanomaterials to the scientific and technical progress.

Finally, as regards the content of this Regulation, the Commission's margin of discretion was limited by the scope of the power of delegation conferred to it by the co-legislators to adapt the definition of 'engineered nanomaterials' referred to in point (f) of Article 3(2) of Regulation (EU) 2015/2283 to scientific and technical progress and to definitions agreed at international level. Thus, the revision was largely based on the technical and scientific elements that underpinned the revision of the nanomaterial definition of Commission Recommendation 2022/C 229/01 and as a result that definition is essentially transposed to the extent possible in this Regulation.

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.

[12] Commission Implementing Regulation (EU) 2022/1373 of 5 August 2022 authorising the placing on the market of iron hydroxide adipate tartrate as a novel food and amending Regulation (EU) 2017/2470 (OJ L 206, 8.8.2022, p. 28).

COMMISSION DELEGATED REGULATION (EU) …/...

of 14.3.2024

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 1852/2001[1], and in particular Article 31 thereof,

Whereas:

(1) Taking into account the possibility of food consisting of engineered nanomaterials being a novel food, 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 Council[2] refers to the definition of 'engineered nanomaterials' as established by point (f) of Article 3(2) of Regulation (EU) 2015/2283, in order to inform consumers of the presence of engineered nanomaterials in food.

(2) On 10 June 2022, Commission Recommendation 2022/C 229/01[3] was adopted, updating the definition of nanomaterial set out in Commission Recommendation 2011/696/EU[4], 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 for Policy Reports "Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Parts 1[5], 2[6], and 3[7] 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).

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 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[10], 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"[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, a description of the term 'manufactured' should be included in the definition to introduce existing objective technical elements that encompass the processes of manufacturing nanomaterials

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

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

which are produced, synthesised or generated by physical/mechanical, and/or biological, and/or chemical processing, formulation and/or transformation of raw and/or starting materials.

(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 in Recommendation 2022/C 229/01[12], by the guidance documents of the European Food Safety Authority ('the Authority') on the risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health[13] and on technical requirements for regulated food and feed applications to establish the presence of small particles including nanoparticles[14]. 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 NanoDefine[15] project demonstrated that, in a broad range of materials tested, there were no inconsistencies in classification of non-nanomaterials, based on the median

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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). https://doi.org/10.2903/j.efsa.2021.6768

14 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 https://doi.org/10.2903/j.efsa.2021.6769.

15 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, Wohlleben, W., Mielke, J., Bianchin, A. *et al.* Reliable

value determined from the particle number-based size distributions and on the volume specific surface area being less than 6 m^2/cm^3 (even if particle shape is unknown), respectively. Therefore, a material with a volume specific surface area less than 6 m^2/cm^3 should not be considered a nanomaterial.

(15) In its guidance documents on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health, and on technical requirements for regulated food and feed applications to establish the presence of small particles including nanoparticles, the Authority stated that materials should be also considered on the basis of their solubility and/or dissolution/degradation properties in water and not solely on the basis of their physical form. The Authority also identified flexible approaches, and the technical conditions that allow for a proper evaluation of the solubility and/or dissolution/degradation properties of materials in water 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 in water, measured according to the approach and technical elements set out by the Authority guidance documents, above the thresholds established by the Authority, should not be considered engineered nanomaterials.

(16) In order to provide business operators with sufficient time to comply with the requirements of this Regulation, the applicability of this Regulation should be deferred. Transitional measures for foods lawfully placed on the market and labelled before the date of application of this Regulation should be also provided in order to avoid any unnecessary food waste. Furthermore, a food lawfully placed on the market before the date of application of this Regulation and which falls within the scope of this Regulation, should in principle be allowed to continue to be placed on the market until the risk assessment and authorization procedures taking into account the definition laid down in this Regulation, have been concluded. The applications under Regulation (EU) 2015/2283 for foods falling within the scope of this Regulation for which a final decision has not been taken before the date of application of this Regulation, should be updated by the applicant in order to allow for appropriate risk assessment. Therefore, transitional provisions should be laid down to ensure a smooth transition to the application of the definition laid down in this Regulation.

(17) Regulation (EU) 2015/2283 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment of the definition of the engineered nanomaterial

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:

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nanomaterial classification of powders using the volume-specific surface area method. *J Nanopart Res* **19**, 61 (2017). https://doi.org/10.1007/s11051-017-3741-x.

(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 manufactured material with a specific surface area by volume of < 6 m^2/cm^3, and/or with high solubility and/or dissolution/degradation rate values in water as determined using the thresholds andmethodologies identified by the Authority shall not be considered an engineered nanomaterial.'

Article 2

Transitional measures

Foods lawfully placed on the market or labelled prior to [the date of application of this Regulation], which fall within the scope of this Regulation may be marketed until their date of minimum durability or use by date.

Authorised novel foods that were lawfully placed on the market before [the date of application of this Regulation] and fall within the scope of this Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 of the Regulation (EU) 2015/2283 following an application for authorization of novel food submitted no later than [24 months after the date of application of this Regulation].

The applications submitted under Regulation (EU) 2015/2283 for which a final decision has not been taken before [the date of application of this Regulation] and which concern food falling within the scope of this Regulation, shall be updated by the applicant no later than [24 months after the date of application of this Regulation].

Article 3

Entry into force and application

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 *[18 months following the entry into force of this Regulation]*.

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

Done at Brussels, 14.3.2024

For the Commission
The President
Ursula VON DER LEYEN