EUROPEAN
COMMISSION

Brussels, 4.2.2026
COM(2026) 60 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the delegation conferred to the Commission pursuant to Article 31 of Regulation (EU) 2015/2283 on novel foods

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1. INTRODUCTION

This report meets the obligation set for the Commission by Article 32(3) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods[1] ('the Novel Foods Regulation'). The Novel Foods Regulation establishes the general principles, requirements and responsibilities governing the authorisation of novel foods on the Union market, ensuring the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

Article 31 of the Novel Foods Regulation empowers the Commission to adopt delegated acts 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.

2. LEGAL BASIS

According to Article 32(3) of the Novel Foods Regulation, the power to adopt delegated acts under Article 31 was conferred on the Commission for an initial period of 5 years from 31 December 2015. The Commission was tasked to present a report on the exercise of the delegation of power conferred by the Novel Foods Regulation no later than 9 months before the end of the 5-year period. The delegation of power was to be extended tacitly for periods of 5 years, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

3. EXERCISE OF THE DELEGATION

In the exercise of the delegation conferred by Article 31 of the Novel Foods Regulation, the Commission has taken steps to adopt a delegated act to adjust and adapt the definition of engineered nanomaterials.

Point (f) of Article 3(2) of the Novel Foods Regulation defines 'engineered nanomaterial' as

> '*any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less,*

[1] 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. OJ L 327, 11.12.2015, p. 1.

including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

Properties that are characteristic of the nanoscale include:

(i) those related to the large specific surface area of the materials considered; and/or

(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.'

This definition built on a Commission Recommendation of 18 October 2011[2] that had introduced a definition of nanomaterial.

Subsequently, on 10 June 2022, a new Commission Recommendation on the definition of nanomaterials ('the Commission Recommendation') was adopted based on state-of-the-art technical and scientific developments[3]. The Commission Recommendation was the result of a thorough review[4] and a targeted stakeholder consultation[5] [6].

Taking into account the revised definition introduced by the Commission Recommendation, and its call to align existing legislation accordingly, since October 2022 a Commission Expert Group[7] composed of national experts assisted the Commission in preparing a delegated act to adjust and adapt the definition of engineered nanomaterials for the needs of the Novel Foods Regulation. In that work, the EFSA "Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health"[8], adopted on 30 June 2021 and published on 3 August 2021, was taken into account. It was also essential to draw on the experience of the stakeholders in order to identify practical issues related to the definition of

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

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

[4] Commission's Joint Research Centre's (JRC) Science for Policy reports:
- '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).
- '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).
- '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:10.2788/678452 (2015).

JRC reports:
- 'An overview of concepts and terms used in the European Commission's definition of nanomaterial'. EUR 29647 EN; doi:10.2760/459136 (2019).
- 'Identification of nanomaterials through measurements'. EUR 29942 EN; doi:10.2760/053982 (2019).

[5] The targeted stakeholder consultation run between 6 May and 30 June 2021.

[6] The results of the review and the stakeholder consultation are explained in the Commission staff working document (SWD(2022)150) accompanying the Commission Recommendation.

[7] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&do=groupDetail.groupDetail&groupID=3560&Lang=EN

[8] https://www.efsa.europa.eu/en/efsajournal/pub/6768

engineered nanomaterials, and their feedback was notably sought alongside the consultation that took place between 30 November 2023 and 12 January 2024[9].

The Commission adopted a delegated regulation amending the Novel Foods Regulation as regards the definition of 'engineered nanomaterials' ('the Commission delegated regulation') on 14 March 2024[10]. It aimed at ensuring the coherence of the definition of engineered nanomaterials in the EU regulatory framework, and at addressing the issues identified in the implementation of the definition of 'engineered nanomaterials' in the Novel Foods Regulation for the purposes of achieving the objectives of that Regulation. To do so, the Commission delegated regulation incorporated the main technical elements of the general definition of engineered nanomaterials established in the Commission Recommendation, that included state-of-the-art technical and scientific developments. In particular, the amended definition included the size limit (< 100 nm), the exclusion from the definition of materials with a surface to volume ratio below 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.

In line with procedure for adopting delegated acts, the Commission delegated regulation was sent for scrutiny to the European Parliament and Council. On 24 April 2024, the European Parliament objected to the Commission delegated regulation[11]. In its objection, the European Parliament argued that the Commission delegated regulation was not compatible with the aim and the content of the Novel Foods Regulation and exceeded the delegated powers conferred by Article 31 of that Regulation. On 29 August 2024, the Commission responded officially to the European Parliament's objection[12]. In view of that objection, the Commission delegated regulation did not enter into force. The definition of 'engineered nanomaterial' of point (f) of Article 3(2) of the Novel Foods Regulation therefore remains unchanged.

4. CONCLUSION

The Commission has over the past years taken steps to exercise the delegated powers conferred to it under Article 31 of the Novel Foods Regulation. The Commission sees the need to extend the empowerment because it is essential to ensure that the definition of engineered

[9] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14049-Revision-of-the-definition-of-engineered-nanomaterial-in-food_en

[10] 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'. C(2024) 1612 final.
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:C(2024)1612

[11] Objection to a delegated act: Novel foods - the definition of 'engineered nanomaterials'. European Parliament resolution of 24 April 2024 on the Commission delegated regulation of 14 March 2024 amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of 'engineered nanomaterials'. C(2024)01612 – 2024/2691(DEA).
https://www.europarl.europa.eu/doceo/document/TA-9-2024-0316_EN.pdf

[12] Document SP(2024)399. Follow up to the European Parliament non-legislative resolution on the Commission delegated regulation of 14 March 2024 amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of 'engineered nanomaterials'.
https://oeil.secure.europarl.europa.eu/oeil/en/procedure-file?reference=2024/2691(DEA)

nanomaterials referred to in point (f) of Article 3(2) of the Novel Foods Regulation is adapted to technical and scientific progress or to definitions agreed at international level. This technical alignment is fundamental to guarantee the level playing field on internal market while providing a high level of protection of human health and consumers' interests, which are the purposes of the Novel Foods Regulation. With the continuation of the *status quo,* materials that should be defined as 'engineered nanomaterials' will continue not being defined as such, thereby depriving consumers from receiving the necessary information about their presence in products.

With this report the Commission complies with the reporting requirement under Article 32(3) of the Novel Foods Regulation and invites the European Parliament and the Council to take note of this report.