



NOTIFICATION

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| 1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved: |
| 2. Agency responsible: European Commission, Health and Food Safety Directorate-General |
| 3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Novel foods |
| 4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries: |
| 5. Title of the notified document: Draft Commission Delegated Regulation 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). Language(s): English, French and Spanish. Number of pages: 7 https://members.wto.org/crnattachments/2024/SPS/EEC/24_02425_00_e.pdf https://members.wto.org/crnattachments/2024/SPS/EEC/24_02425_00_f.pdf https://members.wto.org/crnattachments/2024/SPS/EEC/24_02425_00_s.pdf |
| 6. Description of content: The measure updates the definition of 'engineered nanomaterials' of Regulation (EU) 2015/2263 on novel foods in line with technical and scientific progress. The measure transposes the main elements of the general nanomaterial definition of Commission Recommendation 2022/C 229/01 which is in turn underpinned by extensive technical and scientific elements and developments. The act maintains the current definition size limit (< 100 nm) below which a material would be considered as a nanomaterial; 2) introduces a default threshold value of 50% of particles (by number) being at the nanoscale for a material to be considered a nanomaterial; 3) includes provisions on its applicability taking into account the external dimension and shape of the material; 4) excludes from the definition single molecules and materials with a surface to volume ratio below a certain value; 5) defines the terms 'particle', 'aggregate' and 'agglomerate'; and 6) includes only materials in solid state to exclude particles with highly dynamic external dimensions such as micelles, liposomes, or nanoscale droplets in emulsions. In addition, the Regulation includes elements specifically aimed to address the subjectivity elements in interpreting the 'intentionally produced' notion of the current definition which have hampered its implementation. |
| 7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests. |

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| <p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p> |
| <p>9. Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> - Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial https://publications.jrc.ec.europa.eu/repository/handle/JRC132102 - Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health https://www.efsa.europa.eu/en/efsajournal/pub/6768 - Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6769 |
| <p>10. Proposed date of adoption (dd/mm/yy): 11 June 2024</p> <p>Proposed date of publication (dd/mm/yy): 12 June 2024</p> |
| <p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 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.</p> <p><input type="checkbox"/> Trade facilitating measure</p> |
| <p>12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 3 June 2024</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p> |
| <p>13. Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p> |