



The Revision of the 'engineered nanomaterial' definition of the Novel Food Regulation (EU) 2015/2283

PLENARY MEETING OF THE ADVISORY GROUP ON
SUSTAINABILITY OF FOOD SYSTEMS

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Setting the stage

Definition of Article 3(2)(f) of Regulation (EU) 2015/2283

'engineered nanomaterial' means 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, 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*
- Specific physico-chemical properties that are different from those of the non-nanoform of the same material*

Revision of the definition (Article 31 of Regulation (EU) 2015/2283)

For the purposes of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts adopted in accordance with Article 32, 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.

Basis for the revision of the 'engineered nanomaterial' definition - 1

- Regulatory/Technical/Scientific
 - Revision of 'general' nanomaterial definition (Commission Recommendation C(2022)3869)
 - Commission Staff Working document accompanying Recommendation C(2022)3869
 - EFSA guidance on RA of nanomaterials and guidance on materials containing small particles, including nanoparticles
 - The Joint Research Centre work and reports on the revision, terms and implementation of the 'general' definition of 2011
 - EU research projects (e.g. NonoDefine)



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Nanomaterial definition of Recommendation C(2022)3689

- *Nanomaterial' means a **natural, incidental or 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*
- *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.*
- *However, a material with a specific surface area by volume of $< 6 \text{ m}^2/\text{cm}^3$ shall not be considered a nanomaterial.*



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Basis for the revision of the 'engineered nanomaterial' definition - 2

- **Experience with the current definition**
 - Notion of 'intentionality' in the manufacture of a nanomaterial and its linkage to a specific nano-enabled function
 - Not many examples – One nanomaterial fitting the definition authorised as NF
 - Lack of threshold in the definition



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Basis for the revision of the 'engineered nanomaterial' definition - 3

- *Recognition of link between nanomaterial definition (or not) and safety – Need to ensure safety of all materials*
- *Dual, pragmatic approach to ensure that materials are assessed in a manner appropriate to their nature and according to the respective guidances:*
 - Defined as 'engineered nanomaterials' according to the Novel Food definition, and
 - Not defined as such but which may contain small particles, including nanoparticles,
- *Applicants of regulated food products and EFSA operate on this basis*



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Basis for the revision of the 'engineered nanomaterial' definition - 4

Technically, the definition aims to define in chemical and physicochemical terms whether a material as a nanomaterial (or not).

In practice, as this definition is linked to a specific Regulations, it has repercussions in terms of

- Risk assessment and safety
- Labelling of food products (FIC Regulation)
- Public perception
- Thereby establishing a *de facto* linkage between the definition and Risk assessment/safety!!



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Way forward

- Define/identify, assess and manage risks of all (nano)materials in a manner proportionate to their nature and behaviour in biological systems.
- Inform consumers of the presence and risks of nanomaterials in foods.
- Strike a balance between regulatory constraints on one hand and on the other the non-rigid (in terms of size, distribution, levels, etc.) behaviour of materials containing nanoparticles in biological systems.
- Avoid 'over' and 'under' defining
- Ensure proper functioning of the market in terms of innovation, placing products in the market, and enforcement.

Commission Expert Group on Nanomaterials in Food

- Assist in the preparation of the delegated act on the revision of the “engineered” nanomaterial definition of Regulation (EU) 2015/2283
- 1st meeting 13 October 2013
- Transparent and engaging process - Formal and informal consultations with stakeholders and civil society
- Aim is to have the delegated act by end of 2023

- Thank you!!!
- https://food.ec.europa.eu/safety/novel-food/nanomaterials_en