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

17 November 2023

Takis Daskaleros, Ph.D.
European Commission,
DG Health and Food Safety,
Unit E2 "Food processing technologies and novel foods

The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission

European Commission

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*

European Commission

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
  - Revised of 'general' nanomaterial definition (Commission Recommendation 2022/C 229/01
  - Commission Staff Working document accompanying Recommendation 2022/C 229/01
  - 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)

Nanomaterial definition of Recommendation 2022/C 229/01

- *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 m2/cm3 shall not be considered a nanomaterial.*

European Commission

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

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

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!!

Objectives of the revision

- Ensure regulatory consistency, high level of safety, proper functioning of the market in terms of innovation, placing products in the market, and enforcement.

- Assess and manage risks of engineered nanomaterials,

- Inform consumers of the presence and risks of nanomaterials in foods.

- Strike a balance between regulatory constraints and on the other the non-rigid (in terms of size, distribution, levels, solubility, etc.) behaviour of materials in biological systems.

- Avoid ‘over’ and ‘under’ defining

European Commission

Commission Expert Group on Nanomaterials in Food

- Preparation of the delegated act on the revision of the “engineered’ nanomaterial definition of Regulation (EU) 2015/2283
- Four meetings in 2022 and 2023
- Draft act undergoing internal Commission scrutiny
- Feedback mechanism consultation foreseen to be launched shortly
- Aim is to have the delegated act by early 2024

Health and Food Safety

European Commission

- Thank you!!!

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

Health and Food Safety