



STATE OF PLAY REGARDING NANOMATERIALS

**PLENARY MEETING OF THE ADVISORY GROUP ON THE FOOD
CHAIN AND ANIMAL AND PLANT HEALTH
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DG SANTE, Unit E2 – Food Processing Technologies and Novel Foods
Food Contact Materials**

Nanomaterials in the EU

Nanomaterial definitions in EU Food legislation (Novel Food, Food Information to Consumers (Food Additives) stemming from the Definition of Commission Recommendation 2011/696/EU

Some differences (e.g. intentionally produced, number size distribution)

No definition of nanomaterials in Food Contact Material legislation – direct reliance on Commission Recommendation definition



Nanomaterials in NOVEL FOODS (Regulation (EU) 2015/2283)

Definition of Engineered nanomaterial (**Art 3, (f)**)

intentionally produced material that has

either one or more dimensions of the order of 100 nm or less

or composed of discrete functional parts, with one or more dimensions of the order of 100 nm or less either internally or at the surface,

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.



Nanomaterials in Food Information to Consumers (incl. Food ingredients, Food Additives) (FA)(Regulation (EU) No 1169/2011)

Definition (**Art. 2(2)(t)**):

Definition of 'engineered nanomaterial' same as in the Novel Food Regulation

*Labelling requirements using term 'nano' to follow in brackets after the name of the food ingredient (**art.18(3)**)*

*Commission to adjust/adapt definition to technical and scientific progress or to definitions agreed internationally (**recital 39, Article 31**)*

Nanomaterials Foods – Developments, Needs and Challenges

Definition Implementation issues

- Analytical work in some MS in the area of Food Additives
- Notion of 'intentionality' difficult to document/implement
- Use of terms 'manufactured' rather than 'engineered'
- Use of a % thresholds identified in the materials versus no % thresholds in the definition

Delegated act under the Novel Food Regulation to be based on the revision of 2011/609/EU

Risk Assessment methodologies and Guidance (EFSA guidance being developed)

Analytical tools (needed) for Risk Assessment and Enforcement

- Identification and characterisation method development and validation
- Reference materials
- Reference/appropriate food matrices
- Laboratory capacity for enforcement



Nanomaterials in Foods – Developments

Update of definition

- **Revision of the 'general definition' of Commission Recommendation 2011/696/EU (led by DG EN)**
Revision work is to resume soon
- **Work on revision of NF definition via delegated act to start once revised general definition work is completed**

Enforcement

JRC technical support on methods and analyses – SANTE/JRC agreement

Possible CEN activity on nano in foods

Risk Assessment

EFSA revised guidance on the risk assessment of nanomaterials (2018)

EFSA draft guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles



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Thank you!