



STATE OF PLAY REGARDING NANOMATERIALS

**PLENARY MEETING OF THE ADVISORY GROUP ON THE FOOD
CHAIN AND ANIMAL AND PLANT HEALTH
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Food Contact Materials**

Nanomaterials in the EU

General considerations

Principles

EU Food and Food Contact Material Legislation

- **Novel Foods**
- **Food Contact Materials**
- **Food Information to Consumers/Food Additives**
- **Developments**

Nanomaterials in the EU

EU only region in the world having provisions for nanotechnology and nanomaterials in its legislation

Nanomaterials in Food and Food Contact Materials (FCM)

EU Food and Food contact Legislation

- **Novel Foods**
- **Food Contact Materials (incl. Active and Intelligent Materials)**
- **Food information to Consumers (impacts Food Additives)**

EU Non-food legislation

- **Specific provisions: Cosmetics, Biocidal products, Reference to nano: REACH, Medical Devices**

Nanomaterials in the EU

Principles

- **Framework for proper functioning of the internal market and a high level of health protection**
- **Science based, workable definition**
- **State of the art risk assessment approaches**
- **Consistent application across pieces of legislations**
- **Ensuring proper enforcement**
- **Transparency**

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

Revision/adaptation of Commission Recommendation 2011/696/EU ongoing



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

- Foods consisting of engineered nanomaterials should be considered as Novel Food (**recital 10, Art. 3(2)(viii)**)
- Vitamins, minerals or other substances containing or consisting of engineered nanomaterials should also be considered novel foods (**recital 12, Art. 3(2)(ix)**)
- Food consisting of engineered nanomaterials should be assessed using the most up-to-date test methods to assess their safety and specific methods applicable to them may be needed (**recitals 23, 24, 25, Article 10.4**)
- Commission to adjust/adapt definition via delegated act to technical and scientific progress or to definitions agreed internationally (**recital 39, Article 31**)



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 Contact materials (FCM)

Regulation 1935/2004/EC is the harmonised legal framework

- **FCM must not**

- endanger human health;

- Bring about an unacceptable change in the composition of the food;

- Bring about a deterioration in the organoleptic characteristics

- No specific reference to nanomaterials

Nanomaterials In Food Contact materials (FCM) – Plastics

Regulation (EU) No 10/2011 makes specific reference to nano-substances in plastic FCM

- Substances in nanoform shall only be used if explicitly authorised (**Article 9(2)**)
- EFSA assesses case-by-case before authorisation
- Authorisation of conventional substance does not cover the same substance in nanoform (**recital 23, Article 13 and Annex I**)
- Nanomaterials not covered by the functional barrier concept of the regulation (**recital 27, Article 14**)
- Several substances in nanoform are authorised

Nanomaterials in Active and intelligent food contact materials

Active and intelligent materials actively improve the shelf life of packaged food, or indicate its conditions

- **Active: e.g. absorbers of gasses or liquids**
- **Intelligent: Time Temperature Indicators**
- **Regulation (EC) 450/2009**

Not yet fully in force: Union list to be established

Reference to nano materials indirect:

- **'substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale'**
- **used to exclude nano substances from a derogation**



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 in Food Additives (FA)(1333/2008/EC)

Article 12

*"When a food additive is already included in a Community list and there is a **significant change** in its production methods or in the starting materials used, or there is a change in particle size, **for example through nanotechnology**, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market"*



Food Additives (FA) Regulation 1333/2008/EC

Pre-market authorisation of FA including those which fit the definition of engineered nanomaterials

Re-evaluation of FA (Regulation (EU) No 257/2010 includes EFSA's assessment of specific data on the specifications of the food additives presently in use, including information on particle size and relevant physicochemical characteristics and properties → update of Regulation 231/2012 on the specifications of FA



Nanomaterials Foods – Needs and Challenges

Updated definition

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**
- **No migration of authorised FCM nano substances – if migration limits, then methods to measure needed**



Nanomaterials in Foods – Developments

Update of definition

- **Revision of the 'general definition' of Commission Recommendation 2011/696/EU (led by DG EN)**
 - Public consultation to be launched 2Q 2018**
 - Adapted definition end of 2018**
- **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 symposium on nano in food (May 2017)**
- JRC meeting of group of MS designated laboratories (April 2018)**
- Possible CEN activity on nano in foods**

Risk Assessment

- EFSA revised guidance on the risk assessment of nanomaterials**
- Public consultation ended in March 2018 – revised guidance to be adopted 3Q 2018**



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Thank you!