Nanomaterials in the EU Food Regulations

EFSA stakeholder workshop on nanoscience and nanotechnology

1-2 April 2019 – Parma, Italy

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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

Nanomaterials in the EU Food Regulations

General considerations

EU Food and Food Contact Material Legislation

Principles

Sector legislation

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

Regulation and nanotechnology

- Challenges and possible answers

Nanomaterials in the EU

General considerations

- **Regulation and nanomaterials : Friends or foes?**
- **Question pertinent to all cutting edge technologies**

  e.g. IT, Nanotechnology, new generation (driverless) automobiles, Biotechnology (human cloning)
- **What is the common denominator?**

  Regulation seems to lag behind nanomaterials innovation? 'Pulls'
  Innovation seems to run without looking at regulation? 'Pushes'
  A bit of both?
- **How can we ensure that they are in harmony?**

  Regulatory preparedness and proper implementation
  Innovating safety
  State of the art risk assessment methodologies
  Analytical capacity/enforcement
  Upstream communication, synergy, need to address secrecy/confidentiality

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**
- **Food information to Consumers (impacts Food Additives)**

EU Non-food legislation

- **Specific provisions: Cosmetics, Biocidal products, Active and Intelligent Materials**
- **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 2

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 the EU 3

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

Revision/adaptations aims to include state of the art innovative materials

Adaptation of Recommendation 2011/696/EU will serve as the basis for the update/revision of Food nanodefinition

EFSA updated (2018) guidance on the Risk Assessment of nanomaterials

NOVEL FOODS (Regulation (EU) 2015/2283)

- **General requirements**
  - Functioning of the internal market and high level of protection of human health and consumers' interests
- **Specific safety conditions**
  - Food poses no safety risk
  - Intended use does not mislead the consumer (esp. if replaces another food and there is a change in the in the nutritional value)
  - If intended to replace another food, normal consumption should not be nutritionally disadvantageous for the consumer

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 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)

What is a food contact material?

- Intended to be brought into contact with food

- Already in contact with food and intended for that purpose

- Can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or foreseeable conditions of use

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)

- **Regulation (EU) No 10/2011 on plastics**

  and Regulation (EC) No 282/2008 on recycled plastics

- **Exclusive measures for plastics including plastics in multi-material multi-layers**

  authorised list of substances with restrictions e.g. specific migration limit (SML),

  rules on testing

  requirements on Declaration of Compliance (DoC) and Supporting Documentation

- **Regular amendments to add substances**

- **Regulation is technically complex and time consuming**

  an observation with consequences for harmonisation

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 in Foods and Food Contact Materials –

Consolidated legal framework to ensure

- **Proper functioning of the market**
- **High level of safety**
- **Consumer/societal expectations are met**
- **Clarity for economic operators**
- **Transparency**

…needs to be supported by

- **Science based (revised) definition**
- **Continuing work on risk assessment (EFSA)**
- **Appropriate enforcement**

Nanomaterials in Novel Foods – Needs and Challenges 1

Updated definition

Implementation of current definition

Implementation of the EFSA Guidance

Analytical tools for Risk Assessment and Enforcement

Lack of definition in the legal text – reliance on the Commission Recommendation/Definition (specific to FCM)

Challenges in risk assessment / toxicology (in particular for FCM)

Nanomaterials in Novel Foods – Needs and Challenges 2

Updated definition

- Technical and Scientific Robustness
- Practical and pragmatic
- Implementable
- Enforceable

Nanomaterials in Novel Foods – Needs and Challenges 4

Implementation of current definition in the context of the various Regulations

Basic Approach

- Regulatory status: Does it 'fit' the food nano definition?
- Labelling: Depending on the Regulatory status
- Safety: Is to be taken care at any rate!
  - either, in the context of the specific legislation to which the material 'fits'
  - or, under the GFL, if it doesn't 'fit the foo nano definition

Key challenges

- Intentionally engineered/manufactured versus 'fortuitous' presence
- Functionality linked to intention
- % of nano in product that makes it nano (i.e. gives it the specific nano properties)

Nanomaterials in Novel Foods – Needs and Challenges 5

Implementation of current definition in the context of the various Regulations

Functionality linked to intention

Intentionally engineered/manufactured to deliver a nano enabled function

Intentionally engineered/manufactured versus ‘fortuitous’ presence difficult if not impossible to establish analytically.

Reliance on economic operators’ declarations

Nanomaterials in Novel Foods – Needs and Challenges 6

Implementation of current definition in the context of the various Regulations

Material does not fit intentionally engineered definition

May be in nanoform or contain a nanofraction

Fortuitous presence: nature of the material, result of food processing/manipulation.

Still requires a safety assessment

Can we develop a set of technical criteria which will help establish presence or absence of nano (fraction)?

Nanomaterials in Novel Foods – Needs and Challenges 3

Implementation of the EFSA Guidance

To be discussed here….

Nanomaterials in Novel Foods – Needs and Challenges 4

Need for analytical tools for Risk Assessment and Enforcement;

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

- the authorised nano substances do not migrate (FCM)
- main control tool: Good Manufacturing Practices (FCM)
- if migration allowed analytical methods required (FCM)

Thank you!