Regulating Nanomaterials

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1. Regulatory framework for nanomaterials – “Hard” and “Soft” law
2. The definition question
3. Current definitions in different regulated products
4. New regulatory initiatives
LEGAL FRAMEWORK

- **Horizontal Legislation**: (binding, but pre-nano)
  - General Product Safety and Product Liability; Workers’ Protection; Environmental; Chemicals Legislation (REACH and CLP)

- **Vertical (application specific) Legislation**: (more and more nano-specific):
  - Food / (Novel Food) / Food contact /Cosmetics /Biocides /RoHS/ Medical Devices etc.

- **Guidelines and Recommendations**:
  - Commission Recommendation 2011/696/EU on the definition of nanomaterial
  - EFSA Guideline on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain
  - Union Guidelines on Regulation (EU) No 10/2011
HORIZONTAL LEGISLATION
REACH (Regulation (EC) No 1907/2006)

- Covers all chemical substances; also in their nano forms
  - Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process [...] Article 3(1)
  - Present interpretation: Nano-forms of existing bulk equivalents are not “new” substances under REACH; hence no registration requirements until relevant phase-in deadlines for total volumes (< 100 MT: June 2018)
  - No registration requirement if < 1MT/year (together with bulk equivalent)

REACH review (ongoing):
  - Need for legal definition to determine scope
  - Modifying Annexes and Technical Guidance Documents
  - Interpretation is challenged in Substance evaluation
NANO UNDER THE REACH REGULATION

Nano is **not explicitly mentioned** in REACH

But: Extensive implementation projects (**RIP-oN**)  

- o\textbf{N1}) Substance **identification**: to identify nanomaterials based on relevant parameters in existing case studies (CNT; nAg; nTiO2; nCaCO3); **no final consensus**

- o\textbf{N2}) **Information requirements**: final guidance documents published by JRC

- o\textbf{N3}) **Chemical Safety Assessment**: final guidance documents published by JRC
EFSA GUIDELINES

EFSA Guidelines on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain; allowing the petitioning and appropriate listing of authorized engineered nanomaterials (ENMs) - published on 9 May 2011 (after public consultation)

- Covers: food and feed additives, flavourings, food contact materials, enzymes, novel foods and pesticides
- Risk assessment paradigm (Risk = Hazard x Exposure) is considered applicable
- Characterization of ENMs in five stages: (1) pristine state (as manufactured); (2) as delivered to be used in food/feed; (3) as present in food/feed matrix; (4) as present in biological matrices; (5) as tox tested;
- Risk determined by: chemical composition, phys-chem. properties; interaction with tissues and potential exposure (which contributes to the extent of hazard characterization)
Six approaches to tox. testing:

- ENM is not present in food/feed due to (a) degradation; (b) no migration: **No additional testing**
- ENM is transformed before ingestion: testing for **non-nano form**
- ENM transformed in the gastro-intestinal tract: same as above
- ENM persists, but there is info on the non-nano form: compare info for both (ADME)

ENM persists and no info on non-nano form: **full testing**

- In vitro and in vivo studies; follow EFSA Guidance
- **Uncertainty analysis** (characteristics; hazard; exposure)
RECOMMENDED NANO DEFINITION

EU Commission Recommendation (18 October 2011) – Adopted with changes

- Consists of natural, incidental or manufactured particles, in an unbound state or as an aggregate or agglomerate with one or more external dimensions in the size range 1nm – 100nm for more than 50% 1% of their number size distribution, in specific cases between 1-50%

- Has internal or surface structures in one or more dimensions in the size range 1nm-100nm. Fullerenes, graphene flakes and SWCNT with one or more external dimensions below 1 nm are nanomaterials

- Has a specific surface area by volume greater than 60m²/cm³, excluding materials consisting of particles with a size lower than 1nm, but number size distribution prevails

- Particle: means a minute piece of matter with defined physical boundaries (ISO 146446:2007)
PRESENT RECOMMENDED NANO DEFINITION

- Member States, Union agencies and economic operators were invited to use the definition.
- The recommendation should not prejudice nor reflect the scope of application of any Union legislation.
- The definition should have been reviewed by December 2014.

- Need for legal certainty!
Towards a review of the EC Recommendation for a definition of the term “nanomaterial”

Part 1: Compilation of information concerning the experience with the definition (published in July 2014)

Part 2: Assessment of collected information concerning the experience with the definition (published in August 2014)

Part 3: Indications on how the definition could be modified to improve its clarity, effectiveness and implementability (was expected to be published last year…)

Challenges:

- Sample preparation (complex matrices: food, cosmetics, …)
- Measurement techniques; validated size measurement methods (constituent (primary) particles – agglomerates/aggregates)
- Evaluation and interpretation of data (number size distribution)
JRC REPORTS ON NANO DEFINITION

**COMMISSION RECOMMENDATION on the definition of nanomaterial**

"Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

Need to know how to consider aggregate/agglomerates

Many proteins and natural polymers are nanosized

Refers to primary (constituent) particles

No upper size considered

No routine methods of directly “counting” particles*

High risk of false results by conversion of mass based measurements

Few methods can detect 1nm

*Possible by EM or Coulter
DIFFERENCES BETWEEN EXISTING BINDING NANO DEFINITIONS

➢ Cosmetics Regulation (1223/2009):
  • Insoluble or biopersistent; intentionally manufactured material
  • One or more external dimensions on the scale of 1 to 100 nm or an internal structure

➢ Food Information Regulation (1169/2011):
  • engineered nanomaterial; intentionally produced material
  • 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.
DIFFERENCES BETWEEN EXISTING BINDING NANO DEFINITIONS (cont.)

- Biocidal Products Regulation (528/2012):
  - a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm (almost identical to Commission Recommendation)
  - The approval of an active substance does not cover the nanoform, unless explicitly mentioned
  - Where nanomaterials are used in a product, the risk to human health, animal health and the environment has to be assessed separately
NANO DEFINITION IN FOOD CONTACT LEGISLATION

- Regulation 1935/2004 (Framework Regulation):
  - Nanoform is **not defined**, but specific provisions on safety also applies for nanomaterials
  - **Article 11(5):** The applicant or any business operator using the **authorized substance** shall **immediately inform the Commission of any new scientific or technical information**, which **might affect** the safety assessment of the authorized substance in relation to human health –

- **Covers nanomaterials with potential health hazard?**
NANO DEFINITION IN FOOD CONTACT LEGISLATION (cont.)

➢ Regulation (EU) No 10/2011 (Plastics Regulation):
  • Nanoform is **not defined**, but specific provisions on safety also applies for nanomaterials
  • **Whereas 23**: New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at larger scale, e.g. nanoparticles. Further: “…authorizations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.
  • **Art.9(2)**: Substances in *nanoform* shall only be used if explicitly authorized and mentioned in the specifications in Annex I
  • The positive listing of a substance may not be claimed to also cover its nano-form
  • Substances in nanoform are treated the same way as CMRs

- Definition: **Substances in nanoform** refers to nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial.

- Remark: Once discussions are concluded on how to implement in the food area the definition of nanomaterials included in the Recommendation, an amendment to the Plastics Regulation will be proposed, taking into account the definition in the food area and the specific requirements of the food contact materials sector.

Need for legal certainty!
EXISTING LEGAL FRAMEWORK FOR FOOD CONTACT MATERIALS

- **Plastics Regulation (EU) No. 10/2011**
  - The *individual authorization* of the nano-form is required by the Authority
  - TiN nanoparticles; Carbon black and Synthetic amorphous silica are listed on Annex I of the Regulation with nano specifics.
  - Positive EFSA opinion (dated 16 April 2014) on butadiene, ethyl acrylate, methyl methacrylate, styrene copolymer, crosslinked or not with divinylbenzene and/or 1,3-butanediol dimethacrylate, *in nanoform* based on migration modelling, resulting in an estimated worst case migration of $1 \times 10^{-6}$ mg/kg food.
The assumption is that nanoparticles are immobile when incorporated into FCM plastics
- Testing done on spherical nanoparticles of silver and nTiN
- Migration from LDPE

Safety is demonstrated on a case-by-case basis:
- Either with sufficient toxicological information;
- Or with demonstrating the lack of any exposure; no migration
EXISTING LEGAL FRAMEWORK FOR FOOD CONTACT MATERIALS

- **Active and Intelligent Packaging Regulation (EC No. 450/2009)**

- Excludes “nanoparticles” (defined as: “substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale”) from the exemption to authorize substances behind a Functional Barrier

- Iron (II) modified bentonite (FCM Substance No 1003) intended to be incorporated in monolayer or multilayer packages or in sachets for absorbing oxygen from the food environment –

- **EFSA opinion: no safety concern** for the consumer when used as oxygen absorber incorporated without compatibilizers in polyolefin layers of food packages at levels up to 15% w/w.
EU Parliament Environment and Food Safety Committee on 24 November 2014 proposed to include a requirement for a report on nanomaterials in food contact materials (FCMs) in the proposed draft Novel Foods Regulation (COM(2013) 894 final, published on 18 December 2013)

- Table **one year after** the entry into force of the new Novel Foods Regulation
- Elaborate on **tests methods** need and required **migration limits**
NEW INITIATIVES FOR THE REGULATION OF NANOMATERIALS IN FOOD AND FOOD CONTACT USES (cont.)

- MEPs proposed a moratorium on the use of nanomaterials in food, based on the precautionary principle. All novel food should also be subject to post-market monitoring.

- MEPs also proposed to amend the definition of nanomaterials in the draft Novel Foods Regulation: food containing or consisting of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 (the Food Information Regulation)

- MEP proposal: 10% nano-particles threshold for a food ingredient to qualify as “nano”, whereas the Commission’s present recommended level is 50%
NEW INITIATIVES FOR THE REGULATION OF NANOMATERIALS IN FOOD AND FOOD CONTACT USES (cont.)

- Call for publicly available list of foods and food packaging containing nanomaterials (those given positive Opinion by EFSA and other foods which appear to have nanoscale elements)
  - Difficult to gauge extent of nanotechnology use in food sector – definition?
  - Food industry should avoid secrecy: GMO comparison
  - Balance industry confidentiality concerns with need to gain consumer confidence

- Voluntary vs. mandatory requirements
QUESTIONS?

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