The Regulatory Scenario: Present and Future Challenges for Nanomaterials

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LEGAL FRAMEWORK

- **Horizontal Legislation**: (applicable, but pre-nano)
  - General Product Safety and Product Liability Legislation
  - Workers' Protection Legislation
  - Environmental Legislation
  - 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:** (not legally binding) such as **EFSA** on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain – more to come

HORIZONTAL LEGISLATION
PRODUCT LIABILITY DIRECTIVE (85/374/EEC)

- (Article 1) The producer shall be liable for damage caused by a defect in his product
- (Article 4) The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage
- (Article 6) A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
  - (a) the presentation of the product;
  - (b) the use to which it could reasonably be expected that the product would be put;
  - (c) the time when the product was put into circulation.
- (Article 7) The producer shall not be liable as a result of this Directive if he proves:
  - (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered;

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)
  - Current 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)

NANO UNDER THE REACH REGULATION

- Nano is **not explicitly mentioned** in REACH

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

- o**N1**) Substance identification: to identify nanomaterials based on relevant parameters in existing case studies (CNT; nAg; nTiO2; nCaCO3);

CEFIC: Impact assessment of RIP-oN1. The amount of all possible substances produced in nanoform and all possible surface treatments covered by the regulatory definition is in the range of 500 – 2,000

- o**N2**) Information requirements: final guidance documents published by JRC

- o**N3**) Chemical Safety Assessment: final guidance documents published by JRC

- REACH review: Modifying Annexes and Technical Guidance Documents

- Need for legal definition to determine scope

RECOMMENDED NANO DEFINITION (FINAL)

- EU Commission Recommendation (18 October 2011)
  - 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)

RECOMMENDED NANO DEFINITION (FINAL)

- Member States, Union agencies and economic operators are invited to us the definition
- The recommendation should not prejudge nor reflect the scope of application of any Union legislation
- The definition should be reviewed by December 2014!

- **No legal certainty**

EXISTING LEGAL FRAMEWORK FOOD CONTACT MATERIALS

- **Regulation 1935/2004 (Framework Regulation):**
- Specific provisions on safety – also applies for nanomaterials
- The Framework Regulation also provides, that:
  - *…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*.
- What "might" affect the safety assessment is left for the business operator to judge
- May cover nanomaterials with potential health hazard
- "Nanoform" is not defined

EXISTING LEGAL FRAMEWORK FOOD CONTACT MATERIALS

- **Regulation (EU) No 10/2011 (Plastics Regulation):**
  - 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*. The article further states that "…*authorizations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles*."
  - Art.9(2) provides, that "*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

EXISTING LEGAL FRAMEWORK 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.

EXISTING LEGAL FRAMEWORK FOOD INFORMATION

- **Regulation (EU) No 1169/2011 on the provision of food information to consumers**
  - **Definition:** *'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.*
  - All ingredients present in the form of engineered nano-materials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

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)

EFSA GUIDELINES

- 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)

EFSA GUIDELINES (cont.)

- 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)

OTHER EU REGULATORY DEVELOPMENTS

- **Vertical Legislation: Biocidal Product Regulation (EU) N° 528/2012**
  - **Definition** : *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)
  - **Positive list**: The approval of an active substance does not cover the nanoform, unless explicitly mentioned
  - **Labelling**: if nanomaterials are contained in a product it should always be listed with "nano" in brackets
  - **Authorization**: where nanomaterials are used in a product, the risk to human health, animal health and the environment has to be assessed separately

OTHER EU REGULATORY DEVELOPMENTS

- **Vertical Legislation: Cosmetics Regulation (EC) No. 1223/2009**
  - Specifically addresses nano materials – Substances listed in Annexes III-VI do not cover nanomaterials, unless it is specifically mentioned
  - Intention to place a product containing nanomaterials on the market must be notified to the Commission 6 months is advance (no obligatory assessment by SCCS)
  - Definition for nanomaterials as *"insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure on the scale of 1 to 100 nm"* (no particle number distribution limit)
  - "Moving" definition; it creates difficulties in interpretation and enforcement

LABELLING AND INVENTORY UNDER THE COSMETIC REGULATION

- **Inventory**: by 11 January 2014 the Commission should publish – and regularly update – a catalogue of all nanomaterial used in cosmetic products placed on the EU market (including colorants, UV-filters and preservatives), indicating foreseeable exposure conditions.
- **Status report**: by 11 July 2014 the Commission should submit – and annually update – a status report on the use of nanomaterials in cosmetic products in the EU.
- **Labelling:**
  "All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the words "nano' in brackets"

DIFFERENCES BETWEEN EXISTING DEFINITIONS

➢ **Existing Definition in Cosmetics Regulation:**

- Insoluble or biopersistent; Intentionally manufactured material
- One or more external dimensions on the scale of 1 to 100 nm or an internal structure

➢ **New Definition in Food Information Regulation:**

- 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.

OTHER REPORTING/INVENTORIES

- 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 precisely extent of nanotechnology use in food sector – definition?
  - Food industry should avoid secrecy: GMO comparison
  - 'exactly the type of behavior that may bring about the public reaction [industry] is trying to avert'
  - secrecy breeds mistrust
  - Balance industry confidentiality concerns with need to gain consumer confidence
- Voluntary vs. mandatory requirement

FRENCH NANO DECREE

- **Décret n°2012-232 (17 February 2012) and Arrêté 6 August 2012** concerning the yearly declaration of substances in nanoform. In force since 1 January 2013 (sanctions from 1 July 2013).
- Mandatory: covering all manufacturers, distributors and importers above 100 g/year. Declaration by 1 May each year, covering the previous year.
- Definition: as “substance” under REACH; manufactured intentionally to be in nanoform, containing minimum 50% of unbound particles between 1-100 nm or their aggregates and agglomerates.
- Reporting obligation on substance identity; quantity; uses and supply chain – issues of treatment of confidential information

POTENTIAL FURTHER DEVELOPMENTS

- Ten other MS (Austria, Belgium, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden) + Croatia have asked the Commission to propose legislation on registration and market surveillance of nanomaterials and products containing nanomaterials
- Amending the Annexes and updating Technical Guidance documents is not considered sufficient by these countries
- They call for lowering tonnage bands for nano registration
- They call for binding nano definition under REACH
- They call for revisiting workers exposure limits
- Call for mandatory inventories based on the French model?
- Calls for discussions on labelling

➢ Addressed by impact assessment suggested by the Commission

CONCLUSIONS

- Regulatory framework need to balance economic potential with both ensuring safety and gaining public trust (avoid GMO backlash)
- Existing vertiacl food/food contact legislative framework being extended to cover nanomaterial specifics
- For nano-specific risk assessment, verify or develop:
  - adequate risk assessment tools
  - ability to know the form of substance being used
- Call for harmonized approach – issue with Member States initiatives
- General impact assessment is an important next step

THANK YOU

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