Nanomaterials under REACH

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Content

1. Current Regulatory Framework – Horizontal and Vertical Regulations
2. Scope of the REACH Regulation
3. The Definition Question
4. National initiatives (Member States and beyond)
5. Further Developments

- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

General EU Legal Framework

- **Horizontal Legislation**: (applicable, but not nano specific)
  - 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; ECHA Guidance on Information Requirements and Chemical Safety Assessment; – 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**; - "State of the art" defense**

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 (Last tier: 1-100MT/year/legal entity: June 2018)
  - No Registration requirement if < 1MT/year (together with bulk equivalent)
  - But other REACH provisions (Authorization, Restriction, CLP) apply

Nano Under the REACH Regulation

- Nano is not explicitly mentioned in REACH

But: Extensive implementation projects (RIP-oN)

  - **oN1)** Substance identification: to identify nanomaterials based on relevant parameters in existing case studies (CNT; nAg; nTiO2; nCaCO3); no agreement whether nano is an identifier or characterizer

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

  - **oN2)** Information requirements: final guidance documents
  - **oN3)** Chemical Safety Assessment: final guidance documents

- **Need for legal clarity**
- **REACH review: Modifying Annexes and Guidance Documents**

Nano Under the REACH Regulation

- REACH Review (Feb 2013): …*REACH sets the best possible framework for the risk management of nanomaterials…*
- No changes to the enacting terms of REACH is proposed
- Commission Consultation on policy options for the modification of technical provisions of the REACH Annexes
- 5 Options reviewed for Cost, Safety and Efficiency:
  - 1. Baseline option (as today)
  - 2. Clarity option (add guidance but no added obligations)
  - 3. Soft law option (new, non binding measures – may produce legal effects)
  - 4. Test data based on ECHA's advice (new binding measures)
  - 5. Considerations based on drive for reduced burden for REACH compliance
  - 6. Very detailed characterization requirements to reduce uncertainty
- Deadline for input was 13 September 2013…

Nano Under the REACH Regulation

- Updated ECHA work plan on nanomaterials for 2014-15
- Four strategic objectives:
  1. Maximize the availability of high quality data to enable safe manufacture and use. Solving key challenges on:
     i. substance identification/characterisation
     ii. risk assessment (hazard and exposure)
     iii. grouping/read across
  2. Mobilise authorities to use data intelligently to identify and address chemicals of concern
     i. harmonise the views of ECHA and MS experts re dossier and substance evaluation
     ii. informal discussions with industry – improve "best practices"
  3. Establish ECHA as a hub for regulatory and scientific support on NM
  4. Resource optimisation

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% 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 60m^2/cm^3, 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 use 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!
- **Not harmonized with the US (or other jurisdictions)**
- **No legal certainty**

Conflict with 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 "S*ubstances 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 nanoform
  - Substances in nanoform are treated the same way as CMRs
  - "Nanoform" is not defined

Conflict with 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

Conflict with 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 100nm 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 100nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100nm 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

Conflict with Existing Legal Framework: Biocidal Products

- **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 1-100nm* (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
  - **In force since 1 September 2013!**

Conflict with Existing Legal Framework: Cosmetics Products

- **Cosmetics Regulation (EC) No. 1223/2009**
  - Specifically addresses nano materials – Substances listed in Annexes III-VI (approved/restricted to be used in cosmetics) do not cover nanomaterials, unless it is specifically mentioned
  - Intention to place a product containing nanomaterials on the market must be the subject of additional notification to the Commission 6 months in advance
    - except where they have already been placed on the market by the same responsible person before 11 January 2013 (should have been notified before 11 July 2013)
    - except if they are used as colorants, UV-filters or preservatives (can be listed in main cosmetic product notification)
  - 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 100nm*" (no particle number distribution limit)
  - "Moving" definition; it creates difficulties in interpretation and enforcement while acknowledging the need to align it with other regimes
  - Specific data call for ingredient: styrene/acrylates copolymer (nano): comments by 30/06/2015

National Initiatives: 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 100g/year – Declaration by 1 May each year, covering the previous year
- Definition: as "substance" under REACH; manufactured intentionally to be in nano-form, containing minimum 50% of unbound particles between 1-100nm or their aggregates and agglomerates
- Reporting obligation on substance identity; quantity; uses and supply chain – issues of treatment of confidential information and of enforcement for the first year
- As a measure potentially restricting trade between EU Member States, French decree was notified to the EU Commission, however, without the sanctions chapter.

Other Advanced National Initiatives

- **Belgium**:
  - Bill notified to the EU Commission in February 2014, the draft does not apply to chemicals or materials already regulated, such as biocides, cosmetics, food, medicinal products, etc.
  - Applicable to substances on 1/1/2016, and to mixtures and articles on 1/1/2017.
  - Pre-marketing declaration for >100 g; yearly updates on 31 March, including on volulmes actually marketed the previous year
  - Identification of substance, (B2B) customers and uses, estimated volumes for the reporting period
- **Denmark**:
  - Existing data base for products which either contain nanomaterials or are claimed to be a nano product
  - In July 2013: Danish Environmental Protection Agency launched consultation on relevance of register for mixtures and consumer products that contain or release nanomaterials, based on annual declarations (B2B exempt, products falling within scope of other regulations exempt). Operational in 2014 (first year to be reported)

Other Advanced National Initiatives

- **Canada**:
  - Proposed approach to address nanosclae forms of substances on the Domestic Substances List (DSL) – February 2015
  - New substances: under the New Substances Notification Regulations for pre-market assessment: 20 nanoforms assessed
  - Criteria: cumulative: size (1-100 nm) **and** nanoscale properties/phenomena
  - Declaration: >100 g; excludes: polymers, organic and organo-metallic pigments, naturally occurring or incidentally manufactured nanoforms, biological materials
- **USA:**
  - EPA Proposed Rule for Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements – March 2015
  - One-time reporting for existing nanoscale materials – to inform EPA's decision making
  - Criteria: cumulative: size (1-100 nm) **and** nanoscale properties; three factors in combination: (i) change in the process; (ii) change in mean particle size by min. 10% and (iii) 7 fold measured change in at least one of the following properties: zeta potential, specific surface area, dispersion stability or surface reactivity.

Potential Further Developments in the EU

- Some MS (Austria, Belgium, Croatia, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden) 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 under REACH
- 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**

Questions?