Market Alert: Learn About Changes to New EU Laws on Nanomaterials

U.S. Commercial Service Webinar

Dr. Anna Gergely, Director EHS Regulatory
Indiana de Seze, Sr. Associate

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Steptoe
STEPTOE & JOHNSON LLP

Dr. Anna Gergely

- Director, EHS regulatory in Steptoe's Brussels office where, in a role equivalent to partner, she is the firm's principal scientist
- Practice covers chemicals with a sharp focus on nanotechnology; including food contact materials, REACH regulation, agro-biotechnology, biocides, cosmetics, food and feed, medical devices, and a range of consumer and industrial products
- Recommended by *Legal 500 EMEA* for EU Regulator: Environment and Chemicals (REACH)
- Chair of European Commission NANO*futures* Regulation working group and AMCham EU's Nanotechnology Task Force
- PhD in analytical chemistry and quantum chemistry, and a registered European patent attorney

Indiana de Seze

- Senior Associate in Steptoe's Brussels office
- Regularly advises REACH clients and provides legal support for the management of REACH consortia
- Developed particular experience on a selection of EU regulatory and environmental areas such as - waste—batteries, electronic waste (WEEE) and market access—eco-design, energy-using products, CE marking, labeling, hazardous substances in electronic goods (RoHS), nanomaterials, food (claims, additives, food-contact), medical devices, pharmaceutical products, biocides and pesticides

Steptoe & Johnson LLP: Practice Overview

- S&J has more than 500 lawyers; represented in the regulatory capitals of the world (financial, insurance, tax, energy, export control, trade, environment etc.)
- Our Brussels office with the largest environmental practice in town represent a number of premiere companies in the regulatory areas of:
  - Chemicals (including REACH, Biocides, Agrochemicals and Cosmetics)
  - Environment (including WEEE and RoHS)
  - Biotechnology (GMOs)
  - Nanotechnology
  - Food and Food Contact Materials
- Consistently ranked as market-leading practice (Legal 500, Chambers & Partners)
- Multidisciplinary team combining lawyers and scientists
- Seamless advice across areas of law:
  - Competition/antitrust aspects of chemicals regulation
  - Impact of regulation under WTO trade rules

Our Nanotechnologies Practice

- Recent and ongoing engagements:
  - Ensuring compliance of nanomaterials and nanotechnology-enabled products with regulatory requirements in the EU and US
  - Contributing to the developments of evolving regulations in the European Union
  - Maintaining expert-level knowledge of nanotechnology applications in all sectors of application, including cosmetics, construction products, electronic devices, pesticides and biocides, food and food contact materials,
  - Helping companies with voluntary and mandatory reporting requirements and related IP, liability, insurance, and other issues
  - Supporting product stewardship efforts related to nanotechnologies, including efficient communication strategies in the supply chain

Content

1. Current Regulatory Framework – Horizontal and Vertical Regulations
2. The Definition Question
3. Reporting/Labelling
4. Member States' initiatives
5. Case study: Nano silver
6. Conclusions

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

Legal EU 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 – 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" defence**

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 (1-100MT/year/legal entity: 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)

  - 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 will be 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

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 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!
- **Not harmonized with the US (or other jurisdictions)**
- **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 "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 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 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.

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)

EFSA Guidelines

- 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 1-100nm* (almost identical to Commission Recommendation)
  - **Positive list**: The approval of an active substance does not cover the nano-form, 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!**

Other EU Regulatory Developments

- **Vertical Legislation: 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

Labeling 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 separately 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*"
- **Review** by the Commission to be undertaken by 11 July 2018

SCCS Reviews

- Scientific Committee for Consumer Safety (SCCS) is an independent risk assessment and advisory body that issues recommendations on safety of use of cosmetic products in general and of nanomaterials in cosmetic products (based on information submitted)
- Taking into account the opinion of the SCCS, and where there is a potential risk to human health, including when there is insufficient data, the Commission may amend Annexes II (prohibited substances) and III (restricted substances).
  - 22 July 2013: SCCS opinion on Titanium Dioxide (nano form)
  - 23 July 2013: addendum to SCCS opinion on Zinc Oxide (nano form)
  - 23 July 2013: revision of the March opinion on nano size Methylene bis-benzotriazolyl tetramethylbutylphenol
- All three open for public consultation until 18 September 2013.
- 27 June 2012: Publication of SCCS Guidance On The Safety Assessment Of Nanomaterials In Cosmetics

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, does not apply to chemicals or materials already regulated, such as biocides, cosmetics, food, medicinal products, etc.
  - Scheduled to be applicable to substances on 1/1/2015, and to mixtures and articles on 1/1/2016.
  - Pre-marketing declaration/notification for volumes >100 g; yearly updates on 31 March, including on volumes 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) to be operational in 2014 (first year to be reported)

Case study - nano silver

- Obligations and considerations when manufacturing or importing into the EU
  - Nano silver dispersions (as raw material for further use)
    - REACH obligations: Silver metal, silver nitrate and disilver oxide have been registered for the 2010 deadline (evaluation of the Silver dossiers by The Netherlands in 2013)
    - Special risk assessment of nanosilver under REACH – detailed substance characterization and possible additional data requirements according to the updated REACH Annexes
    - CLP obligations: classification based on the form and physical state of the substance placed on the market
    - Worker's safety and general product safety and liability obligations
    - Member States' national reporting requirements
  - Products containing nano silver - application specific
    - Cosmetics - binding notification and labelling obligations
    - Food contact materials - binding listing on the Union list (use specific)
    - Biocides - authorization of the nanoform is required – transition period applies
    - Medical devices - under revision to cover nano
    - RoHS – call for regulatory considerations
    - … etc.

Potential Further Developments

- Eleven 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
- 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 vertical 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 for Your Attention

Dr. Anna Gergely
agergely@steptoe.com

Indiana de Seze
ideseze@steptoe.com

http://www.steptoe.com/nanoresourcecenter