Regulation of Nanomaterials in Consumer Products – A European Perspective

Andreas Luch
Nanomaterials: What is so Special about the Nanoscale?

- Nanoscale dimensions exhibit new physico-chemical properties
- The size attributable properties are retained even when the end product is not entirely within the nanoscale
- Nano-enabled composites and articles exhibit new properties

<table>
<thead>
<tr>
<th>Nanometer</th>
<th>Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>Water molecule</td>
</tr>
<tr>
<td>1</td>
<td>Glucose</td>
</tr>
<tr>
<td>10</td>
<td>Antibody</td>
</tr>
<tr>
<td>100</td>
<td>Virus</td>
</tr>
<tr>
<td>1000</td>
<td>Bacteria</td>
</tr>
<tr>
<td>10,000</td>
<td>Cells</td>
</tr>
<tr>
<td>100,000</td>
<td>Human Hair</td>
</tr>
<tr>
<td>1,000,000</td>
<td>Insects</td>
</tr>
<tr>
<td>10,000,000</td>
<td>Tennis ball</td>
</tr>
</tbody>
</table>
Regulation of Nanomaterials: Different sides of the same coin?

Unknown potential risk to humans

Regulatory Bodies
EU Commission, National Governments
Risk Assessors

High potential benefit for consumers, (workers, patients)

Predict potentially harmful effects

Monitor potentially harmful effects

Identify potentially harmful effects

Measure potentially harmful effects

Nanomaterials

Regulatory Challenges

Industry
Industry Associations
Regulatory Landscape

Europe
Areas of Legislation affected by Nanotechnology

- Nanotechnology
  - Areas of Legislation affected
    - Addressed by BfR
    - Addressed by other Institutions
      - Pharmaceuticals
      - Medical Devices
      - Electronic Devices
      - Building Materials
      - Occupational Health and Safety
      - Environment
    - Chemicals
    - Food & Feed
    - Food Contact Materials
    - Cosmetics
    - Pesticides
    - Biocides

A. Luch, 1st Joint Symposium on Nanotechnology, 05 - 06 March 2015
Areas Affected: Current Regulatory Landscape

Definition of NM (Recommendation) (2011/696/EU)

Specific Regulation including Definition

REACH (1907/2006/EC) & CLP (1272/2008/EC) Regulations

Cosmetics Regulation (1223/2009/EC)

Biocidal Regulation (528/2012/EC)

Food Contact Materials (FCM; 1935/2004/EC)

Plastic Materials (10/2011/EC)

Regulation on Case by Case Basis without Definition

Food Contact Materials (FCM; 1935/2004/EC)

Textiles

Provision of Food Information to Consumers (1169/2011/EU)

Non-regulated Areas

Detergents & Cleaning Agents

Novel Food (258/97/EC)
Definition
What are Nanomaterials? Recommendation of the European Commission: 2011/696/EU

2. „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.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.

3. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.
Questions around an unspecific definition

**Size Range: 1 nm - 100 nm**

- Rigid limits in view of enforceability, with lower limit to exclude large atoms and molecules. Exception: fullerenes, graphene flakes and single wall carbon nanotubes. What about new entities?

- 100 nm upper limit does not capture all types of materials with genuine nanoscale properties: More parameters needed? What qualifiers should be selected?

**50% or more of the overall particle size distribution**

- What particle size population should be considered? Do we need an upper size limit (e.g. 1µm) for practical reasons?

- Mixture of particles within and outside the nanoscale: How to select the correct parameters whether a material meets the definition of nanomaterials?

**Particles in the number size distribution**

- How is it measured correctly? What has to be chosen? Single particle measurement methods vs. ensemble methods; Size distribution by mass, surface area, etc. Is it possible to convert?
Scientific Documents Towards the Review of the EC Definition

Reports: Joint Research Centre, Ispra, 2014

- 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
- Towards a review of the EC Recommendation for a definition of the term "nanomaterial"
  Part 2: Assessment of collected information concerning the experience with the definition

Regulatory developments over the last decade
Regulation in the European Union: Historical overview

- **2005**
  - Risk assessment methodology for nanomaterials reviewed by the Scientific Committee (2005-04-28)

- **2006**
  - Opinion on nanosciences and nanotechnologies: An action plan for Europe 2005-2009 published

- **2008**
  - Regulation of nanoscale silver products as pesticides demanded (2008-11-19)

- **2009**
  - Report on Nanomaterials under REACH published (2009-11-17)
  - Adoption of EU Cosmetics Regulation (1223/2009)

- **2010**
  - Final SCENIHR opinion for a definition of "nanomaterial" adopted (2010-12-08)
  - Plastics Directive: Enforcement of positive list of additives (no nanoclay & nanosilver) (2010-01)

- **2011**
  - National Action Plan to focus on nanomaterials (2011-03-10)
  - Food-Contact Materials Plastics (EU) No 10/2011 (Novelty specifications (ANNEX I)) (2011-01)
  - Report on nanomaterials in consumer products released (2011-05-02)
  - European Commission publishes final Reports on REACH Implementation Projects on Nanomaterials (RIP-oN) (2011-10-18)
  - Guidance document on the safety assessment of nanomaterials in cosmetics (2011-10-07)
  - "Nanomaterial" defined (2011-10-20)

- **2012**
  - Consultation on safety, health and environmental effects of nanosilver launched by SCENIHR (2012-04-01)
  - Second Regulatory Review on Nanomaterials (2012-10-03)
Regulation in **Single EU Member States: Historical overview**

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Action</th>
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<tr>
<td>2008</td>
<td>Netherlands</td>
<td>Government requests advice on workplace exposure to nanoparticles (2008-09-05)</td>
</tr>
</tbody>
</table>
| 2010 | Belgium | Presidency discussed measures on nanomaterials in consumer products (2010-09-14)  
 | Germany | Legal feasibility study on the introduction of a nanoproduct register (2010-09-29) |
| 2011 | France | Draft French decree on an annual declaration on nanomaterials released (2011-01-05)  
 | Germany | Action Plan Nanotechnology 2015 released (2011-01-12)  
 | Netherlands | EU action on nanomaterials requested by the Netherlands |
| 2012 | France | Notice to importers and exporters of hazardous chemicals regarding the update of annex I of Regulation EC/689/2008 (2012-12-29)  
 | France | Declaration of Nanomaterials required (2012-02-17)  
 | Netherlands | Working with engineered nanoparticles: Exposure registry & system of health monitoring (2012-05-22)  
 | Germany | Recommendation on Risk assessment of nanomaterials at workplaces (2012-05-29)  
 | Switzerland | Swiss action plan for synthetic nanomaterials (2012-05-02) |
| 2013 | France | Implementing a mandatory reporting program (2013-01-11)  
 | Norway | Chemicals register requires nano status update (2013-01-17)  
 | EU | JRC scientists investigate toxicity of gold nanoparticles  
 | Germany | Nanomaterials and REACH - Background Paper on the Position of German Competent Authorities (**BAUA, UBA, BfR**) (2013-01-28) |
| 2014 | Denmark | Implementing mandatory reporting program (2014-06-18) |
| 2016 | Belgium | Nanomaterials to be registered, taking effect on January 1, 2016 |
National Nanomaterials Registers

Opinion: DG Environment: RIVM 2010

Dr. S.W.P. Wijnhoven
Dr. Ir. A.G. Oomen
Dr. A.J.A.M. Sips
Drs. F.C. Bourgeois
G.J.P.M. te Doresteijn
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Development of an inventory for consumer products containing nanomaterials
Final Report
070307/2010/580587/SER/D3

This investigation has been carried out at the request of DG Environment within the framework of ENV/D3/SEN/2010/0056r
Why National Nanomaterials Registers are being implemented?

- REACH Amendments not finalized
- No EU-wide Nanomaterials register
- 3 Member States: national registers:
  - France, Denmark, Belgium
- Objective: provide regulators with a better overview of the NM on the market
  - Includes NM either as such, in mixtures or products

What is required under the National Nanomaterials Registers?

France and Denmark:
- annual reporting requirements on manufacturers and importers
- “substances with nanoparticle status” as such or contained in mixtures or articles

Denmark:
- covers also natural and incidental NM

Belgium:
- notification before importing or placing NM on the market
- substantial fines
# Regulation in Single EU Member States: NM Registers

<table>
<thead>
<tr>
<th>National Nano Registers</th>
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<tbody>
<tr>
<td>Requirements</td>
</tr>
<tr>
<td>In Force</td>
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<tr>
<td>When must the nanomaterial be notified?</td>
</tr>
<tr>
<td>Scope by Product</td>
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</table>

*Fullerenes, graphene flakes and single wall carbon nanotubes with an external dimension below 1 nm*
REACH
REACH (1907/2006/EC) & CLP (1272/2008/EC) Regulation

REACH: Registration, Evaluation, Authorisation, Restriction of Chemicals: Addresses the production and use of chemical substances

European Commission (EC): Advice on the management of NM under the REACH & CLP Regulation
Co-operation with member states, stakeholders
Experts of the CARACAL sub-group on nanomaterials (CASG Nano)

“… nanomaterials that fulfill the criteria for classification as hazardous under the CLP Regulation must be classified and labelled. This applies to nanomaterials as substances in their own right, or nanomaterials as special forms of the substance.”

REACH Implementation Projects on Nanomaterials (RIP-oNs): To provide advice on key aspects of the implementation of REACH with regard to nanomaterials.

- Substance Identification of NM (RIP-oN 1)
- Specific Advice on Fulfilling Information Requirements for NM under REACH (RIP-oN 2)
- Specific Advice on Exposure Assessment and Hazard/Risk Characterization for NM under REACH (RIP-oN 3)
Cosmetic Products
Article 2 Definitions – 1. (k)

‘nanomaterial’ means an **insoluble or biopersistant** and intentionally manufactured material with **one or more external dimensions**, or an **internal structure**, on the scale from **1 to 100 nm**;

Article 2 Definitions – 3.

In view of the various definitions of nanomaterials published by different bodies and the **constant technical and scientific developments** in the field of nanotechnologies, the Commission **shall adjust and adapt point** (k) of paragraph 1 to technical and scientific progress and to definitions subsequently agreed at international level.
Nanomaterials in Cosmetics - Regulation

**Article 19**

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 word ‘nano’ in brackets.
The information notified to the Commission shall contain at least the following:

(a) the **identification** of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;

(b) the specification of the nanomaterial including **size of particles, physical and chemical properties**;

(c) an estimate of the **quantity** of the nanomaterial contained in cosmetic products intended to be placed on the market per year;

(d) the **toxicological profile** of the nanomaterial;

(e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;

(f) the reasonably **foreseeable exposure** conditions.
Scientific Committee on Consumer Safety (SCCS)

Opinion:

- SCCNFP/0005/98: Titanium dioxide (in Revision) as UV-Filter, as pigment
- SCCS/1489/12: Zinc oxide
- SCCP/0932/05: Zinc oxide in suncream
- SCCP/1147/07: Safety of NM in cosmetic products

Guidance Documents:

- SCENIHR: Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance
  - SCENIHR approved this opinion at the 6th plenary of 10-11 June 2014

- SCCS: Guidance on the safety assessment of nanomaterials in cosmetics
  - The SCCS adopted this opinion at its 15th plenary meeting of 26-27 June 2012
Food Contact Materials

(FCM)
At the moment no specific regulation for nanomaterials used in food contact materials:

**HOWEVER**

REGULATION (EC) No 1935/2004

… on materials and articles intended to come into contact with food

**Article 3** General requirements:

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

   (a) endanger human health;

   or

   (b) bring about an unacceptable change in the composition of the food;

   or

   (c) bring about a deterioration in the organoleptic characteristics thereof.
At the moment no specific regulation for nanomaterials used in food contact materials:

**HOWEVER**

REGULATION (EC) No 1935/2004

… on materials and articles intended to come into contact with food

**Article 3** General requirements:

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

**Article 11** Community authorisation:

5. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment.
Paragraph (23):

New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards to their risk until more information is known about such new technology. Therefore it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.
Section 2, Article 9:

Specific requirements on substances:

Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I.
Issue: Exposure Model
Schematic outline for risk assessment of ENM

Source: EFSA Scientific Committee

Guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food and feed
Risk assessment for the finished product?

**Free nanoparticles**
- Example: DIY Surface treatment, e.g. nanosilver (cleaning products, also in possible contact with food)

**Surface bound nanoparticles**
- Example: Surface coating of polypropylene (storage) boxes

**Matrix embedded nanoparticles**
- Example: Nano-clay incorporated in polymer layer, middle layer of multilayer foils
Current Challenges in Risk Assessment

General
- Consistent nomenclature
- Read a cross concepts

Analytic (Nano-Analytic)
- Measurements at the ultra trace level
- Adapt known techniques or develop new
- Robust and cost-efficient techniques
- New standards, reference materials and international norms

Exposure Assessment
- Development of adequate exposure scenarios
- Integration of the particle number concentration

Toxicology (nano-toxicology)
- Determination of adequate endpoints
- Development of new test methods
- New norms and standards
- Tox21

First certified reference material for real-world nanoparticle size analysis

21 February, 2011
The JRC’s Institute for Reference Materials and Measurements (IRMM) has developed the world’s first certified nanoparticle reference material based on industry-sourced nanoparticles. This new material will help ensure the comparability of measurements worldwide, thereby facilitating trade, ensuring compliance with legislation.

Nanotechnology offers a range of benefits over traditional materials and enables the development of innovative applications and products. However, there are often concerns about the safety aspects and to what extent these have been investigated. High-quality
Thank you for your attention

Andreas Luch

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