Current legislative framework for **nanomaterials** & Introduction to the impact assessment on **transparency measures**

Validation workshop

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Definition of a nanomaterial: Commission recommendation

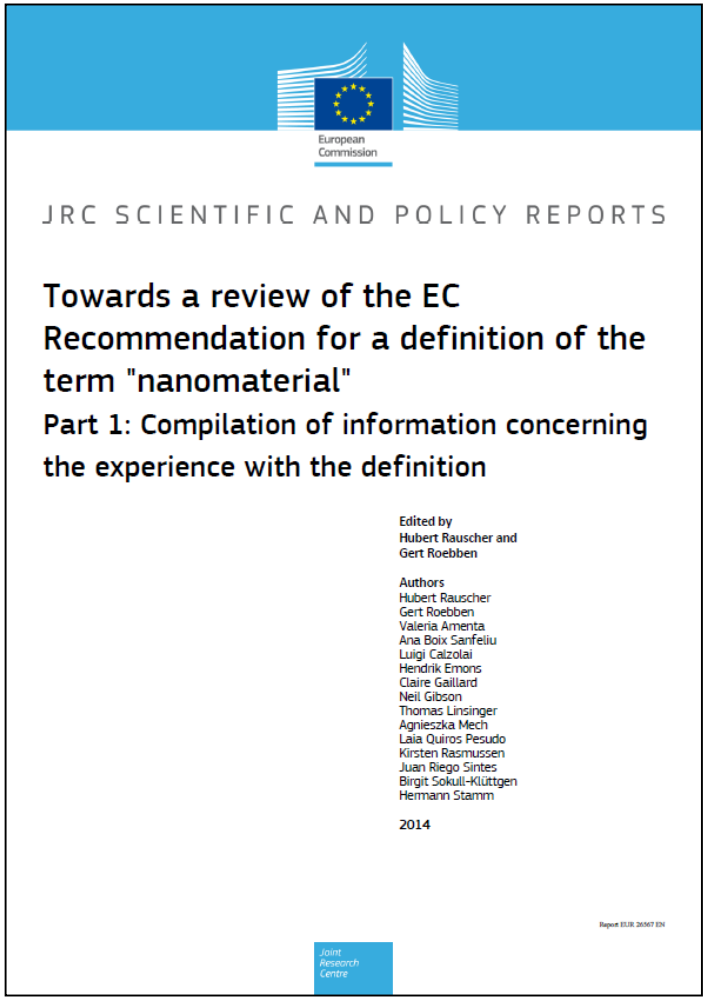
Commission Recommendation 2011/696/EU

- "'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"
- Number size distribution percentage can be adapted
- Fullerenes, graphene and carbon nanotubes are nanomaterials

To be integrated in EU legislation, where appropriate; recommendation to other actors (EU Agencies, Member States, industry)

Definition of a nanomaterial:
Commission review

- *"By December 2014, the definition set out in points 1 to 5 will be reviewed in the light of experience and of scientific and technological developments."*
- JRC reports 'Towards a review of the EC Recommendation for a definition of the term "nanomaterial"' (Part 1 available)


European Commission

JRC SCIENTIFIC AND POLICY REPORTS

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

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Joint Research Centre

Second regulatory review (2012)

- Overview of nanomaterials on the market and available information on hazard properties (in-depth information in attached Staff Working Paper)
- Background information on definition
- Assessment of regulatory options for REACH, including possible amendments of REACH annexes
- Overview of other relevant legislation

EUROPEAN COMMISSION

Brussels, 3.10.2012
COM(2012) 572 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Second Regulatory Review on Nanomaterials

(Text with EEA relevance)

{SWD(2012) 288 final}

Second regulatory review (2012)

- Nanotechnology identified as a key enabling technology
- Global market evaluated at around 11 million tonnes (roughly 20 bn €)
- Direct employment in nanotechnology estimated as 300.000 to 400.000 jobs (figures from KETs report)

Second regulatory review (2012)

Three main types of nanomaterials

- Commodity materials (e.g. carbon black or synthetic amorphous silica) – more than 95% of market, used for decades, including in high exposure situations
- Newly developed medium volume substances (e.g. nano-TiO_2, carbon nanotubes etc.) – some of them under discussion for safety aspects
- Newly developed low volume substances (a large variety of substances) – most of them used in technical applications such as catalysts, batteries, solar cells etc.

Carbon black	*9 600 000 tonnes/annum*	*Cerium oxide*	*10 000*
Synthetic amorphous silica	*1 500 000*	*Zinc oxide*	*8 000*
Aluminium oxide	*200 000*	*Carbon nanotubes and nanofibres*	*Hundreds or a few thousand*
Barium titanate	*15 000*	*Nanosilver*	*20*
Titanium dioxide	*10 000*		

Second regulatory review (2012): Hazards & risks

Key statement by SCENIHR 2009

- Potential toxic effects of nanomaterials for man and the environment
- Not all nanomaterials induce toxic effects. Some have already been in use for a long time (e.g., carbon black, TiO2) showing low toxicity
- The hypothesis that smaller means more reactive, and thus more toxic, cannot be substantiated
- Nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not.
- Case-by-case approach for the risk assessment of nanomaterials is still warranted
- While risk assessment methodologies are generally applicable to nanomaterials, specific aspects related to nanomaterials still require further development

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Relevant legislation

Legislation applicable to nanomaterials or products containing nanomaterials

- Horizontal legislation
  - REACH
  - CLP
  - Occupational health & safety
- Product-specific legislation
  - Cosmetics ✓
  - Food safety ✓
  - Biocides ✓
  - Pesticides
  - Toys
  - Electrical equipment
  - Waste & environmental legislation

REACH

Regulation (EC) No 1907/2006 of the EP and of the Council of 18 December 2006 concerning the **registration, evaluation, authorisation and restriction of chemicals**.

- Nanomaterials covered by substance definition,
  but currently not explicitly mentioned within REACH

REACH

- Registration: Registration obligation for substances either on their own, in mixtures or in certain articles with staggered timelines
- Evaluation: Dossier & substance evaluation
- Authorisation: Identification of substances of very high concern, inclusion in the candidate list and subsequently in Annex XIV, individual authorisation decisions (regardless of tonnage)
- Restriction: Restricted substances, mixtures or articles to be listed in Annex XVII case of an unacceptable risk to health or env.
- Information for downstream users: Safety Data Sheets

Exemptions from registration:

- *< 1 tonne manufactured per year*
- *Substances in Annex IV about which sufficient information is known*
- *Substances in Annex V for which registration is unnecessary*
- *Medicinal products, food and feedstuff (also exempt from authoris.)*

REACH: nanomaterials

- Voluntary tickbox "nanomaterial" for registration dossiers
- Many registration dossiers unclear in whether and how they cover nanoforms of substances
- Commission prepares modifications in some of the REACH Annexes
  - *to ensure clarity on whether and what nanoforms are covered in registration dossiers*
  - *to clarify how the safe use of nanoforms needs to be demonstrated (read-across etc.)*
  - *to adapt information requirements to specificities of nanomaterials (e.g. characterisation of nanoforms)*

CLP

Regulation (EC) No 1272/2008 on **Classification, Labelling and Packaging** (CLP) of dangerous substances and mixtures entered into force on 20 January 2009.

- CLP Article 9: Evaluation of hazard information for substances and mixtures
  - *"When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used."*
- Different forms/particle sizes may have different classifications
- Substances incl. nanomaterials classified as hazardous to be notified
- Classification & Labelling inventory includes nanoforms

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Labelling of nanomaterials

- Hazard labelling according to CLP
- Ingredient labelling in product-specific legislation:
  - Supported for all consumer products where ingredient lists exists
  - Labelling should be risk-independent and be done by a mention of the term “nano” in brackets after the ingredient in question.
  - No indications that nanomaterials pose high levels of hazards or exposure in other products that would justify the introduction of labelling for products where no ingredient lists exist.

  → *Food information for consumers, cosmetics, biocides*

Cosmetics

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on **cosmetic products**

- Notification to the Commission of cosmetic products containing nanomaterials 6 months prior to marketing, incl. safety data & toxicological profile → *CPNP*
- Commission may ask SCCS to give opinion on safety of the nanomaterial
- Catalogue to be made avalaible of all nanomaterials used in cosmetic products placed on the market
- Risk-independent labelling of nano ingredients

Food safety

Regulation No 178/2002: general food safety framework, based on the precautionary principle (no specific mention of nanomaterials)

Regulation No 1333/2008 on Food Additives, introducing a positive list for authorised substances

Article 12:

> When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or **there is a change in particle size, for example through nanotechnology**, the food additive prepared by those new methods or materials shall be considered as a **different additive** and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.

Food safety

Regulation 1169/2011: Food information to consumers (FIC), covering all foods

- Definition for engineered nanomaterials ("intentionally produced"), to be aligned with Commission recommendation by delegated act
- Risk-independent labelling of nano ingredients

Biocides

Regulation (EU) No 528/2012 on biocide products (BPR)

- Approval of active substances and marketing authorisation of products (simplified authorisation procedure is possible)

Nanomaterials in BPR:

- Contains standard definition of nanomaterials
- Simplified authorisation procedure possible, but not for products containing nanomaterials
- Approval of active substance does not generally cover the nanomaterial form of active substance - separate dossier needed.
- A dedicated risk assessment needed for the nanomaterial form of the active and non-active substances
- Risk-independent labelling of nano ingredients

National initiatives

- French registry “r-nano” launched in 2012 (deadline June 2013) for >100g nano substance
- Draft decree/order for Belgian and Danish registry notified to the Commission
- UK/NO initiatives

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Impact assessment: Background

Second regulatory review:

"Need for better accessible information:

✓ *As a first step, the Commission will create a web platform with references to all relevant information sources, including registries on a national or sector level, where they exist. […]*

In parallel, the Commission will be launching an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes."

Impact assessment: Problem definition

- The main problem that this initiative aims to address is that the **current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient** for an **adequate response to health and environmental risks and for informed consumer choice.**

***Caveat**: premise of insufficiency of information for aforementioned purposes not generally accepted*

→ *to be assessed in this exercise*

Impact assessment: Problem definition

- The main problem that this initiative aims to address is that the **current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient** for an **adequate response to health and environmental risks and for informed consumer choice.**

- Concerns about **market fragmentation and a divergence of requirements** for the marketing of nanomaterials in different Member States.

Impact assessment: policy objectives

- Ensure the protection of human **health** and the **environment** & ensure **consumer** protection related to nanomaterials on the market

- Ensure a proper functioning of the **internal market** and a level playing field for businesses marketing nanomaterials

Impact assessment: policy objectives

- Provide **decision-makers, regulatory/risk assessment authorities**, **professional users** and **workers** with information that allows for an appropriate response to possible health or environmental risks of nanomaterials

- Provide **consumers** with relevant information on products containing nanomaterials on the market and hence contribute to consumer trust

- Maintain **competitiveness** and **innovation** of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs).

- Ensure the **proportionality** of the information requirements and the associated costs and administrative burden.
- Protect **confidential** business information

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External study

Study in support of the impact assessment conducted by RPA & BiPRO.

Deliverables:

- Three reports
- Public consultation
- Validation workshop

External study

- **Evaluation report**, comprising the results of the evaluation of existing notification and registration systems (FR / CPNP)
- **Building blocks report**, providing the background information for the better definition and refinement of the policy options
- **Options assessment report**, providing the results of the full analysis the policy building blocks.

	Evaluation	Building blocks	Options assessment
6 March	1st	1st	-
12 June	Final	2nd	1st
8 Aug	-	Final	2nd
22 Sept	-	-	3rd
29 Oct	-	-	Final

External study

Evaluation report (focused on French notification system)

- Information on notified substances
  (what kind? use? innovative? REACH/C&L status?)
- Notifiers (size, value chain)
- Notified information (information requirements; confidentiality)
- Compliance
- Costs (authorities, firms across value chain)
- Value added
- Innovation & competitiveness

External study

Building blocks report

- Profiling risks and hazards
- Value chain characterisation
- Growth and innovation
- Indicators on fitness-for-purpose

Options assessment report

- Modelling potential impacts on health/env. & on internal market
- Assessing administrative and other costs
- Analyses in line with impact assessment guidelines

Today's workshop

Presentations on
(1) existing notification systems
(2) hazards/risks of nanomaterials & benefits of transparency measures
(3) nanomaterial markets & impacts of transparency measures

- Presentation by RPA (20-25 min.)
- Panel (short opening statements followed by 20 min. panel discussion)
- General discussion / Q&A (30-60 min.)

Presentations on next steps: policy options & options assessment

More information

Websites:

DG ENTR website on nanomaterials:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm

Commission websites on nanotechnology:

http://ec.europa.eu/nanotechnology/links_en.html

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