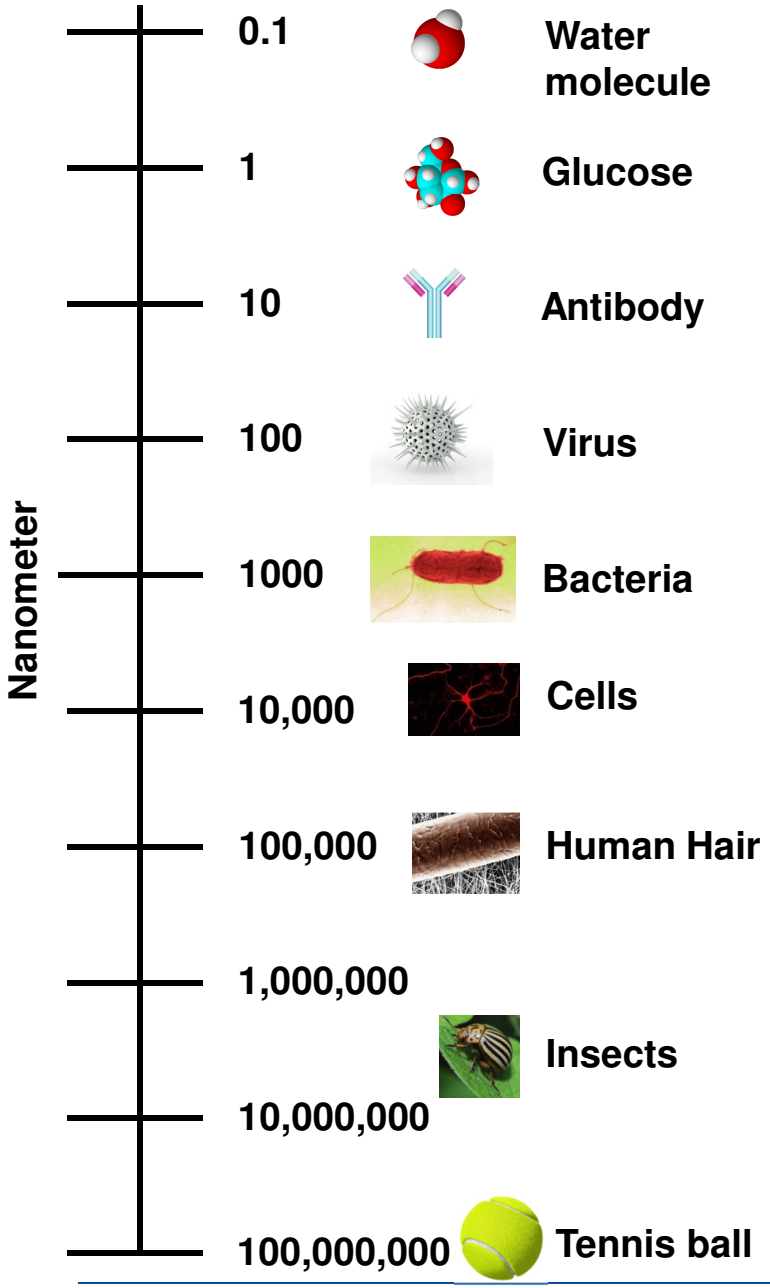
FEDERAL INSTITUTE
FOR RISK ASSESSMENT

BfR
Bundesinstitut für Risikobewertung

# 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

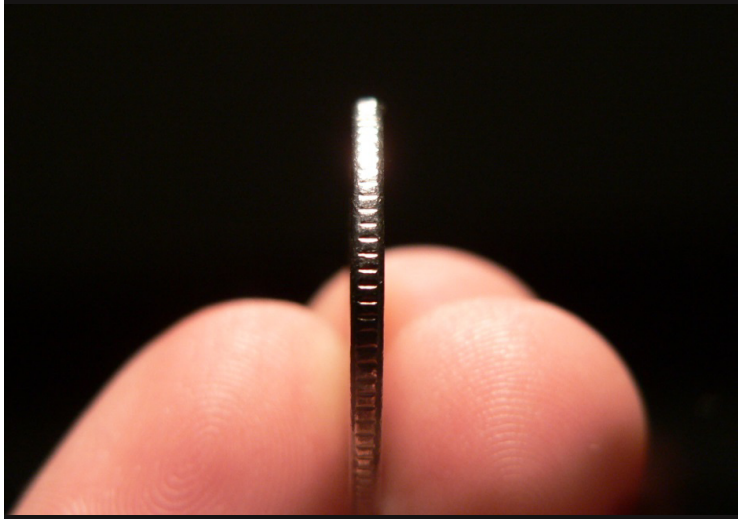

# Regulation of Nanomaterials: Different sides of the same coin?

Regulatory Bodies
EU Commission, National Governments
Risk Assessors

Predict potentially harmful effects

Monitor potentially harmful effects

**Nanomaterials**



**Regulatory Challenges**

Unknown potential risk to humans

High potential benefit for consumers, (workers, patients)

Identify potentially harmful effects

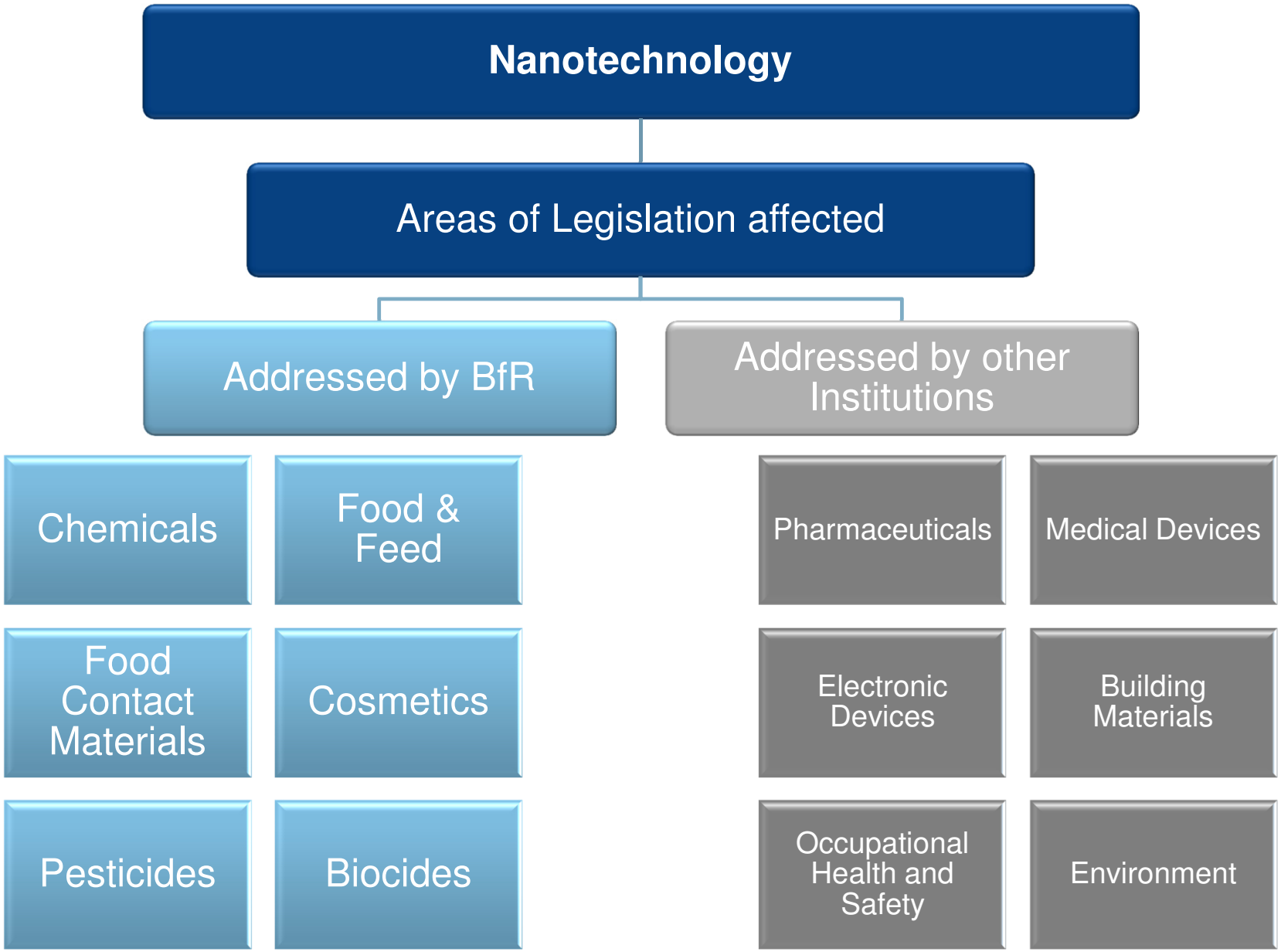
Measure potentially harmful effects

Industry
Industry Associations

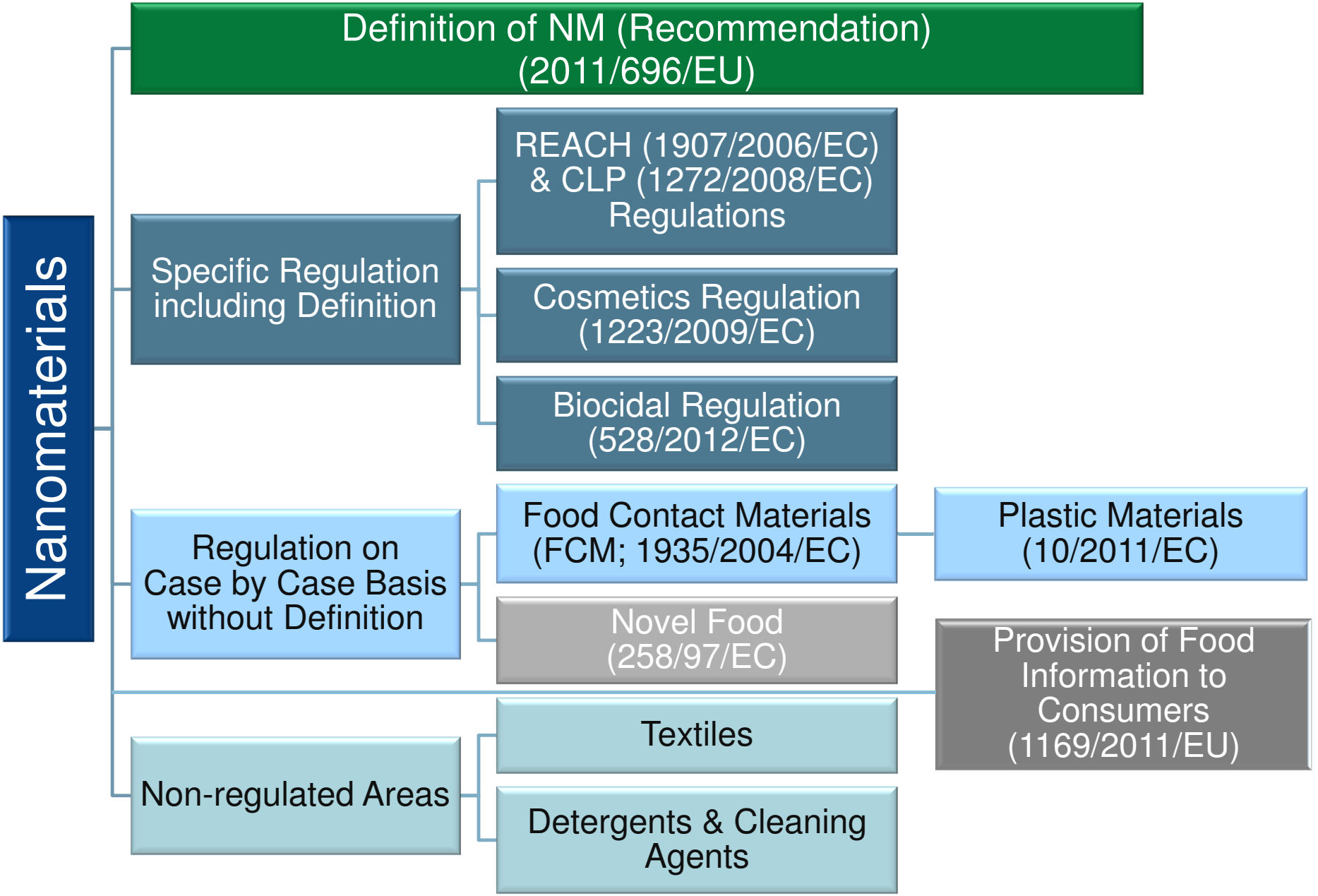
# Regulatory Landscape

# Europe

# Areas of Legislation effected by Nanotechnology



# Areas Affected: Current Regulatory Landscape



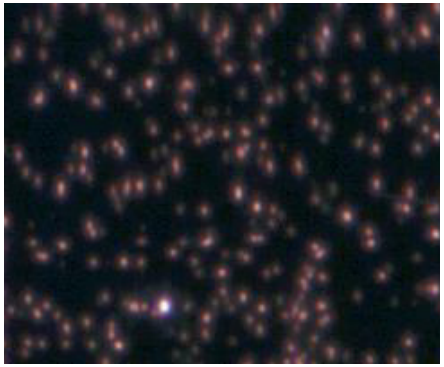
# Definition

# What are Nanomaterials? Recommendation of the European Commission: 2011/696/EU

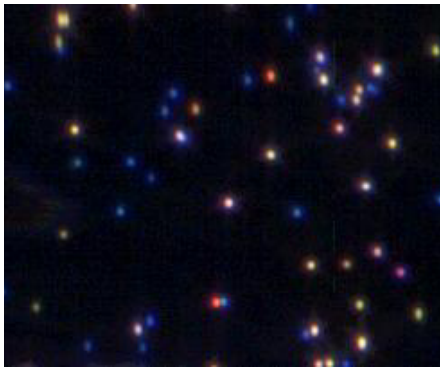
2. „Nanomaterial" means a natural, incidental or manufactured material containing **particles**, in an unbound state or as an aggregate or as an agglomerate and where, for **50 % or more** of the **particles in the number size distribution**, one or more external dimensions is in the size range **1 nm-100 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.



Silver nanoparticle of different sizes , dark field microscopy, Cytoviva Inc., BfR



# 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?

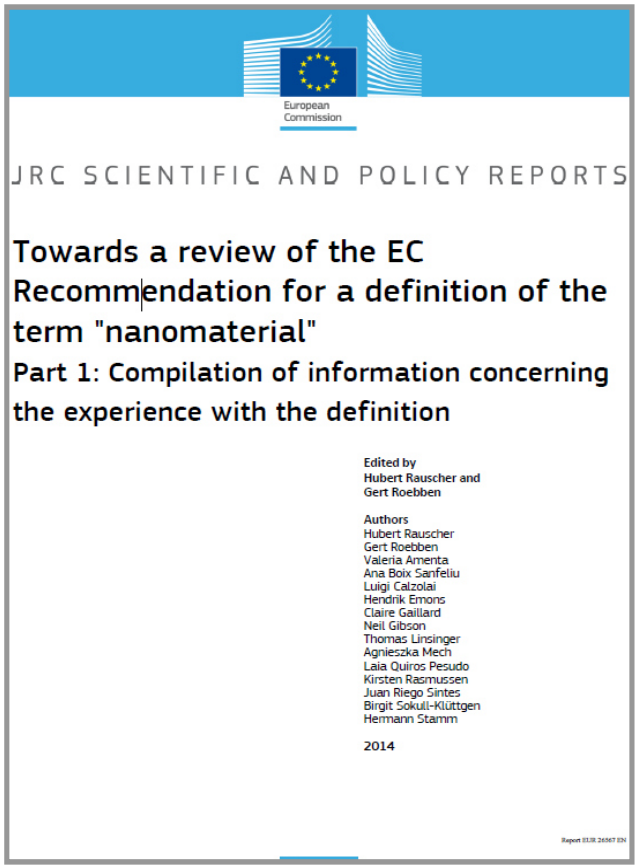
- Mixture of particles within and outside the nanoscale: How to select the correct parameters whether a material meets the definition of nanomaterials?

## 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


European Commission

JRC SCIENTIFIC AND POLICY REPORTS

Towards a review of the EC Recommendation for a definition of the term "nanomaterial"

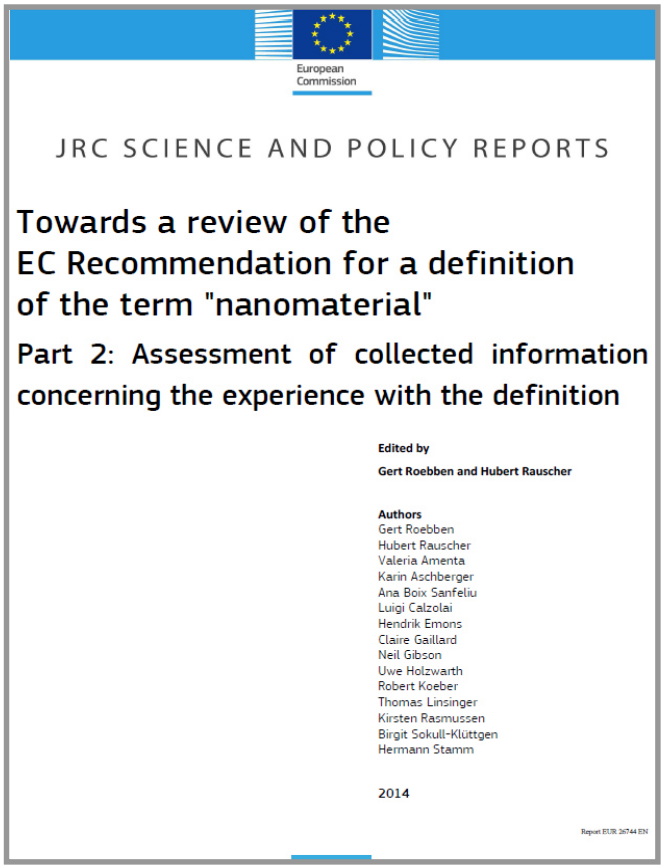
Part 1: Compilation of information concerning the experience with the definition

Edited by
Hubert Rauscher and Gert Roebben

Authors
Hubert Rauscher
Gert Roebben
Valeria Amenta
Ana Boix Sanfeliu
Luigi Calzolai
Hendrik Emons
Claire Gaillard
Neil Gibson
Thomas Linsinger
Agnieszka Mech
Laia Quiros Pesudo
Kirsten Rasmussen
Juan Riego Sintes
Birgit Sokull-Klüttgen
Hermann Stamm

2014

https://ec.europa.eu/jrc/sites/default/files/lbna26567enn.pdf


European Commission

JRC SCIENCE AND POLICY REPORTS

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

Edited by
Gert Roebben and Hubert Rauscher

Authors
Gert Roebben
Hubert Rauscher
Valeria Amenta
Karin Aschberger
Ana Boix Sanfeliu
Luigi Calzolai
Hendrik Emons
Claire Gaillard
Neil Gibson
Uwe Holzwarth
Robert Koeber
Thomas Linsinger
Kirsten Rasmussen
Birgit Sokull-Klüttgen
Hermann Stamm

2014

https://ec.europa.eu/jrc/sites/default/files/jrc_nm-def_report2_eur26744.pdf

# 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)
**European Parliament „Own Initiative Paper": „no data, no market" (2009-04-04)**
**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

**2007**
**Switzerland**: Report on risk assessment and management of synthetic nanomaterials (2007-09-01)

**2008**
**Netherlands**: Government requests advice on workplace exposure to nanoparticles (2008-09-05)

**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 Dorsthorst
Drs. M.W. Kooi
Dr. M.I. Bakker

Contact:
Dr. M.I. Bakker
Centre for Substances and Integrated Risk Assessment
martine.bakker@rivm.nl

**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/SER/2010/0060r

# Regulation in Single EU Member States: NM Registers

**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

| National Nano Registers | | | |
|---|---|---|---|
| Requirements | France | Denmark | Belgium |
| In Force | January 11, 2013 | June 18, 2014 | January 1, 2016 |
| When must the nanomaterial be notified? | Annual reporting after placed on the market | | Before it is placed on the market<br>Before the entry into force of the regime if it has already been placed on the market (2016-01-01) |
| Scope by Product | Substance at nanoscale level intentionally produced as such, as part of a mixture or in articles (release) | Mixtures and articles containing nanomaterials (natural, incidental or manufactured) intended for sale to consumers | Manufactured nanoparticle substance as such or as part of a mixture (2017-01-01)<br>Articles (not yet) |
| | *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: **R**egistration, **E**valuation, **A**uthorisation, **R**estriction of **C**hemicals: 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

# Cosmetic Products: Regulation (EC) No 1223/2009

**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.

# Nanomaterials in Cosmetics - Regulation

**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;

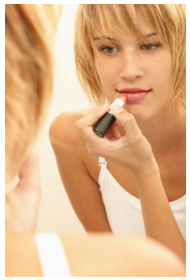
(d) the **toxicological profile** of the nanomaterial;

(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.

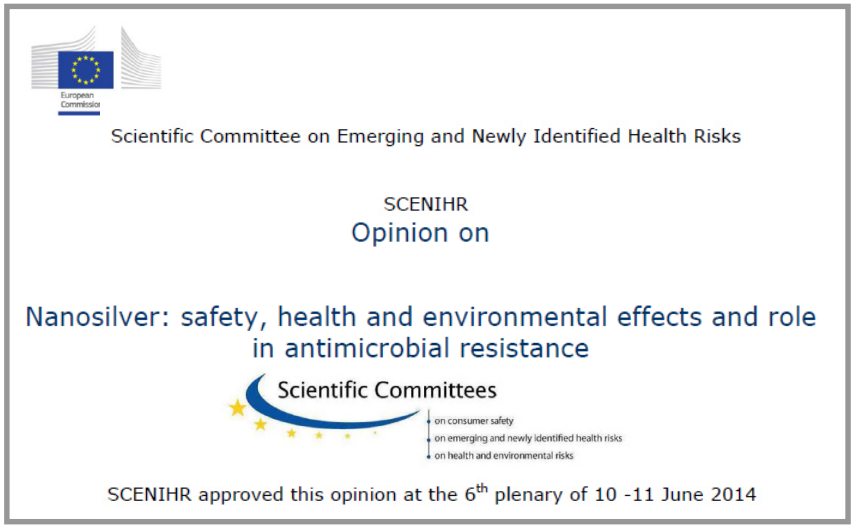
# Scientific Committee on Consumer Safety (SCCS)

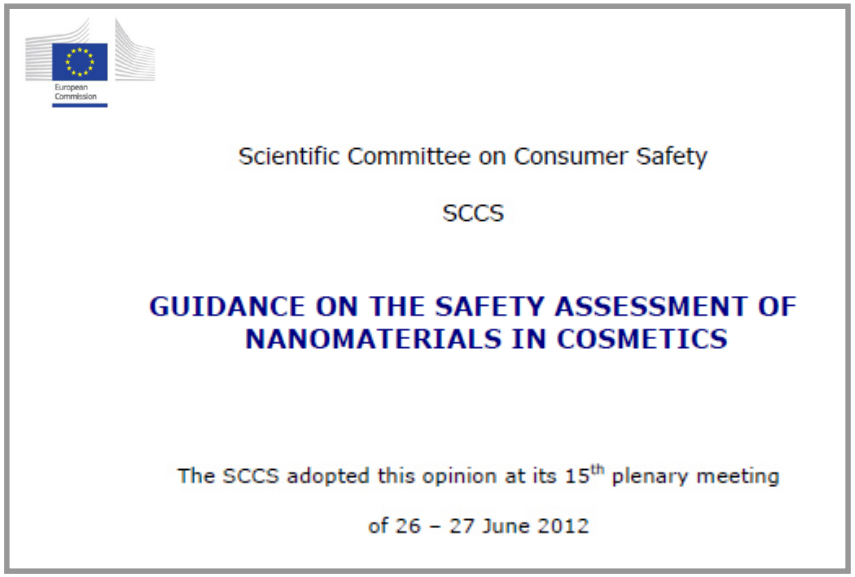
## Opinion:



- 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



# Food Contact Materials

# (FCM)

# Nanomaterials in Food and Food Contact Materials

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.

# Nanomaterials in Food and Food Contact Materials

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.

# FCM: Regulation 10/2011/EC on plastic materials and articles

***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.**

# FCM: Regulation 10/2011/EC on plastic materials and articles

***Section 2, Article 9:***

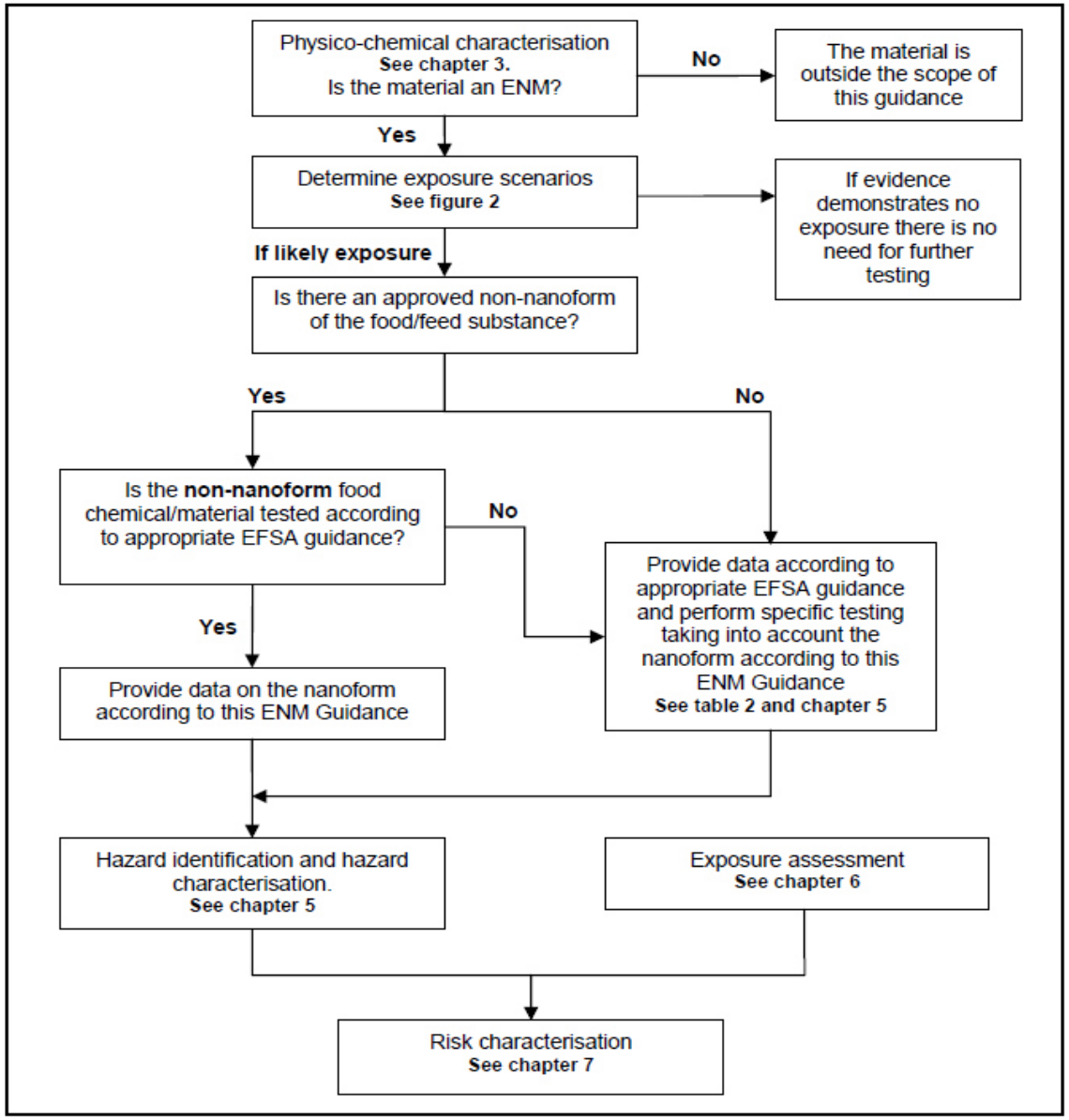
***Specific requirements on substances***:

Substances in **nanoform** shall only be used **if explicitly authorised and mentioned** in the specifications in Annex I.

# Issue: Exposure Model

# Nanomaterials in Food Contact Materials and Food

## 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

# Kinds of Application and Impact for Risk Assessment

## 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

FEDERAL INSTITUTE
FOR RISK ASSESSMENT

BfR
Bundesinstitut für Risikobewertung

# Thank you for your attention


Andreas Luch

Federal Institute for Risk Assessment
Max-Dohrn-Str. 8-10 • 10589 Berlin, GERMANY
Tel. +49 30 - 184 12 - 0 • Fax +49 30 - 184 12 - 47 41
bfr@bfr.bund.de • www.bfr.bund.de