NANOREG

Nanoparticle producers: How to deal with the legislation

Costa da Caparica

2 April 2014

Background

Regulatory Landscape

Nanomaterials are currently governed by a variety of legislative instruments at EU and national level.

Definitions have been developed on a case-by-case basis and vary across sectors, creating unnecessary burdens for industry and hampering public debate about risks and benefits of these substances.

The experience of the first registration deadline under **REACH** (30 November 2010), the EU's overarching chemicals policy, showed that companies needed more clarity about their obligations with regard to nanomaterials.

REACH has a key role to play in generating information about the properties of nanomaterials as chemical substances.

National and EU Initiatives (Ilustrative)

Belgium ratifies National Nano Reporting Scheme

The Belgian Council of Ministers has validated the country's mandatory nanomaterial reporting scheme. This will require companies who put substances and mixtures containing nanomaterials on the Belgian market to register their materials. An evaluation is set to be run on whether products containing the materials will also need to be registered.

US and Canada develop Classification Scheme for Nanomaterials

US and Canadian regulators seeking to harmonize their legislative approaches for nanomaterials have created a classification scheme for the materials. Developed as part of the RCC's Nanotechnology Initiative, it is said to be 'the first time regulatory programs are considering a classification scheme [...] to increase the utilization of read-across and analogue data'.

Swedish Nano Action Plan did not thoroughly consider Impact on Industry

In a recent interview with BNA Bloomberg's International Environment Reporter, NIA Director of Advocacy David Carlander stated that the Swedish action plan for nanomaterials had "not thoroughly considered" the potential impact it could have on industry. He noted that "the proposals fail to realize that nanomaterials are similar to conventional chemicals, in that some may be toxic and others not", and that this is likely the reason why "some of the suggested proposals seem to be too far-reaching".

Austrian EPA publishes final Version of Study reviewing the RoHS2 List of Restricted Substances

Environment Agency Austria has published the final version of its study into a methodology for updating the List of Restricted Substances used in EEE, specifically Annex II of the RoHS2 Directive. The review process began in 2012, and undertook three stakeholder meetings and four internet consultations.

New Proposal for a Regulation on Novel Foods targets Nanomaterials

The European Commission has published a new proposal for a Regulation on Novel Foods 2013/045(COD); this draft document is a new attempt to review the legal framework for novel foods that was set in Europe with the 1997 Regulation on Novel Foods (EC) 258/97.

Danish Nano Register Notice to EC claims "it is becoming clear that many nano-Product uses do not pose a Risk"

The Danish EPA has informed the EC of a 'draft Order on a register of mixtures and articles that contain nanomaterials as well as the requirement for manufacturers and imports to report to the register'. In its notification the Danish EPA states that 'it is becoming clear that many nano product uses do not pose a risk to consumers and the environment'.

France publishes Results from the first Round of its Mandatory Nano Reporting Scheme

On 1 January 2013 France launched its mandatory reporting scheme for substances at the nanoscale that are produced or imported into France. A report, entitled Elements from the Declarations of Substances at Nanoscale, was published by the Ministry of the Environment and analyses the results of the first round registration

Source: NIA – Nanotechnolgy Industries Association

Exposure Limit Values

- **Limit values for nanomaterials**

- Several generic, non-specific limits set; examples

Organisation	Type of nano-particles	Generic limit
BSI (UK)	insoluble non-carcinogenic	0.066 * limit for non-nano form
IFA (DE)	biopersistent granular, density > 6000 kg/m^3	20,000 particles/cm^3
RIVM (NL)	rigid, biopersistent nanofibres	0.01 fibres/cm^3

- Few specific limits

Organisation	Type of nano-particles	Recommended limit
NIOSH (USA)	Ultrafine titanium dioxide (≈ nano)	0.3 mg/m^3
NIOSH (USA)	Carbon nano-tubes and -fibres	0.001 mg/m^3
NEDO (Japan)	Fullerenes C_{60}	0.116 mg/m^3

- DNELs by registrants: generally in mg/m^3

TNO triskelion bv 35

General Industrial Regulation

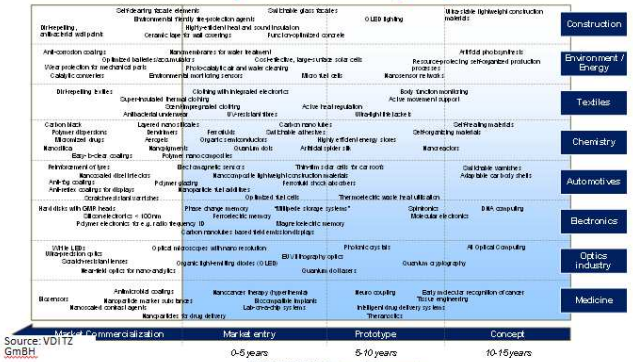
Estudo / Medição	Âmbito	Legislação	Periodicidade
Medição efluentes gasosos	Ambiente	DLº 78/2004, 03/04; Portaria 80/2006, 23/01; Portaria 675/2009,23/06	2 vezes/ano
Ruído Ambiental	Ambiente	DL 9/2007, 17/01	Anual
Ruído Laboral	SHT	DL 182/2006, 06/09	Anual
Iluminância	SHT	Portaria 702/80, 22/09; DL243/86, 20/08	Anual
Temperatura, Humidade, velocidade do ar	SHT	Portaria 702/80, 22/09; DL243/86, 20/08	Anual
Parâmetros químicos do ar interior	SHT	DL 24/2012, 06/02 Portaria 702/80, 22/09;	Anual
Poeiras/ Partículas em suspensão	SHT	Lei n.º3/2014, 28/01; Port.353-A/2013, 04/12; NP 1796:2007 Portaria 702/80, 22/09	Anual
Radiações ionizantes	SHT	DL 222/2008, 17/11 Portaria 702/80, 22/09	Anual
Máquinas (Aplicação Directiva)	SHT/ Seg. Industrial	DL 103/2008, de 24/06	--

Example based on the Portuguese Legislation

Why should we care about nano?

Nanotechnology: a world of applications

Nanotechnology will find applications in practically all sectors of the economy over the next few years…



Source: VDITZ GmbH

Nanotechnology as the answer to key challenges faced by mankind

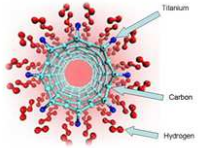
… decisively contributing to solve some of the toughest and most critical problems of today and tomorrow

Water Supply

- *Solutions for water treatment (filtering and disinfection)*

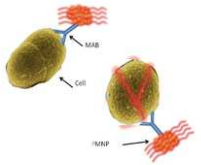
Energy

- *Solutions for energy production and storage*



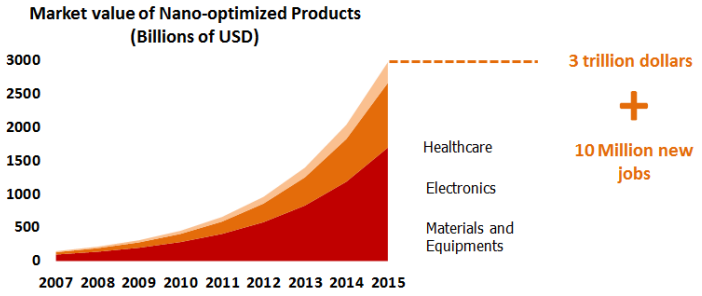
Health

- *Solutions for the treatment of cancer cells*



Nanotechnology's economic and social impact

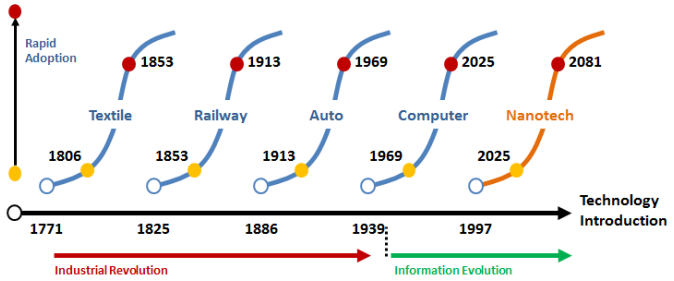
Most estimates point to an exponential growth in both the sector's production value and jobs creation over the coming years



Source: Lux Research

Nanotechnology: the next wave?

The impact of Nanotechnology in modern civilization can only be compared to the 4 previous technology waves of the last two centuries



Source: Norman Poire

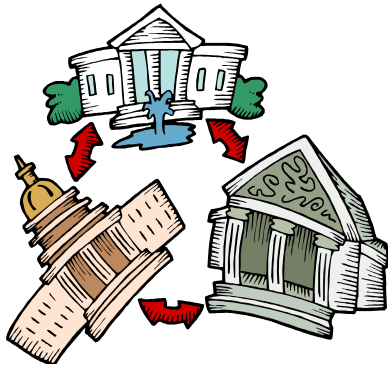
Regulatory challenges

The concept of a European Register of Products Containing Nanomaterials based on present substance and product related regulations presents several advantages:

- Significantly lower cost than independent register which causes duplicate obligations: For substances under REACH 90-95%* savings are expected, 80%* in the area of cosmetics (cosmetics regulation), 95%* for food (Novel Food Regulation and Food Packaging), and 40%* for cleaning and desinfection (partly Biocidal Products Regulation)
- A single European Register would cause less market distortion on innovation and competition than individually different registers at the national level

*Assessment of impacts of a European Register of Products Containing Nanomaterials – Umwelt Bundesamt

Regulatory challenges

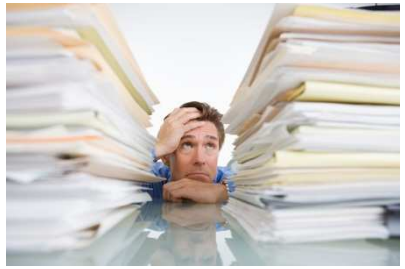


The concept of a European Register of Products Containing Nanomaterials based on present substance and product related regulations presents several advantages:

- Public authorities and governments are provided with a comprehensive overview on the use of nanomaterials in various sectors, information on the possible exposure of humans and the environment to nanomaterials and support in the possible risk management measures
- Manufacturers of a final product benefit from the improved knowledge about the use of nanomaterials throughout the entire value chain
- Consumers can choose between products containing nanomaterials and products without nanomaterials.

Regulatory challenges

Overview of the estimated number of notifications in total for each sector, and the number per company affected (having to notify a product)



Sectors	Notifications									
	Total		Total per company affected		Substances		Mixtures		Articles	
	Min	max	min	max	min	max	min	max	min	max
Total	2.400.000	4.100.000	16	57	7.000	10.500	1.574.800	2.641.500	838.200	1.480.500
1. Substances	7.000	11.000	5	16	7.000	11.000	--	--	--	--
2. Cosmetics	23.000	35.000	7	13	--	--	23.000	35.000	--	--
3. Health Care	70.000	145.000	23	75	--	--	70.000	145.000	100	200
4. Food & Feed	2.000	15.000	2	32	--	--	2.000	15.000	--	--
5. Coatings & Inks	1.500.000	2.400.000	350	610	--	--	1.500.000	2.400.000	--	--
6. Cleaning & Disinfection	11.000	26.000	4	20	--	--	11.000	26.000	--	--
7. Rubber Products	85.000	170.000	11	27	--	--	--	--	85.000	170.000
8. Building & Construction	2.800	5.300	3	12	--	--	1.300	3.300	1.500	2.000
9. Textiles	20.000	185.000	2	31	--	--	--	--	20.000	185.000
10. Paper Products	650.000	950.000	43	86	--	--	--	--	650.000	950.000
11. Complex Objects & Other Products	100.000	150.000	16	59	--	--	--	--	100.000	150.000

*Assessment of impacts of a European Register of Products Containing Nanomaterials – Umwelt Bundesamt

Regulatory challenges

- Defining “nano”
- Distinguishing nano
- Characterisation
- Adapting existing paradigms

Definition of nanomaterials

EC recommendation

2011/696/EU, OJ L 275, 20.10.2011

- 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 %. Alternatively, it is also a nanomaterial if it has a specific surface per unit volume of greater than 60 m2/cm3. There are specific inclusions such as graphene.

- Naturally occurring and incidental materials are included, as well as manufactured particles. Aggregates and agglomerates of such particles are included.

This recommendation gives EU legislators a legal reference for nanomaterials, when adopting new or implementing existing legislation.

Nanomaterials under REACH

Substance identification

A substance is defined in REACH (Article 3(1)):

*"**Substance**: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;"*

Nanomaterials under REACH

Substance identification

REACH distinguishes between **non-phase-in and phase-in substances.**

A phase-in substance is defined by a substance meeting the criteria of Article 3(20) of REACH. Unless the substance is a no-longer polymer or has not been placed on the market in line with Article 3(20)(b), this means that the substance must have been listed in the ***European Inventory of Existing Commercial Chemical Substances (EINECS)****.*

The intention behind this provision is to give phase-in status to substances which have been listed in EINECS in the past and which therefore were considered as existing substances before the entry into force of REACH.
In interpreting whether a concrete material is covered by a particular EINECS entry, therefore historical criteria need to be applied.

In other words, whenever the material was considered to be covered by a particular EINECS entry in the past, it should be considered to have phase-in status under REACH.

Whenever the substance was considered to be subject to notification as a new substance in the past, it should be considered as a non-phase-in substance under REACH.

This also applies to nanomaterials.

Nanomaterials under REACH

Registration

Since 1 June 2008, substances at the nanoscale which are considered as non-phase-in substances and which are manufactured or imported in quantities of 1 tonne/year or more need to be registered before manufacturing or importing.

Substances at the nanoscale, which are phase-in substances, can benefit from the extended registration deadlines, provided they have been pre-registered.

These extended deadlines are:

- 1 December 2010 for:
- substances that are CMRs (Carcinogenic, Mutagenic or Toxic for Reproduction) cat. 1 or 2 in a volume ≥ 1 tonne/yr, substances
- classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) and in a volume ≥ 100 tonnes/yr
- substances manufactured or imported in volumes ≥ 1000 tonnes/yr
- 1 June 2013 for substances manufactured or imported in volumes ≥ 100 tonnes/yr
- 1 June 2018 for substances manufactured or imported in volumes ≥ 1 tonne/yr

Nanomaterials under REACH

4 Case Studies: 3 substances and 1 class of substances

1) Form: means any chemical which can be attributed to a specific substance identity, as defined in Art. 3 and Annex VI.2, and is defined by additional characterisers.

2) Nanoform: means any form, as defined in (1), which falls into the scope of the nanomaterial definition relevant for REACH.

3) Generic nanoform: means a group of nanoforms, as defined in (2), which is deemed by the participants of the joint submission to be representative for the purpose of gathering (eco)tox information.

4) Product grade: a nanoform, as defined in (2), with specific parameters (e.g. functionality, colour, surface treatment, BET).

What is covered in the submitted registration dossiers?

	Generic Nanoforms	Nanoforms	Product Grades
SiO_2	1	4	> 500
Fe_xO_y	2	2	> 100
TiO_2	1	1	>> 100
Organic pigments (in total)	~ 120 – 150 (whole organic pigment industry in Europe)	?	~ 2,000 – 5,000 (whole organic pigment industry in Europe)
ZnO	1	1?	?
Nano Ag	1	4?	?

From CARACAL meeting 27 November 2013

Nanomaterials under REACH

4 Case Studies: 3 substances and 1 class of substances

Information	Costs per nanoform (range) *(NB total higher than for bulk)*
Information about particle size distribution (qualitative)	[1] 2,000 – 4,000 €
State of aggregation and agglomeration	2,000 € (up to 20,000 €)
Morphological characterisation (primary particle size distribution, crystal structure, shape, aspect ratio, information on assembly structure including shell like structures or hollow structures)	2,000 – 4,000 € (up to 7,000 €)
Surface properties (zeta potential, isoelectric point, information on coating or surface functionalization, information on surface chemistry (acidity, reactivity, catalytic properties)	3,000 – 5,000 € (up to 8,000 €)
Total costs per nanoform	9,000 – 15,000 € (up to 39,000 €)

[1] Approx. 10x higher for reliable quantitative determination against Recommended Definition

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Costs if generic nanoforms, nanoforms, or product grades where characterized

	all generic nanoforms	all nanoforms	all product grades
SiO_2	10,000 – 25,000 €	40,000 – 100,000 €	5 – 12.5 mio. €
Fe_xO_y	40,000 €	40,000 €	> 2 mio. €
TiO_2	10,000 – 25,000 €	10,000 to 25,000 €	>> 10 mio. €
Organic Pigments	1.2 – 2.2 mio. €	?	20 – 75 mio. €

Nanomaterials under REACH

Consequences for the Industry

- Moving away from substance characterisation to individual product grade characterisation makes joint registration difficult or even impossible.
- The associated financial burden cannot be supported by some industries incl. SMEs.
- Strenuous characterisation of nanoforms has little impact on better hazard characterization.

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Nanomaterials under REACH

What is already part of business routine?

Information under REACH	
• Information about particle size distribution	YES[1] / NO[5]
• State of aggregation and agglomeration	YES / NO[5]
• Morphological characterisation • primary particle size distribution • crystal structure, shape, aspect ratio • information on assembly structure including shell like structures or hollow structures	YES / NO[5] YES[1] / NO[5] YES[2,3] / NO[5] YES[2,3] / NO[5]
• Surface properties • Specific surface area • zeta potential • isoelectric point • information on coating or surface functionalization, information on surface chemistry (acidity, reactivity, catalytic properties)	YES[4] YES NO NO NO

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[1] volume/mass based, not number based

[2] measured only in R&D phase

[3] crystalline or amorphous structure of substances are known; but no routing testing

[4] only for special customer applications

[5] Answer YES or NO depends on specific case

Nanomaterials under REACH

Industry Proposal

Annex VI.2 could include per **nanoform** (incl. range for product grades):

- Information on particle size distribution
- State of aggregation
- Morphological characterisation (range of primary particle size distribution - qualitative, shape and aspect ratio)

Annex VII could include on agreed **generic form(s),** as range:

- Morphology, crystalline phase, shape, surface structure
- External particle size and size distribution
- Agglomeration and aggregation in material and preparation (qualitative description)
- Specific surface area
- Water solubility
- Surface chemistry/coating /modification

From CARACAL meeting 27 November 2013

Nanomaterials under REACH

Industry Position

- Technical data sheets, safety data sheets and classification and labelling requirements do already cover sufficiently the specifications and safety information on nanomaterials.

From CARACAL meeting 27 November 2013

CEFIC Generic Comments

on public consultation for REACH options

Although there is an overarching definition in place, the **lack of validated and certified measurement techniques is hampering efforts to better address nanomaterials in REACH**.

CEFIC supports the Commission in improving the EC Recommendation of a definition of nanomaterial and look forward to discussing the implications of the Commission's Recommendation in the context of REACH.

The context for regulatory control of nanomaterials must include the increasing understanding of leading scientists that a **nano-specific toxicity does not exist and that conventional data are useful and relevant to the evaluation of nanoparticle hazard**.

Donaldson/Poland, Current Opinion in Biotechnology 2013, 24:1–11

Kenneth Dawson at the EuroNanoForum in Dublin 2013

CEFIC Generic Comments

on public consultation for REACH options

The antithesis to Article 5 of REACH “no data, no market”, **does not automatically mean that *more data* means *more market* or even *more safety*** but rather it has the potential to restrict competition. With regard to animal protection, the safety testing should be limited to only meaningful and necessary studies.

In the light of registration obligations, Cefic shares the view of the Commission communicated in its 2nd Regulatory Review on Nanomaterials that **under REACH, different forms can be considered within a single registration of a substance.**

Cefic is committed to working with both industry and stakeholder experts to **develop solutions for effective application of the existing legislative tools to nanomaterials.**

Nano Specific Regulation (Ilustrative)

Impact	Title	Country	Document Type	Status	New Content	Updated	Update Importance
Medium	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) - 2011/65/EU	European Union	Legislation	Implemented		06 Feb 2014	Minor
Medium	Regulation on Novel Foods - 2013/0435(COD)	European Union	Legislation	On-going		07 Jan 2014	
Very High	Regulation on the Provision of Food Information to Consumers - 1169/2011	European Union	Legislation	Implemented		06 Jan 2014	Critical

Source: NIA – Nanotechnolgy Industries Association

How does INNOVNANO monitors Nano specific Regulation?

International Organisation for Standardization (ISO)

The International Organisation for Standardization (ISO) Technical Committee (TC) 229 on Nanotechnologies was established in 2005 and has been developing standards related to the field of nanotechnologies.

The committee's work has been divided as follows:

- **JWG 1 Terminology and nomenclature, linked to IEC/TC 113**
- **JWG 2 Measurement and characterization, linked to IEC/TC 113**
- **TG 2 Consumer and societal dimensions of nanotechnologies**
- **TG 3 Nanotechnologies and sustainability**
- **WG 3 Health, Safety and Environmental Aspects of Nanotechnologies**
- **WG 4 Material specifications**

International Organisation for Standardization (ISO)

Definition of roles within TC 229

- JWG1 has been given the task of developing definitions for various nano-related terms such as 'nanoscale', 'nanomaterial', 'nanoparticle' amongst many others.
- JWG2's focus is on developing measurement methods, with early work concentrating in particular on the characterization of single and multiwall carbon nanotubes, an important group of nanomaterials.
- Task Groups deal with consumer and societal issues (TG2) and sustainability (TG3).
- The role of Working Group 3 is related to the health- and safety-aspect of nanotechnologies, for example the handling and disposal of nanomaterials, risk assessments performed on nanomaterials, etc.
- The role of Working Group 4 is to develop specifications for nanomaterials, in order to support their growing use by industry.

Conclusions

1. Many national initiatives undergoing - complying w/ regulation will become increasingly hard and costly for SMEs
2. Regulatory uncertainty may impact on investment
3. Specific nano regulation is mostly application oriented:
   - Food
   - Cosmetics
   - Pharma & Medical
   - Biocidal
4. REACH can potentially be an effective framework to cover the issue of regulation for nanomaterials
5. Due to the absence of uniformity between countries being part of an Industry Association may be helpful for export oriented companies
6. Despite legislation nanomaterial manufacturers will benefit from early adoption of best practices regarding exposure control

Thank You!