

The logo for the Nanotechnology Industries Association (NIA) is displayed in large, bold, blue letters. The background features a dark blue diagonal band, a light gray diagonal band, and a pattern of blue spheres on the right side.

# NIA

Nanotechnology  
Industries Association

*Nanomaterials on the Market:  
What Regulators need to know*  
Brussels, 9<sup>th</sup> October 2009

***Industry Comment on:***  
***Information from Industry***  
***on Applied Nanomaterials and their Safety***

# *The Scope of this Comment*

- originally asked to comment on the presentation provided in the 'Is REACH sufficient'-session
- ... but: due to unforeseeable delays, the presentation was not available, so that these comments refer to *Deliverable 1: Information from Industry on Applied Nanomaterials and their Safety*

## DISCLAIMER:

- *The following comments were **not subjected to consultation with NIA Member companies***
- *The following comments are based on **my own opinion***



*Dr Steffi Friedrichs*

## *'Nano' under the EC's Verdict (June 2008)*

*'REACH is based on the principle that manufacturers, importers and downstream users have to ensure that they manufacture, place on the market or use such **substances that do not adversely affect human health or the environment**. Its provisions are underpinned by the precautionary principle.*

*There are no provisions in REACH referring explicitly to nanomaterials. However, **nanomaterials are covered by the "substance" definition in REACH.** '*

*' Manufacturers and importers would therefore have to cover the nano form in the **same registration as the bulk substance**. The following information about the nano form would be required in cases where properties or uses differ between the nano and the bulk:*

- (1) the information about the properties and uses,*
- (2) safety assessment for the nano form,*
- (3) any different or additional classification with regard to hazardous properties of the nano form, and*
- (4) any risk management measure and operational conditions required. In order to address the specific hazards associated with the nanoform, additional testing or information may be required.*

[Regulatory Aspects of Nanomaterials, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM (2008) 366 final dated 17.06.2008.]

## *'Nano' under the EC's Verdict (June 2008)*

*'For substances produced or imported in quantities of one tonne or more per year, the manufacturers and importers must elaborate and submit a technical dossier and, for substances in quantities of 10 tonnes or more, a chemical safety report, based on a chemical safety assessment.'*

*'REACH contains detailed requirements as regards the composition of the Technical Dossier and the Chemical Safety Report. Information required varies according to the tonnage manufactured or imported per year per manufacturer/importer and to the needs of the chemical safety assessment.'*

*[Regulatory Aspects of Nanomaterials, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM (2008) 366 final dated 17.06.2008.]*



*Industry Comments: Does REACH provide the necessary answers?*

**Brussels, 9<sup>th</sup> October 2009**

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# 'Nano' in REACH & CLP

## REACH (Regulation (EC) 1907/2006):

*'The tonnage triggers for registration apply to the total volume of a substance manufactured or imported by a registrant. Thus, for substances which exist both in a bulk form and in a nanoform, the total volume determines the need and the timing for registration and the information requirements.'*

## CLP (Regulation (EC) 1272/2008):

### CLP Article 9(5) requires:

*'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.'*

[Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, etc. (OJ L353, 31/12/08, p1).]

## REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) etc., (OJ L396, 30/12/06, p1).]

## REGULATIONS

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 16 December 2008

on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

(Text with EEA relevance)

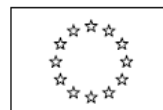
# 'Nano' in REACH & CLP

'The Commission Services and Member State Competent Authorities under ESR and NONS also decided with regard to **classification and labelling of nanomaterials** that:

*Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance.'*

*'It is current practice that a substance with different sizes or forms can have different classifications, as is the case for nickel and nickel powder (particle diameter < 1 mm).'*

NOTE: CLP is independent of tonnage!



EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL  
Water, Chemicals & Cohesion  
Chemicals

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Chemicals, Metals, Forest-based & Textile Industries  
REACH

Brussels, 16 December 2008

Doc. CA/59/2008 rev. 1

**Follow-up to the 6<sup>th</sup> Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH)**

**15-16 December 2008**

**Centre A. Borschette,  
Rue Froissart 36,  
1040 Brussels, Belgium**

**Concerns: Nanomaterials in REACH**

[*Nanomaterials in REACH*, CA/59/2008 rev 1.]

# *Deliverable 1:*

## *Interpretation of 'nano' under REACH & CLP*

REACH (Regulation (EC) 1907/2006):

*'This immediately provides four possible scenarios for nanomaterials:*

- 1) If the **nanomaterial is considered to be the same substance as the bulk form** of the same chemical element or compound, then registration of the substance would include the nanoform and its uses. Where a registrant subsequently introduces a different nanoform of the substance to the market, the registration dossier would have to be updated. [...] However, all the other REACH and CLP provisions would apply to the nanomaterial;*
- 2) If the **nanomaterial is considered to be a distinct substance from the bulk form** of the same chemical element or compound, then the nanomaterial would be exempted from the registration if the quantities involved were **less than one tonne per year**. However, all the other REACH and CLP provisions would apply to the nanomaterial;*
- 3) If the **nanomaterial is considered to be a distinct substance from the bulk form** of the same chemical element or compound and the quantities involved were **greater than one tonne per year**, then registration of the nanomaterial would be required; and*
- 4) Some substances (such as polymers) are **exempt from REACH** and, as such, polymers (and other exempt substances) in nano-form would not require registration in any event. However, even in such cases the CLP provisions would apply.'*

[*Deliverable 1: .Information from Industry on Applied Nanomaterials and their Safety*, prepared for the European Commission, DG ENV, Milieu, September 2009]

# *Deliverable 1:*

## *Interpretation of 'nano' under REACH & CLP*

### *4.7 Information on Nanomaterials under REACH:*

*'However, there are many other scenarios where nano-specific information (on uses) may not be provided including:*

- nano-form is used alongside non-nano-forms in particular uses. In the absence of specific guidance to the contrary, it is possible that some users (and/or manufacturers/suppliers) would highlight the use of nanomaterials;*
- nano-form is used in products covered by other legislation (for example, use of nano-coatings in drink bottles or nanoparticles in cosmetics). In such cases, it is unlikely that the CSA would make reference to the associated safety/risk implications of such uses;*
- nano-form is based on a substance which is not classified under DSD/CLP and therefore does not trigger an EA under REACH (see Box 1); and*
- nano-form is based on a substance which is exempt from some provisions of REACH (polymers, biocides, very low tonnage compounds, etc.).*

[Deliverable 1: .Information from Industry on Applied Nanomaterials and their Safety, prepared for the European Commission, DG ENV, Milieu, September 2009]

# Deliverable 1: Interpretation of 'nano' under REACH & CLP

## Box 1: Carbon Black (EC 215-609-9, CAS 1333-86-4)

The International Carbon Black Association states that carbon black: *is virtually pure elemental carbon in the form of colloidal particles that are produced by incomplete combustion or thermal decomposition of gaseous or liquid hydrocarbons under controlled conditions*

(Source: [http://www.carbon-black.org/what\\_is.html](http://www.carbon-black.org/what_is.html)).

Production of carbon black runs into millions of tonnes per year. The average aggregate particle diameters in several commercially produced carbon blacks range from 50 to 600 nm and the more loosely associated agglomerates can reach up to many micrometers in diameter (IARC, 2006). As such, carbon black contains nanomaterials (as defined).

Carbon black was pre-registered and, as of July 2009, has been successfully registered by a consortium with ECHA (see <http://www.cb4reach.eu/>).

The chemical safety report (CSR) did not include an Exposure Assessment on the grounds that carbon black is not classified as a hazardous material (within the EU).

The presence of nanomaterials in carbon black was dealt with as follows:

*Carbon Black is a so-called "nano-structured material" (ISO TC 229, Draft TS 12921), i.e. consisting of primary particles formed in the carbon black process that combine within milliseconds after formation in the reactor to aggregates and agglomerates. Therefore a differentiation for Carbon Black between nano-material and bulk/conventional material is not necessary* (Source: <http://www.cb4reach.eu/index.php?id=faqonreachbyindustry>).

[Deliverable 1: Information from Industry on Applied Nanomaterials and their Safety, prepared for the European Commission, DG ENV, Milieu, September 2009]

# *CASG Nano: Substance Identification & Sameness*

Nanomaterials in REACH (CA/59/2008 rev 1):

*'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**;"*

*[...] However, the **Technical Guidance Document (TGD)** on substance identification (June 2007) considered that "the current developments in nano-technology and insights in related hazard effects may cause the need for additional information on size of the substances in the future. The **current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD**".'*

[*Nanomaterials in REACH, CA/59/2008 rev 1.*]

# *SCENIHR on Risk Assessment Methodology: Substance Identification & Sameness*

## 1<sup>st</sup> Opinion:

*'Although the **existing toxicological and ecotoxicological methods** are **appropriate to assess many of the hazards associated with the products and processes involving nanoparticles**, they may not be sufficient to address all the hazards.'*

2<sup>nd</sup> Opinion (dealing particularly with the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents ("TGD") for new and existing (chemical) substances for assessing the risks of nanomaterials):

*'[...] **current methodologies** described in the TGDs are likely to identify certain hazards, but **modifications are required** for the assessment of risks to human health and the environment.*

*'[...] The evaluation of nanoparticle formulations should be carried out on **a case by case basis** and it is **important that it is determined whether test procedures will be predictive** for human health hazards for all types of nanoparticles.'*

[1. Scientific Committee on Emerging and newly identified risks; modified Opinion (after public consultation) on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies; adopted during the 7th plenary meeting of 28-29 September 2005.]

2. Nanomaterials in REACH, CA/59/2008 rev 1., rephrasing: SCENHIR, Opinion, approved for public consultation, on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials, approved for the public consultation at the 17th plenary on 29 March 2007.]

# NanoSafety – Case-by-case Approaches

## Example: Size

OECD WPMN Guidance Manual for DDPs:  
Physical-Chemical Properties and Material Characterization

### ANNEX V: Agglomeration/aggregation

*Particle size is a critical parameter in the assessment of environmental, health and safety aspects of nanoscale materials and questions regarding the EHS impacts from nanoscale materials often relate to size. Indeed, relating change in size to changes in other properties might lead to predictable mathematical relationships. The evaluations of EHS impacts necessarily involve biological systems which are themselves complex and may also introduce complications into the evaluation of material properties. Biological systems generally include water, which might encourage an increase in particle size, but might also include biosurfactants that can encourage collections of particle to disperse. Dissolved materials in biosystems may adsorb on or be absorbed by substances potentially affecting particle size and corresponding biological responses. For example, a solid particle that in its dry form is 50 nm may be 1000 nm in biological media. [...]*

*Water samples. Investigators are asked to consider examining physical-chemical properties in the following aqueous solutions:*

1. Medium hardness at pH 7 at 3 concentrations (eg 10, 1 and 0.1 mg/L for more dispersal materials)
2. Medium hardness with pH at 4, 7 and 9
3. Low, medium and hard water at pH 7,
4. pH 7 with a low, medium and high well described NOM isolate (e.g. Standard Suwannee River Humic Acid (SRHA) @ 1, 5, 10ppm)
5. Standardized sea water
6. Iso-tonic solution (0.9% w/v NaCl)
7. Artificial saliva
8. Artificial serum

*Most importantly:*

*... At any time:*

*'On the basis of the evaluation, the **European Chemicals Agency can require further information**, which may include information not required in Annexes VII to X of REACH.'*

[*Nanomaterials in REACH, CA/59/2008 rev 1.*]

*... **Any registrant** may decide that he needs to **generate further information** beyond the information required through Annexes VII-X of REACH in order to be able to **demonstrate and document that the risks of the substance (in all forms) are controlled**.*



*... Any registrant may decide to develop exposure scenarios [...] in order to describe and implement how he controls the nanomaterial at his own site and recommend downstream users to control exposures [...]*

[CASG Nano/03/2008 on 'non-phase-in substances']

# Industries' ongoing global Support

3<sup>rd</sup> Nanotechnology 'Safety for Success'-Dialogue (to be held on the 3<sup>rd</sup> & 4<sup>th</sup> November 2009):

- Industries present 5 case studies of products on the market:
  - Presented by 2 TAs and 3 individual companies



**3<sup>rd</sup> Nano Safety for Success Dialogue: Building Trust in Nanotechnologies<sup>1</sup>**

Venue: Renaissance Hotel, 19, rue du Parnasse, B-1050, Brussels, Belgium

- Answering questions such as:
  - *What are the regulatory requirements that govern its existence on the market?*
  - *What kind of safety testing is being performed?*
  - *What are the expected benefits and risks (consumer, manufacturer, and environment)?*
  - *What is the involvement of stakeholders and citizens' groups?*

# Industries' ongoing global Support

## The OECD Sponsorship Programme on NanoSafety:

	Lead sponsor(s)	Co-sponsor(s)	Contributor
Fullerenes(C60)	Japan, US		Denmark, China*
SWCNTs	Japan, US		Germany, Canada, EC, France, China, BIAC*
MWCNTs	Japan, US	Korea, BIAC	Germany, Canada, EC, France, China, BIAC*
Silver nanoparticles	US, Korea	Germany, Canada, Australia, Nordic Council of Ministers*	EC, France, China*
Iron nanoparticles	China, BIAC*		Canada, US, Nordic Council of Ministers
Carbon black			Canada, Denmark, Germany, US
Titanium dioxide	France, Germany	Austria, Canada, Spain, BIAC, Korea, US	China, Denmark, Japan*
Aluminium oxide			Germany , US, Japan
Cerium oxide	UK/BIAC(NIA), US	Netherlands, Spain, Australia	Germany, EC, Switzerland, Denmark
Zinc oxide	UK/BIAC(NIA)	BIAC(CEFIC), Australia, US, Spain	Canada, Germany, Denmark
Silicon dioxide	France, EC*	Belgium, BIAC, Korea	Denmark, Japan
Polystyrene			Austria, Korea
Dendrimers		Spain, US	
Nanoclays			Denmark, US

### PROSPEcT Project:

Industrial contribution:	£1840840	Start date:	1 <sup>st</sup> January 2009
Government contribution:	£1840767	Duration:	3 years (36 months)
Total:	£3681607		

BIAC: Business and Industry Advisory Committee to the OECD



*Industry Comments: Does REACH provide the necessary answers?*

Brussels, 9<sup>th</sup> October 2009

## Summary:

*'The more common parent substances [...] found in nanomaterials have all been pre-registered under REACH with planned registrations in 2010. [...]*

*Amongst those substances which are less commonly found in nanomaterials, there are many high volume substances for which registration is planned for 2010 [...].*

*Consideration was given to some of the more 'exotic' binary nano-substances (as listed on the Nanomaterials Database from Nanowerk) such as praseodymium oxide, erbium oxide and gallium antimonide – but **all such compounds had been pre-registered (many with a 2010 registration deadline).** [...]*

*Nevertheless, the expected publication of the first registration dossiers in November 2009 (presumably including those for silica and carbon black) **will provide a little more information on how the presence of nanomaterials is being dealt with under the REACH and CLP Regulations.***

***ALSO: upcoming REACH Implementation Project & review of TDGs.***

[Deliverable 1: .Information from Industry on Applied Nanomaterials and their Safety, prepared for the European Commission, DG ENV, Milieu, September 2009]

## *Attempt of a Recommendation:*

*'The more common parent substances [...] found in nanomaterials have all been pre-registered under REACH with planned registrations in 2010. [...]*

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***Take these reports/deliverables as a snap-shot!***

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*Thank you!*