Nanomaterials, REACH and CLP - what is going on at the regulatory front

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EU Approach to Nanotechnologies

- ***Safe**: ensure a **high level of protection** of human health and the environment*
- ***Integrated**: **simultaneous** development of competitiveness and safety aspects in nanotechnologies*
- ***Responsible**: managing the evolving development of nanotechnologies in **a scientifically sound manner***

What is in the REACH Regulation?

- Registration, Evaluation, Authorisation and restriction of CHemicals
- The REACH provisions apply in a tonnage-dependent manner to the substance that is manufactured, placed on the market and used as such, in mixtures or in articles.
- Manufacturers, importers and downstream users must ensure that they manufacture, place on the market and use such substances that do not adversely affect human health or the environment.

= information on chemicals and knowledge of what you really use and market

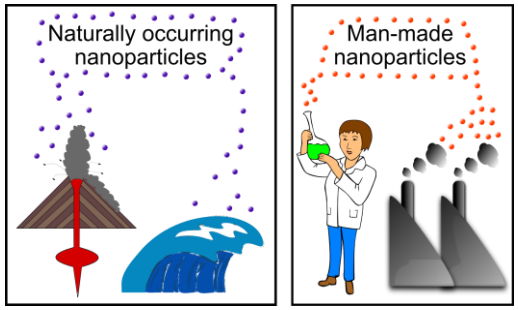
What is in the CLP Regulation?

- Manufacturers, importers and downstream users must classify substances and mixtures before placing them on the market.
- Suppliers must ensure that a substance or mixture is labelled and packaged (in accordance with CLP) before placing it on the market.

= information on chemicals and knowledge of what you really use and market – remember your customers!!

Substances at nano-scale – covered by REACH and CLP?

- REACH deals with substances, in whatever size, shape or physical form.
- CLP applies to all substances and mixtures that fulfil the criteria of classification as hazardous.
- There are no explicit provisions in REACH or CLP specific for nanomaterials.



EU definition of nanomaterials

‘Nanomaterial’ =

- a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate
- 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 %.

By derogation from above:

fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

Commission Recommendation (2011/696/EU) adopted 18 October 2011

EU definition of nanomaterials (2)

(a) 'particle' means a minute piece of matter with defined physical boundaries;

(b) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(c) 'aggregate' means a particle comprising of strongly bound or fused particles.

In addition:

Where technically feasible and requested in specific legislation, compliance with the definition may be determined on the basis of the specific surface area by volume.

- A material should be considered as falling under the definition where the specific surface area by volume of the material is greater than 60 m^2/cm^3.

However, a material which, based on its **number size distribution**, is a nanomaterial should be considered as complying with the definition even if the material has a specific surface area lower than 60 m^2/cm^3.

Can REACH adequately cope with nanomaterials?

- ***All substances***, including nanos, can be addressed
- Focus on ***better implementation***, follow-up of registration dossiers and enforcement so that necessary information becomes available ➔ via Compliance checks or Substance evaluation
- ***Refinement*** where needed through adaptation of ***existing tools, guidance, REACH Annexes***
- Tonnage thresholds and deadlines are considered adequate by COM

The key paper that clarifies the position of nanomaterials under REACH and that has been agreed by all stakeholders is available on the internet:

CA/59/2008 rev.1 "Nanomaterials under REACH" (http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf)

Looking at REACH registrations

What do we see?

REACH: registration

Tonnage thresholds – Deadlines

- Were ***set after careful consideration*** of requirements in "old" legislation, impact on innovation, costs and required resources
- ***Deadlines*** to allow SMEs with low tonnages to cope
- Some nanomaterials are already or will be ***included in registration dossiers of bulk form*** (dossier updates, next registration deadline 2018)
- ***Updates and upcoming dossiers*** will implement recommendations from assessment of 2010 and 2013 dossiers

REACH: Information requirements

- Nanos can require ***more info on physico-chemical properties***

- ***Read-across between bulk and nano*** is difficult but may be possible - provided that relevant justification is given

- ***Additional*** (eco)-tox ***endpoints*** may be needed (e.g. toxicokinetics)
  - Look at on-going OECD programme on validation of testing protocols
  - Cost of additional information requirements difficult to assess
  - Time needed to generate and submit additional information

- If a substance occurs in ***nanoforms only***:
  - "Old" chemicals were tested and are covered by their registration
  - "New" chemicals to be registered prior to marketing

Registered nanomaterials?

By end of February 2012

For **seven** substances "nanomaterial" as the form of the substance in voluntary fields had been selected in their registration dossiers

Other registrations

- **included some relevant information** but had not selected "nanomaterial" as the form of the substance, or
- included **"nano" in the description of** the registered substance but in these the registrant referred to the substance as being nano-structured rather than a nanomaterial, or
- specifically **excluded nanoforms**

Registered nanomaterials? (2)

In 59 registrations **"nano" was mentioned in the context of read-across** from studies performed on nanoforms of the registered substance.

> Based on the information included in the respective dossiers, it cannot be definitely concluded whether or not nanoforms are within the scope of the registered substance.

Many dossiers for substances known to have nanomaterial forms do not mention clearly which forms are covered or how information relates to the nanoform. Why?

- absence of detailed guidance to registrants on registration for nanomaterials?
- absence of a definition of nanomaterials?
- general wording of the REACH annexes?

Problems?

Substance ID

- Very few clearly identified nanomaterials
- No/minimal information on surface treatment
- Typically
    - no nano-specific substance identity information
    - no clear indication in the dossier that nanoforms are within the scope of the substance registered
    - no nano-specific information on tonnages or uses
- In a joint submission the lead registrant submits all the relevant endpoints and the joint Chemical Safety Report: the lead registration may not cover nanoforms while member dossiers do.
- An indication that nanoforms are covered by the scope may be only apparent from the CSR or in the substance sameness documentation attached.

Problems? (2)

Hazard assessment

- It is more or less impossible to systematically link reported physico-chemical properties to the observed effects for adequate hazard identification;

- Serious lack of characterisation of the material tested;

- Use of non-standardised methods, no coherent endpoints, substantially different species tested, methods of administration, dose range, duration of exposure, etc.

➡ data/studies used to fulfil the information requirements does not facilitate (Human Health and Environmental) risk assessment

Problems? (3)

Exposure assessment

- Only limited and uncertain estimates (if any) of the manufacture/import quantities of different nanomaterials and their presence in industrial or consumer products

- Difficulties in monitoring nanomaterials exposure: lack of consistent sampling methods to characterise exposure in real time

- General lack of information on which environmental compartments, number of workers, professional users and consumers might be exposed, where and how they are exposed and at which concentrations

- Lack of information on used or available risk management measures.

Risk assessment / characterisation

- At present the risk assessment of nanomaterials in general seems to pose significant challenges from a scientific and regulatory point of view.

CLP obligations

Classification as hazardous

Classification is the basis for (almost) everything:

- It is required in the registration dossier
- It triggers e.g.
  - the requirement to perform an exposure and risk characterisation
  - the obligation to provide SDS

- The currently used testing methods have so far not been validated for nanomaterials and they might not be sensitive enough to demonstrate specific effects of nanomaterials (e.g. in vitro genotoxicity assays)

How can the current classification system be applied to nanomaterials?

Hazard assessment of nanomaterials

- Being "nano" does not constitute an intrinsic hazardous property *per se* but may impart novel properties and phenomena that differ from that of a bulk-sized substance of same chemical composition.
- Nanoscale substances may have different physico-chemical properties and may or may not result in enhanced toxicity.

→ understanding the biological implications of these unique properties is critical

Short-term priority: to develop dose metrics that allow determination of the toxicokinetics, bioavailability and mode of action of NMs.

Mid-term: appropriate validated *in vitro* and *in vivo* models need to be developed to predict long-term or chronic effects.

Screening of C&L notifications

Notification to the C&L Inventory

- Required of manufacturers and importers of substances (as such or in mixtures).
- 3.2 million notifications screened
- In 18 CLP notifications selection of ‘nanomaterial’ as the form of the substance.
- Further assessment has identified additional substances relating to nanomaterials.

Ongoing activities

ECHA's activities on nanomaterials under REACH

- Providing feedback and advice to (potential) registrants of nanomaterials
- Webinars and workshops concerning the latest developments regarding REACH and CLP processes related to nanomaterials
- Sharing experience with and generating consensus among Member State authorities and ECHA’s committees’ members on safety information for nanomaterials
- Contributing to ongoing international regulatory activities (such as the OECD Working Party on Manufactured Nanomaterials)
- Internal and external capacity building

Working groups on NM (ECHA)

1. Nanomaterials working group (ECHA-NMWG) to discuss scientific and technical questions relevant to REACH and CLP processes and to give recommendations on strategic issues.
   - informal advisory group consisting of experts from Member States, the European Commission, ECHA and accredited stakeholder organisations
   - ECHA-NMWG also aims to have discussions with industry regarding documenting the intrinsic properties of nanoforms using recent methods and obligations towards fulfilling REACH requirements.

2. Group assessing already registered nanomaterials (GAARN) (not active at this moment).
   - To build consensus in an informal setting on best practices for assessing and managing the safety of nanomaterials under the REACH Regulation
   - To increase confidence and mutual understanding among stakeholders so that nanomaterials can be sustainably developed.

Working groups on NM (others)

1. Nanomaterials under Competent Authorities for REACH and CLP (CASG-nano) to discuss policy issues questions relevant to REACH and CLP

2. COM inter-service consultation group on the review of the EC definition of nanomaterial

3. Informal Correspondence Group under UN GHS (ICG):
   - Systematic review of GHS for suitability for nanomaterials in terms of substances, and eventually, of mixtures.
   - To establish whether there is a need to amend the GHS to make clear that nanoforms of a substance are within the scope of the GHS.
   - To review the classification and labelling criteria in the GHS to establish whether they are appropriate for nanos, as well as bulk-forms of a substance.

Actions taken in ECHA

- ECHA's Guidance documents:
  - updated Guidance Chapters R.7a, R.7b and R.7c of the Guidance on Information Requirements and Chemical Safety Assessment (IR & CSA) - three appendices with recommendations for registering nanomaterials.
- Evaluation (both testing proposals and compliance checks) of dossiers related to nanomaterials.
- Substances to be evaluated under REACH (Community Rolling Action Plan, CoRAP): e.g. silicon dioxide, silver, titanium dioxide.
- Regulatory Science Dialogue on Nanomaterials between ECHA and US EPA.

Actions taken in ECHA (2)

- Compilation of an inventory of nanomaterials included in REACH registration dossiers and C&L notifications (as requested by the European Commission).

- Scanning of registration dossiers and C&L notifications to modify IUCLID fields to include features helping companies to indicate that their dossiers include nanomaterials.

ECHA expects to identify between 50-60 REACH registration dossiers that include information on nanomaterials to be sent to the Commission's Joint Research Centre for assessment of how information on nanomaterials is included in REACH registration dossiers.

Questions and comments?

Thank you!

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