1st Regulatory Review of NMs

COM 1st Communication on Regulatory Aspects of NMs, 2008 *(with a promise for an update in 2011);*

The current legislation covers to a large extent risks in relation to NMs and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.

The Parliamentary Resolution, April 2009, calls for e.g.:

- ✓ Explicit definition of NMs in key legislations:
- ✓ European Network for monitoring NT and NMs;
- ✓ Inventory of NM types and uses, incl. their safety aspects;
- ✓ Evaluation of the need to review REACH, worker safety, and environmental legislations.
- ✓ Other

Responsible Care

1

RIP-oN1

Objective

Evaluation of the applicability of existing guidance on substance Identification to nanomaterials

Preliminary outcome

- Fundamental differences of opinion by majority of MS-CA and Industry
- MS-CA interpret Nanospecific parameters (e.g. size, particle size distribution) as identifiers (i.e. separate chemical identity)
- Industry views these as characterisers (i.e. same substance as the “bulk”)
- Final report end of May

Responsible Care

2

RIP-oN2

Objective

Applicability of Info. Requirements, Identification of additional properties, Identification of future R&D further research needs and Analyse option for metrics/parameters

Preliminary outcome

- Current test guidance in principle sufficient to also cover nanomaterials.
- Additional physicochemical information requirements proposed in an extended chapter on granulometry (shape and surface area)
- R&D issues identified with regards to new information requirements (e.g. cardio-vascular toxicity)
- Read-across possible if scientifically justified from the bulk to the nano form

Responsible Care

3

RIP-oN3

Objective

Operational conditions and RMM, exposure estimation, Deriving of DNELs and PNECs, Hazard and Risk Characterisation

Preliminary outcome

Current RA-guidance in principle sufficient to also cover nanomaterials

Highlighting the problems of using the traditional metrics system

Consideration for particle overload in relation to secondary threshold effects such as CM and increased toxicity in long term exposure

PBKT modelling to premature to be included

Responsible Care

4

RIP-oN's Conclusions

- Fundamental differences in opinion regarding substance ID (Meanwhile Cover Letter with acceptable flexibility)
- Current test method guidance is in principle sufficient to also cover the assessment of nanomaterials.
- Shape and surface area proposed in an extended chapter on granulometry
- Reports will be published soon

Scientific Issues

- Relevance of possible new effects (e.g. cardio-vascular toxicity) in a regulatory context
- Read-across from bulk to nano
- Validation of QSARs and in vitro methods for nanomaterials

Responsible Care

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REACH and Nanomaterials

1. **Cefic has jointly with IOM (Commission's consultant), evaluated the applicability of existing REACH guidance to nanomaterials on behalf of the Commission.**
   - The work has shown a reassuring result; the **guidance is applicable with very few proposed revisions**.

2. **The Commission has initiated an Informal Working Group aiming at building consensus on the REACH dossiers, among stakeholders, outside the formal processes within ECHA.**
   - Member states, ECHA, DG's ENTR, ENV, SANCO
   - The work will look at a number of nanomaterials already registered

Responsible Care

6

EU Commission recommendation for a definition of nanomaterials - September 1(2)

EU COM Rec.

Based on particles between 1-100 nm (nano-objects) and their agglomerates/ aggregates

Metrics:
50 or 60 % of the particle number distribution

Different threshold might be used in sector specific applications

Cefic's text from spring 2010

Based on particles between 1-100 nm and their agglomerates/ aggregates

Metrics:
10 weight%

Responsible Care

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EU Commission recommendation for a definition of nanomaterials - September 2(2)

Definition still not published but an agreement has been reached but will be published as a recommendation which have NO legal bearing until it is implemented into legal text.

- Commission admits **further work is needed around ensuring reliable test methods** – "second step"
- **Review clause 2014** – "if scope is too broad or narrow"

Cefic's actions;

1. Further industry expertise is needed around the development of test methods
2. Request an impact assessment
3. A Workshop to illustrate impact on real life examples

Responsible

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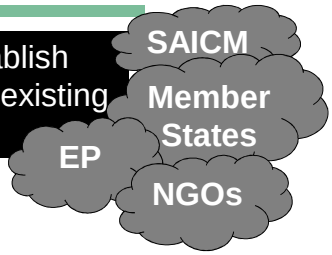
Cefic actions – Mandatory Reporting Schemes

The drive behind initiatives to establish inventories is a lack of confidence in existing legal systems and industry



Cefic position

- **We recognise the need to increase the transparency on nanomaterials.**
- **Avoid creating separate system, instead Cefic promotes utilise the information submitted by industry through REACH registrations, CLP notifications and sectorial legislation (i.e. cosmetic)**

Responsible Care

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