2. Nanomaterials: the state of play

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Overview

OECD WPNM

- History
- Sponsorship program
- Technical guidelines

Europe

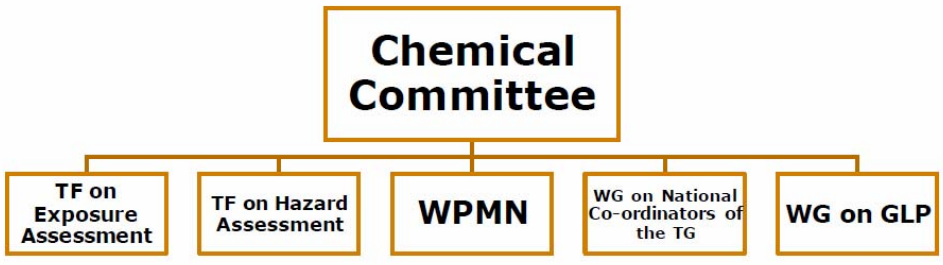
- Commission – REACH revision
- ECHA NMWG

National initiatives

OECD NMWP

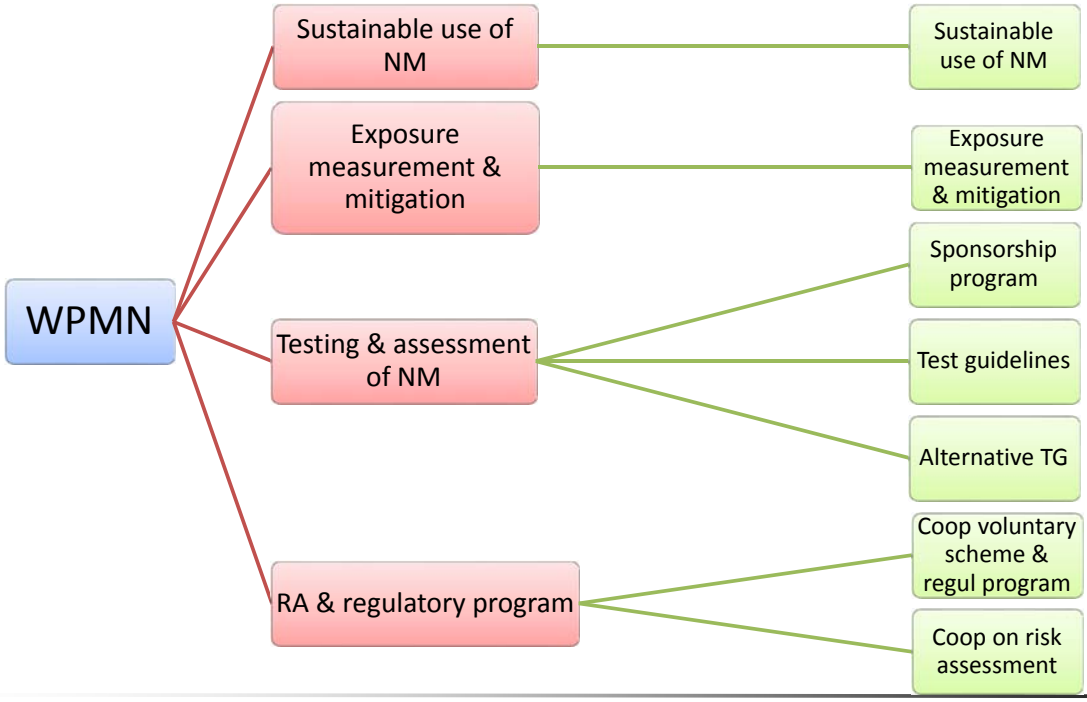
Background

- OECD work on nanomaterials is important because
  - It gives a regulatory awareness at a global level
  - Impact on the implementation of REACH (TG and guidance)
  - Knowledge transfer
- OECD work on nanomaterials – since 2006



Review of WPMN in 2012

- Reduce number of Steering Groups (SG)



SG Testing and Assessment of Manufactured Nanomaterials

5 work-areas

1. Testing guidelines
2. In Vitro methods
3. Communication of the outcome from the Testing Program
4. Assessment of the data from Testing Program
5. Non-testing approaches

Testing guidelines

- **Objective:** Ensure that existing test guidelines are applicable to nanomaterials to support MAD agreement
- 7 SPSFs (standard project submission forms) are under way
  - Amendments to existing TG/GD on inhalation (US)
  - GD on Aquatic and Sediment (CA/US)
  - TG dissolution rate in aquatic media (US)
  - GD dispersion and dissolution in aquatic media (DE)
  - GD accumulation potential (UK)
  - TG on dispersibility and dispersion behaviour in aquatic media (DE)
  - TG removal from waste water (US)
- TG 487, in vitro Genotoxicity, (EU) submitted November to WNT*

*Working Group of the National Coordinators for the Test Guidelines Programme

Testing program

- The data generated from the Sponsorship Program are to be disseminated
- 11 Dossiers have been harmonized in a IUCLID style printed format. They all include a Preamble with the appropriate caveats on the context in which the data was generated.
- 4 assessment reports (SIAR) have been prepared by Lead Sponsors (to be published as separate documents to allow an easier access to them)
- Public Web Site by June 2015 (?)
  - Silver, gold, SiO2, TiO2, ZnO, CeO2
  - Denrimers, CNT, fullerenes, nanoclays

Data assessment from testing program

- To analyse the data generated to explore the possibility to conclude on;
  - the applicability of TGs/GDs used
  - the quality of the data
  - variability within one materials
- Three areas
  - Phys-chem properties (NL lead)
  - human health
  - the environment
- Generate three reports over the next two years

Non-testing approaches

- **Objective:** Develop non-testing approaches to assess potential hazards of nanomaterials
  - Categorisation, grouping and read-across
  - QSARs
  - Cell culture models
  - Etc..

Risk assessment and regulatory program

5 On-going projects:

1. Interspecies Variability in HH RA (final)
2. Dissolution outline (Ag case study) (final)
3. Survey on the use of grouping, equivalence and read across among OECD members (on-going)
4. Analysis of phys-chem properties for RA and read-across purposes (on-going)
5. Uncertainty in a tiered RA (new)

- **Exposure mitigation:**
  - Harmonised Tiered Approach for measuring and assess exposure to airborne nano-objects in the workplace
  - Case Study of Nano-Ag
  - Survey on Consumer and Environmental Exposure
- **Environmentally Sustainable Use of Nanomaterials**
  - Drafting a manual for LCA case-study of MWCNTs

EU Commission

Main subjects

- Revise nano definition
- Revise REACH text with nano definition and characteriser
- Revise REACH annexes with specifics for nanos
- Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market

Nano definition

- Review of the EC Definition of "nanomaterial" by December 2014
- JRC offered to provide 3 reports covering related scientific issues in support of the review (3rd one should be out now)
- COM will consider, consult and reconsider

⇒ there are now > 6 months delay on new deadline, CASG nano has been postponed to November/December 2015

Nano definition key issues

- Ambiguity of the vocabulary:
  - "contain": a NM could contain non-particulate matter
  - "unbound state"
  - "constituent particles" used in recitals 4) and 12)
  - "one or more external dimensions". A non-symmetric particle can have many external dimensions
  - "particle" can be interpreted in different ways
- Ambiguity about materials explicitly included in the definition
- Flexible threshold value (between 1 % and 50 %)
- The volume specific surface area (VSSA) ≠ 50 %

Issues applying the definition

- How to prove that a material is not a nanomaterial?
- How to identify constituent particles in aggregates and measure their size?
- Comparing the chosen thresholds with measured values

Review of REACH annexes

- Clarify what is being registered:
  - Insert legally binding definition (VI)
  - Introduce terminology to explain 'forms':
  - one substance, but several forms in a single joint registration (VI)
  - Introduce requirements to specifically provide information on the nanoforms registered / justify its relevance (I; III; VI; VII – X; XI and XII)
- Introduce 'characteriser' as binding requirement in case of 'nanoform(s)' in member dossier:
  - Name
  - Particle distribution
  - Surface treatment
  - Shape, morphology etc
  - Surface area
  - Analytical methods

How requirements link with the nanomaterials registered

- Introduce more prescriptive information on how information shall be specific and relevant to the 'forms'
- Specify in Annexes VII – X that characterisation of the nanoform and test conditions shall be submitted
- The above shall apply regardless if it is reporting on a test result or using non-test approaches to document safe use (e.g. read-across)

Possible Legislation to Increase Transparency on Nanomaterials on the Market

- The Commission's Working Document sets out the following policy options:
  - Baseline scenario: Revision of REACH Annexes + MS Initiatives
  - Recommendation for national measure for Member States wishing to establish a national system (soft law approach)
  - Structured approach to collect information ("Nanomaterials Observatory")
  - Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor
  - Regulation creating an EU nanomaterial registry with one annual registration per use (including substances, mixtures and articles where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article)
- As of now, no decision taken

ECHA

Improve REACH dossiers quality

- Continuation of ECHA NMWG, informal discussions with registrants and accredited stakeholders – different sub-groups as phys-chem characterisation, read-across, environment risk assessment
- Working on publication of guidance on registration in 2016 for 2018 deadline
- Dossiers evaluation
  - 2012; Silicon dioxide (synthetic amorphous silica - SAS) – by the Netherlands
  - 2014: Silver - by The Netherlands
  - 2015: Titanium dioxide - by France
  - 2016: ZnO – by Germany

Participate in Int. Activities

- OECD
  - Acting as the Chair for OECD WPMN's Steering Group on Testing and Assessment (SG-TA)
- CEN
  - Following the work of CEN/TC 352 on "Standardisation activities regarding nanotechnologies and nanomaterials" under mandate M/461
- GHS
  - evaluate the applicability of GHS criteria to nanomaterials

Scientific hub

- Strengthening scientific capacity
  - Interaction with FP7 projects (NANOREG, Marina, Nanosolutions)
- Topical Scientific Workshop on Regulatory Challenges NM 22-23 Oct 2014 that covered
  - International Regulations
  - Measurements and Characterisation
  - Metrology and dose metrics
  - Environmental fate
  - Read-across and Categories

National Initiatives

French decree 2012

Purpose	Reporting scheme for quantities and uses of NM and public access
Scope/Definition	As EU COM Recom but only for intentionally manufactured NM; includes mixtures and articles with intended release.
Threshold	100 g
Exemptions	none
Timing	Mandatory from 2013 (May for previous year)

Norwegian law 2013

Purpose	1. Product register 2. Information should be submitted for all dangerous chemicals. The information shall cover the composition of the product, where the product is used, what kind of product etc. **3. The NANO box should be marked if the chemical contains nanomaterials.**
Scope/Definition	Scope non nano specific Structures that have a size between 1 and 100 nm. The aim is to reach other properties than the chemical compound usually provide, for example changes in melting point and strength.
Threshold	No specific limits for nanomaterials. The declaration is mandatory for dangerous substances produced/imported/placed on the market in a quantity > 100kg/year
Exemptions	None found

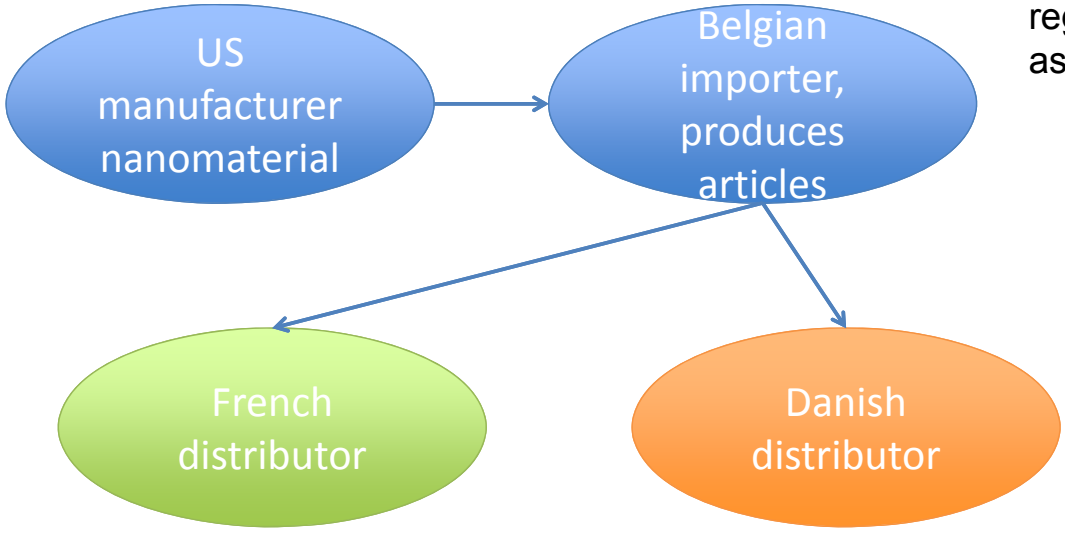
Danish Order 2014

Purpose	Reporting scheme to establish number and type of products containing nanomaterials on the market and their applications
Scope/Definition	"Products containing nanomaterials (EU COM Recom): 1. mixtures and articles where nanoparticles are intended to be released 2. intentionally produced in nano-size 3. that possesses specific properties because of its size"
Threshold	100 g/year for each VAT number
Exemptions	1. nanoproducts sold between business 2. products that fall under areas where specific regulations are already in place (e.g. food, feed, pharmaceuticals, medical devices, cosmetics, pesticides and waste) 3. a number of specific products: nanosized products of substances in REACH Annex V, products where the material is not consciously produced in nanosize, products where the nanomaterial is in a fixed matrix.
Timing	Mandatory, first declaration 31st January 2015 to cover from 2014 data. Declaration is foreseen every year.

Belgian royal decree May 2014

Purpose	1. Traceability purpose 2. gain knowledge on characterisation of nanomaterials , risks and exposure 3. Some public access
Scope/Definition	"Registration of substances/mixtures and a notification for articles containing nanoforms (based on COM Rec.) not falling under the foreseen exceptions. **To be registered**: substances manufactured at the nanoscale, and mixtures containing them **To be notified**: articles, products, complex objects incorporating substance manufactured at nanoscale if more than 100 g/year are placed on the market and the article emits more than 0.1% of substances manufactured at the nanoscale when in use."
Threshold	100 g of concerned nanos
Exemptions	a) **registration** : some pigments when included in mixtures or articles. NP already regulated elsewhere b) **notification**: carbon black, SAS and precipitated, calcium carbonate in articles when used as fillers. Reduced notification for substances in R&D (under some conditions)
Timing	Mandatory before placing on the market; at the latest by 1 January 2016 for substances and 1 January 2017 for mixtures

In practice



Must register NM as importer

must register the NM in France as a distributor

must register the final product as an importer only if it is a consumer product

Conclusions

- Nanomaterials are covered under REACH
- Challenges still remaining, both on scientific and policy level.
- Despite regulatory challenges, ECHA is addressing nanomaterials throughout legal instruments
- Knowledge exchange is key
- Still a long way to go…

Thank you

Questions?