Nanomaterials and Regulatory Challenges in REACH

Workshop on Responsible Development of Nanotechnology

18 May 2015

Abdelqader Sumrein
European Chemicals Agency

Outline

- **REACH:** a quick intro
  - What does REACH require for nanomaterials?
- **Initial observations** on NM in REACH dossiers
- **Evaluation of NM dossiers:** improving dossier quality
- **Conclusions**

REACH: a quick tour

What is REACH?

- Registration, Evaluation, Authorisation and Restriction of Chemicals
- Most complex peace of legislation – covers all chemicals
- Reversed "burden of proof" - industry must ensure the safe use of chemicals
  - ✓ assess the risks for all identified uses
  - ✓ recommend risk management measures

Aims of REACH

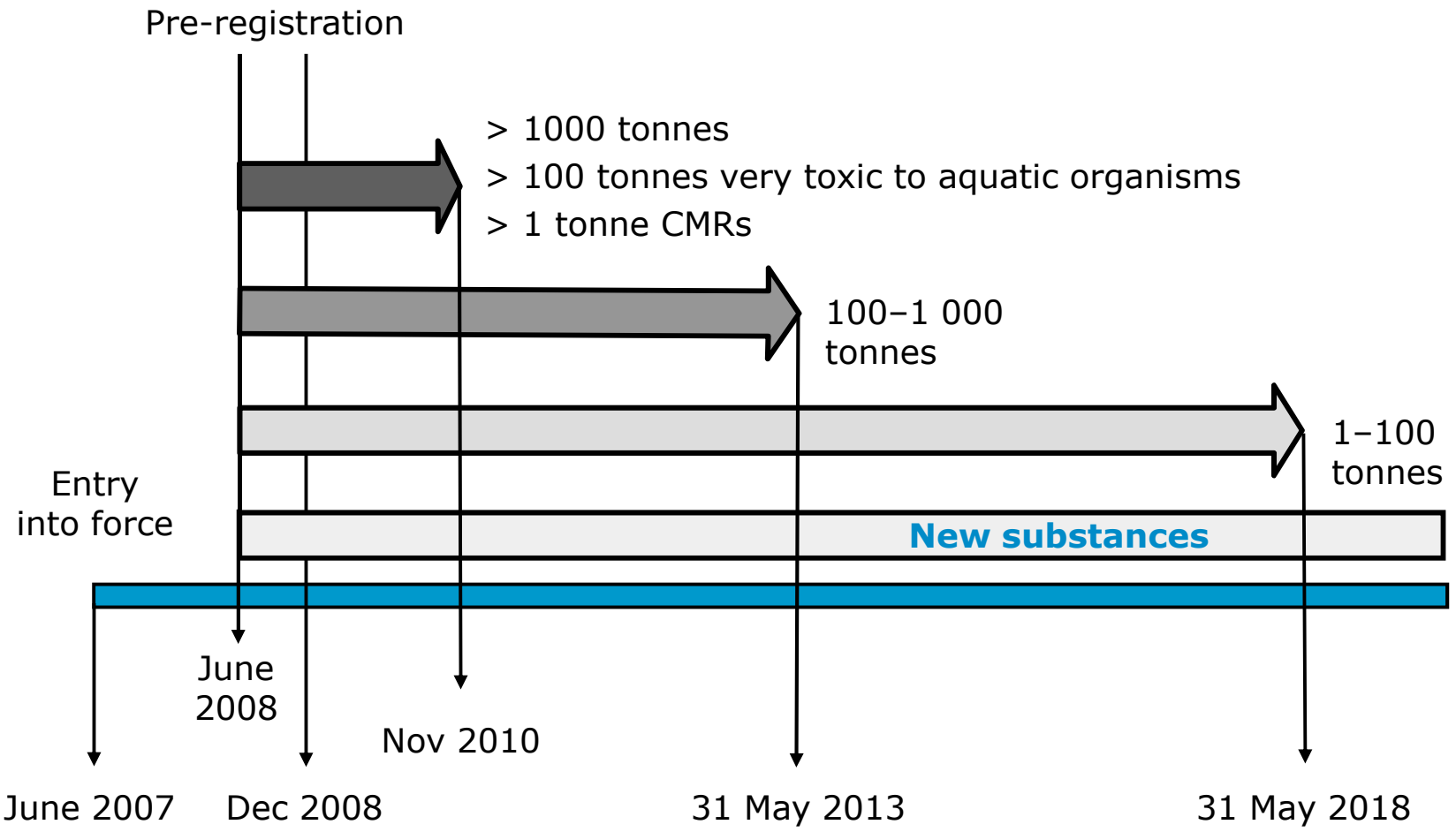
- Improve the protection of human health and the environment
- Enhance the competitiveness of the EU chemicals industry
- Reduce animal testing by promoting alternative methods (e.g. QSARs)

REACH processes

Registration

- Companies have to submit a registration dossier to ECHA by certain deadlines
- "One substance - one registration" principle
- Information in the dossier – tonnage dependent
  - Substance identity
  - Manufacture and uses
  - Hazard characterisation: phys-chem. properties, toxicity to environment, toxicity to human health
  - Exposure and risk characterization – for classified substances and those > 10 tpa

Registration deadlines



REACH processes

Evaluation

- ECHA and the Member States evaluate the information submitted in the registration dossiers
- Dossier evaluation
  - Compliance check - 5 %
  - Testing proposals - all
- Substance evaluation – CoRAP

Once the evaluation is done, registrants may be required to submit further information on the substance.

REACH processes

Authorisation

- Substances of Very High Concern (SVHCs)
  - CMRs – carcinogenic, mutagenic, toxic to reproduction
  - PBTs – persistent, bioaccumulative and toxic
  - ”equivalent concern”

Restriction

- Community wide risk management measures
- Risk assessment analysis + socio-economic analysis

Nanomaterials and REACH

- **No explicit reference** to nanomaterials in REACH in the legal text
  - considered to be covered in substance definition (Art. 3) – confirmed by Commission's Regulatory Reviews on nanomaterials.

- Nanomaterials can either be;
  - A **substance in its own right** and registered as such
  - A **form of a substance** and included in the dossier of the corresponding bulk or other forms of the substance

Challenges for companies and authorities

- Relatively new and rapid development of nanomaterials
- Some nanomaterials already on the market
- Promising new field offering new technologies/opportunities
- **But, how to develop nanomaterials/nanotechnology responsibly?**

Challenges for companies and authorities

- No explicit reference to nanomaterials in the REACH Regulation
- Scientific discussion on-going in relation to their characterisation and assessment of their hazards, exposure and risks
- Limited experience of hazard/risk assessment of nanomaterials

Nanomaterials in REACH

Initial observations

Nanomaterials registered by 2010

- No agreed EC definition of nanomaterials available at the time
- No specific provisions for nanomaterials
- Discussions on REACH Implementation projects on nanomaterials (RIP-oN) ongoing
- IUCLID provided two tickboxes that allowed registrants to indicate if nanomaterials are included in the dossier

Nanomaterials in REACH registrations*

	2010	2013	Non phase-in
# substances	5	4	4
# dossiers in the joint submission	10, 100, 134, 1 individual submission, 54	1, 3, 81, 1 individual submission	NA

*indicated by ticking ”nano” box by the registrants in the IUCLID dossier (section 2.1 & 4.1)

- On 17 April 2014. ECHA’s Database contained **12439 unique substances** and contains information from 47909 Dossiers

Nanomaterials in REACH registrations

	2010	2013	Non phase-in
Substance name	1. Carbon black 2. Cerium dioxide 3. Calcium carbonate 4. Zinc oxide 5. Silver	1. MWNT 2. MWNT as a form of graphite 3. Titanium dioxide 4. Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	1-4 Names claimed confidential under NONS

Nanomaterials registered by 2010 (1)

- JRC and ECHA assessed 45/25 dossiers covering nanomaterials submitted by the 2010 registration deadline
- The project involved an assessment of the information included in nanomaterial registration dossiers, and their adequacy

Nanomaterials registered by 2010 (2)

- Project examined 45 potential nano dossiers (selected based on keyword searches, examination of granulometry, known substance from OECD WPMN)
- More detailed examination of physico-chemical, (eco)toxicological, and toxicological properties on 25 substances

Nanomaterials registered by 2010 (3)

- Key issues noted:
  - Insufficient description of scope of registration in terms of nanoforms
  - Lack of identification/characterization for each nanoform for each registrant (lead/member registrant).
  - Different forms not addressed transparently throughout dossier (including endpoints, manufacturing process, Classification and Labelling, uses, as well as possible exposure assessment and risk characterisation).
- Full details of results can be found at:

http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

Evaluation of NM dossiers: improving dossier quality

Nanomaterials-after 2010

- Significant advancement has taken place since 2010 registrations
  - EC recommendation for the definition of a nanomaterial
  - Publication of RIP-oN results/ updated guidance documents for nanomaterials
- ECHA aims to provide registrants with best practices that can be used to improve the quality and transparency of nanomaterials registration dossiers through a variety of initiatives (GAARN, ECHA NMWG, webinars)

Nanomaterial definition-implications

- The definition is based solely on size, not on hazard or risk
  - Nanomaterial does not automatically imply the substance is hazardous
- The definition itself does not create new information requirements on REACH registration dossiers
- However, it provides clarity on what is considered a nanomaterial

Demonstrating the safety of nanomaterials under REACH

- Registrant needs to **demonstrate the safe use of its substance including (nano)forms**

- **Proper characterisation of any nanoforms is a <u>prerequisite</u>** to the proper determination of hazards and risks of the substance

- ECHA gives a lot of **attention to characterisation**:
  - May indicate a substance/form falls under nanomaterial definition even in absence of specific reference in the dossier
  - **Cornerstone** in proper hazard characterisation and risk assessment

Nanomaterials under REACH Evaluation - 1

Compliance checks in 2013: 2 out of 3 cases, non-compliance detected - ECHA acted through draft decisions:

- Similar conclusions hold for dossiers with nanomaterials

Resulted in 4 key (and general) recommendations to registrants also relevant for nanomaterials:

- Identify clearly your substance
- Demonstrate the relevance of the test material
- Provide clear information on use and exposure
- Make good use of available information and alternative approaches

Nanomaterials under REACH Evaluation - 2

- A number of evaluation decisions addressing nanomaterials. Main focus:
  - Transparent identification of NMs
  - Adequate characterisation. **Granulometry in ECHA's first final decisions addressing Nanomaterials** (Annex VII, 7.14.)

Transparent identification

- Nanoform vs. “bulk” form-separate entries
- Information on surface treatment to be reported in registration dossier
  - physicochemical information on the hazard properties of each form
  - essential as surface modifications may affect the (eco)toxicity testing results for nanomaterials
- Coated and uncoated nanomaterials should have separate IUCLID endpoint study records for the different hazard endpoints

Adequate characterisation

- No single method adequate for (particle size) characterisation
- Characterisation jigsaw puzzle: provide multiple/complimentary pieces of information:
  - Constituent particle size
  - Aggregate/agglomerate
  - Surface area
  - Shape

Adaptations possible, but…

- Use of non-testing data supported for nanomaterials
- If an adaptation to the REACH information requirement is used, the registrant should ensure that it meets the requirements in Annex XI
- A solid scientific justification should be provided
- Insufficient to justify read-across based only on the chemical composition of a nanomaterial
  - Need to take into account potential differences: e.g. aspect ratio, shape, form, solubility, surface area, charge, surface treatment, etc.

Adaptations (2)

- Despite their current limitations for nanomaterials, alternate methods can be useful as a supportive tool for in vivo testing
- Many alternative tests (e.g. *in* vitro) may need to be adapted before they can be applied directly for hazard assessment
  - appropriate sample preparation
  - adequate controls defined to monitor possible interferences

Other approaches

- **Article 36 letters**: require provision of already existing information
- **Substance evaluation:** Member states, going beyond standard information requirements to clarify a concern

Article 36 decisions

- Article 36 decision (So far, ECHA sent 166 decisions):
  - Request information that you as registrant may have available in order to carry out your duties under REACH
  - Does not require generation of new data
  - No information in the dossier showing the substance is nano
- Requires you as registrant to provide available information:
  - e.g. Information on all size grades placed on the market, surface treatment
  - Usually in the form of a questionnaire

Nanomaterials under REACH: Substance Evaluation

Substance evaluation:

- **Substances selected for CoRAP** (Community rolling action plan) based on initial grounds of concern: evaluated by member states, coordinated by ECHA

  - **2012; Silicon dioxide (synthetic amorphous silica - SAS) – Evaluated by the Netherlands:** MSC adopted decision requesting information on characterisation and inhalation toxicity
  - **2015: Silver - Evaluated by The Netherlands**
  - **2015: Titanium dioxide - Evaluated by France**
  - **Zinc oxide, MWCNTs, cerium oxide**

ECHA's key messages on nanomaterials

- **Nanomaterials are covered by EU regulatory framework addressing chemicals.**

- **Challenges still remaining,** both on scientific and policy level.

- Despite regulatory challenges, ECHA **is addressing nanomaterials throughout our legal instruments.**

- ECHA is an **active and credible dialogue partner** in scientific discussions on risk assessment of nanomaterials.

- ECHA encourages **an increased knowledge exchange** at an international level.

Thank you!

Abdelqader.Sumrein@echa.europa.eu