# Nano challenges in the EU

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# Outline

- REACH
- ECHA’s challenges & observations under REACH
- ECHA’s initiatives & legal instruments
- Risk management options (REACH and CLP)
- Biocidal Product Regulation (BPR)

# Ensuring the safety of nanomaterials

- Recognised **need to understand** possible adverse effects of nanomaterials
- **The Commission has concluded that adaptions of the existing regulatory framework are needed** to ensure safety of nanomaterials
  - Definition of nanomaterials, EU Recommendation (2011)
  - Commission Regulatory Reviews of nanomaterials
  - Ongoing discussion on REACH Annexes
- Growing number of **reliable scientific references pointing out behavioural difference** compared to conventional substances
  - SCENHIR opinions recognising non-hypothetical hazards and risks specific to some nanomaterials (2010)

# EU Regulatory Framework for Chemicals

REACH

Product legislation (e.g. BPR)

CLP

# The Road to REACH

Difficult to **identify and address risks;**

- **Lack of information** about marketed chemicals
- **Burden of proof with public authorities**
- **Limited instrument to control problematic substances efficiently**

# REACH – a single system for new and existing chemicals in the EU

- **Registration** of:
  - **substances** ≥ 1 tonne/yr (staggered deadlines) manufactured and/or imported
  - substances in **articles** if certain conditions are met
- More **information/communication** up and down the supply chain
- **Evaluation** of substances
- **Authorisation** only for uses of substances of very high concern
- **Restrictions** - the safety net

# ECHA's observations

Screening of REACH dossiers for nano-specific information (ECHA and EC) showed:

- Limited information provided on nano-specific properties, studies and risk assessment aspects
- "Room for improvement" ➔ recommendations provided for registrants on http://echa.europa.eu/chemicals-in-our-life/nanomaterials

- Dossiers submitted in 2010, 1st deadline:
  - No agreed nano-definition at EU level
  - No explicit reference to nano-materials in legal text;

  ➔ 'learning curve' effect causing uncertainties for many registrants

# 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

# 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 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 contains **12439 unique substances** and contains information from 47909 Dossiers

# Nanomaterials in REACH registrations

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

# ECHA's initiatives – Ensuring appropriate risk management of NM

**Two approaches;**

Supportive:

- Generic activities to the wider audience of registrants and ind. sectors (webinar, workshops, bilateral discussions)
- Invites individual registrants to contact ECHA to seek for help and advice

Formal (using legal instruments):

- ECHA and/or EU Member States have various instruments under REACH

1. Substance/dossier evaluation
2. Restriction
3. Authorisation

# ECHA's initiatives – Supportive (Guidance and Advice)

**Guidance development for nanomaterials**

- ✓ Specific advice on Information Requirements and Chemical Safety Assessment (2012)

**Annual Evaluation report (art 54) provides general recommendations to improve quality of REACH registration dossiers➔ also relevant for nanomaterials**

**Development of additional support documents for NMs registration**

- ✓ ECHA's website – specific nano section http://echa.europa.eu/chemicals-in-our-life/nanomaterials
- ✓ Webinars to interact with industry on nano specific issues
- ✓ IUCLID manual updated (2013)

**Dialogue with registrants: Workshop, Webinar and Events**

# Other initiatives – Supportive

- **Competent Authority Subgroup on Nanomaterials (CASG-Nano)**
  - Discussion on policy related aspects of nanomaterials
- **ECHA Nanomaterial working group (NMWG)**
  - Primary focus is to provide scientific, technical advice and support in the implementation of REACH

Composition: representatives from each MSCA, ECHA, COM services and Accredited Stakeholder observer (3 NGOs + 3 from Industry associations)

- **OECD engagement**
- **Participation in FP7 projects**

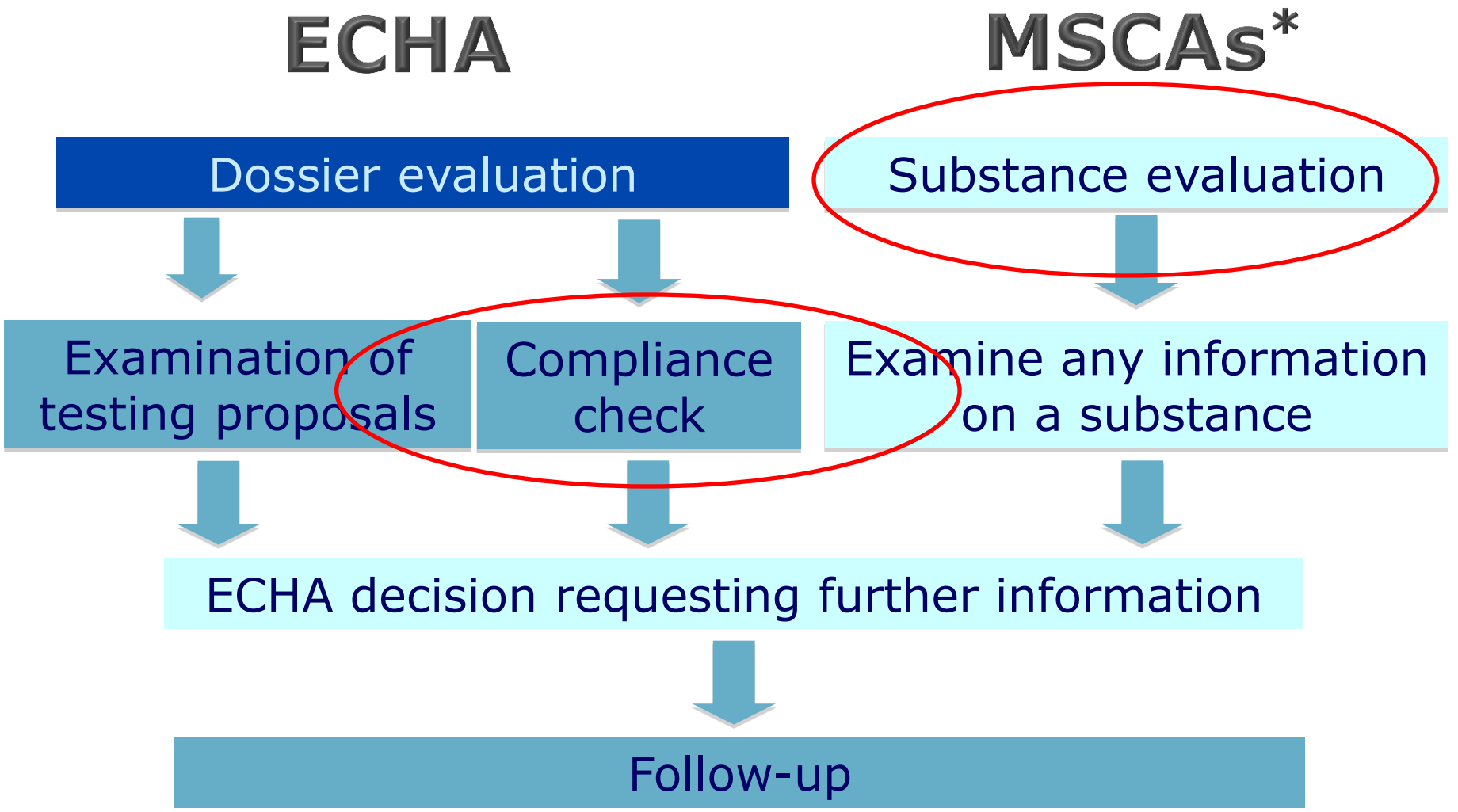
# REACH Legal instruments to request further information on registered substances

- **Art 36 decisions**
- **Dossier evaluation**
- **Substance evaluation**

# Article 36 Decisions

- **Request further information** that registrant may have available in order to carry out your duties under REACH (e.g. Information on all size grades placed on the market, surface treatment)
- **Does not require generation of new data !**
- No information in the dossier showing the substance is nano
- **What Registrant has to do in case of an Art 36 decisions?**
  - Respond to the request (legal duty)
  - Update dossier with the requested information

# Evaluation processes




* MSCA = Member State Competent Authority

# 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

**Main focus on Granulometry in ECHA's first final decisions addressing Nanomaterials** (Annex VII, 7.14.)

# Nanomaterials under REACH Evaluation - 2

## 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**
  - **2015: Silver - Evaluated by The Netherlands**
  - **2015: Titanium dioxide - Evaluated by France**

# Authorisation

- Ensure **risks** from **substances of very high concern (SVHCs)** are **properly controlled:**
  - **CMRs cat. 1 or 2**:
  - **PBTs, vPvBs**:
  - Other **substances of equivalent concern**
- SVHCs **progressively replaced** by **suitable alternatives** (economically and technically viable)
- Substances subject to authorisation may not be placed on the market unless the use has been authorised
- No volume threshold

# Restrictions under REACH

- Restrictions may be imposed on:
  - manufacture, use and/or placing on the market
  - a substance on its own, in mixture or in an article
- When;
  - an **unacceptable risk** to human health or the environment
  - this risk needs to be addressed on a **Union-wide basis**

# Classification and labelling

- The first step to define the hazards of chemical substances and mixtures to facilitate safety
- World-wide system (GHS)
- Companies **need to notify ECHA** on how they label and classify their chemicals. Information available on ECHA website
- CLP/GHS gives the possibility to **classify forms of the same substance differently** (e.g. Ni) based on pchem properties

# ECHA's tasks - Biocidal Product Regulation (BPR)

- Coordinate the **approval processes of biocidal substances and authorisation of biocidal products** at EU level
- Operate a Biocidal Products Committee
- Provide **technical and scientific support to the industry and Member States** through IT tools, guidance and helpdesk service

# Nanomaterials and BPR – 1/2

- Previously: Biocidal product Directive: no provisions for nanomaterials
- Now BPR: definition of nanomaterial in Article 3(1)(z) and approval of biocidal substance **does not cover nanomaterials except where explicitly mentioned** (Article 4(4))
- Commission **published several notes to clarify the status in the Review Programme for the existing active substances**.
- **Label obligation for treated articles** in Article 58(3): the name of all nanomaterials contained in biocidal products, followed by the word 'nano' in brackets

# 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.