“ Nanomaterials under REACH and CLP and Italian Competent Authority’s activities”

2nd Part

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REACH - Title VI: Evaluation

Objective

Evaluation provides a means for the authorities to require registrants to provide further information.

Procedure

Dossier evaluation is conducted by European Chemicals Agency (ECHA) to
(1) examine proposals for testing to ensure that unnecessary animal tests and costs are avoided and
(2) check the compliance of the registration dossier with the registration requirements

Substance evaluation is performed by Member State-Competent Authorities (MS-CAs)
When there is a reason to suspect that a substance presents a risk to human health or the environment.

Output

On the basis of the evaluation, ECHA can require further information which may include information not required in Annexes VII to X of REACH.

REACH - Title VI: Evaluation

What is relevant for substances at nanoscale?

ECHA conducts Dossier EVALUATION

(1) Does the proposal comply with the standard –testing requirements?

(2) Are the reasons for proposing additional testing for endpoints beyond standard testing requirements appropriate?

Testing Proposals

(3) Is the required information included in the technical dossier(s) and do any adaptations of the standard information requirements and the related justifications submitted in the dossier(s) comply with the obligations?

(4) Are any required CSA and CSR compliant with Annex I and are the proposed risk management measures adequate to the substance in th sizes and forms in which it is manufactured and/or for which the registrant and DUs have identified uses?

Compliance Check

REACH - Title VI: Evaluation

What is relevant for substances at nanoscale?

MS-CAs performs Substance EVALUATION

Rolling Plan

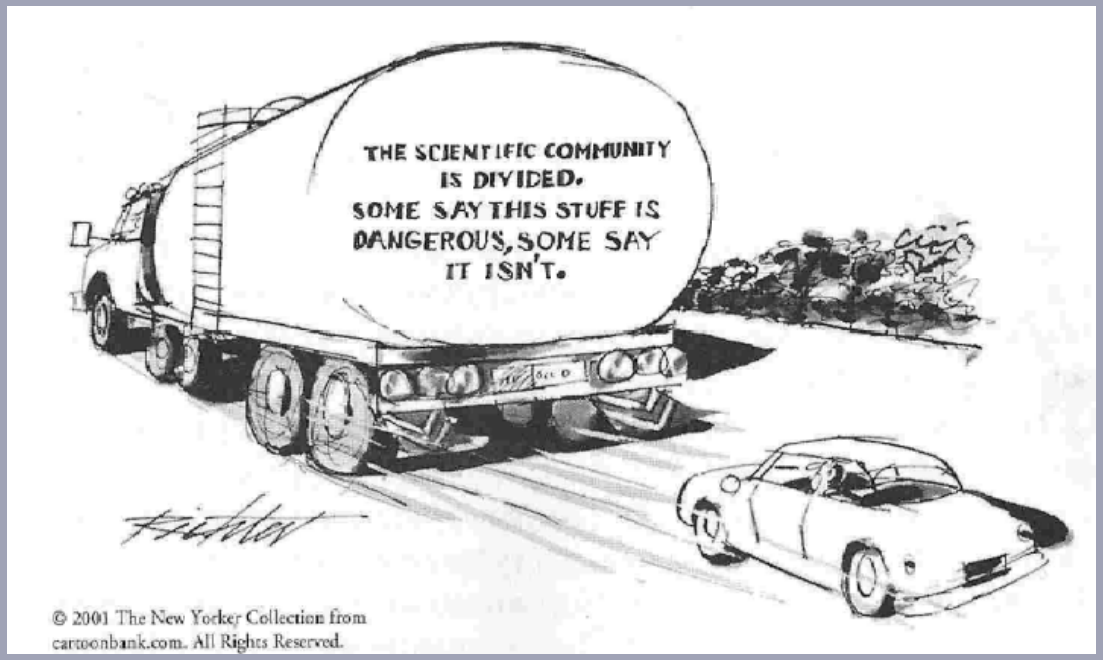
- **ECHA sets criteria for substance evaluation**
- **ECHA adopts the rolling plan as defined by Member State Committee**
- **Each Member State chooses a set of substances to be evaluated**

Relevant for substances at nanoscale for which there are grounds to consider that they may constitute a risk for humans and/or the environment

Output

Following substance evaluation, the MS-CA may come to the conclusion that action should be taken under the **authorisation**, **restriction** or **classification and labelling** procedures under REACH

REACH - Title VI: Evaluation



Nanomaterials EVALUATION specific issues due to

- specific properties
- standard tests not sufficient/appropriate

Key message

It could be useful to prioritise a small number of NMs for evaluation, as this would allow the issues that are likely to occur to be raised, discussed and resolved. This is turn could provide useful guidance to other registrants, MS authorities and the COM on what to do.

REACH - Title VII and Annex XIV: Authorization

Seek for NMs Authorization?

Criteria for Substances to be included in Annex XIV

(Substances of very High Concern SVHC):

- CMRs (carcinogenic, mutagenic or toxic for reproduction) cat 1 and 2
- PBTs (persistent, bioaccumulating and toxic) and vPvBs (very persistent and very bioaccumulating)
- equivalent level of concern as CMRs and PBTs/vPvBs (identified on a case-by-case basis (e.g. endocrine disruptors))

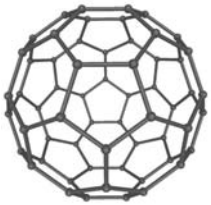
- **Annex XV dossier identifying the NM as a SVHC should be provided for ECHA**
- **It should be clarified in the proposal and the dossier (Art. 59)**
- **If an authorisation application concerns a NM, this should also be clarified in the application (Art. 62 (4)).**

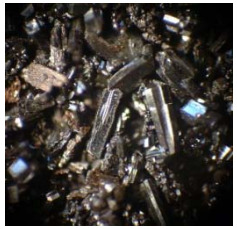
REACH - Title VII and Annex XIV: Authorization

Seek for NMs Authorization?

ECHA guidance on identification of SVHC

"…as yet unidentified substance properties can be captured under the consideration of equivalent concern, where there is scientific evidence that these properties give rise to an equivalent level of concern to those of CMR cat 1 and 2, PBT and vPvB.
It might be that other as yet unidentified aspects of a chemicals behaviour in the environment or its impacts on organisms will lead to a change in the current paradigm for chemical hazard and risk assessment.
Authorities are encouraged to employ the underlying principles behind the preceding sections in considering such aspects and properties in the future."





International activities related to NMs: REACH Competent Authorities Subgroup-Nanomaterials – CAGS Nano

REACH Implementation Projects on Nanomaterials: Agreement between DG ENV e JRC to give technical-scientific support on nanomaterials

Objectives

Elaborate technical-scientifical reports on key aspects of REACH implementation regarding nanomaterials :

- **Task I: Substance Identification (SI)**
- **Task II: Information Requirements (IR)**
- **Task III: Chemical Safety Assessment (CSA)**

International Activities related to NMs: OECD Working Party on Manufactured Nanomaterials - WPMN

Manufactured Nanomaterials and Chemical Safety

In 2006 the OECD established the Working Party on Manufactured Nanomaterials (WPMN)

Objective:

To promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials (MNs), in order to assist in the development of rigorous safety evaluation of NMs.

OECD WPMN Steering Groups

International Activities related to NMs: OECD – WPMN- Steering Groups

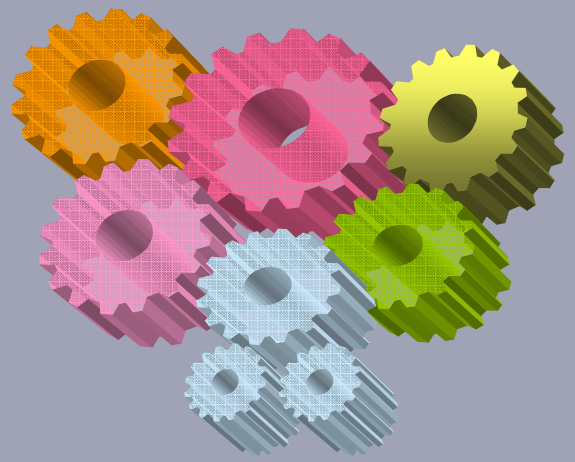
OECD SG5: Co-operation on Voluntary Schemes and Regulatory Programmes

SG5 Objectives:

- **To identify common elements of the various information gathering initiatives, in place or planned.**
- **To identify applicable current and proposed regulatory regimes and how they address information requirements, hazard identification, risk assessment and exposure mitigation/ risk management of NMs.**

National Activities related to NMs

National Coordination Technical Committee for REACH implementation in Italy
Working Groups



- **WG surveillance**
- **WG meeting industries**
- **WG nanomaterials**
- **WG train and inform**
- **WG ECHA committees support**
- **WG COM procedures under REACH art. 133 support**

National Activities related to NMs

National Coordination Technical Committee

WG on nanomaterials Mandate

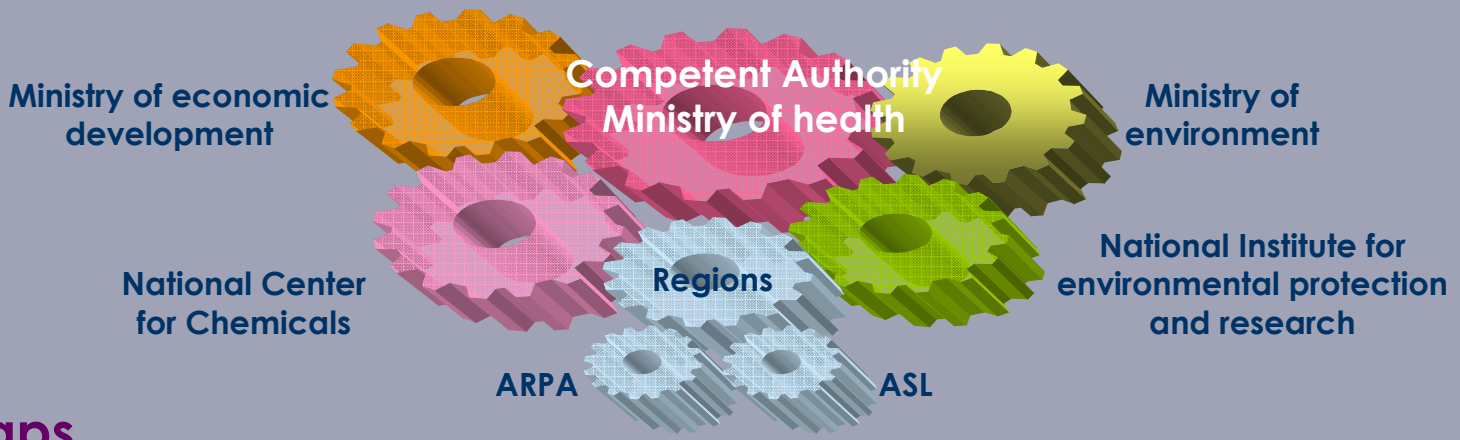
- **Develope a database on R&D and manufacturing activities concerning NM applications and available exposure assessment**
- **Cooperation on NM risk assessment and develope test strategies**
- **Support to international activities (OECD and COM)**
- **Support to REACH and CLP implementation activities related to NMs in Italy**

The Italian nanotech landscape and NM traceability gaps

Stakeholders

- REACH implementation bodies
- National institute for incidents in workplaces insurance (INAIL)
- University and Research centers
- Industrial associations

REACH implementation mechanism



Gaps

- Wide number of ongoing NM research activities to be traced
- Unmonitored growth of NM applications placed on the market
- Impact of NM on human heath and environment

Instrument to collect information: National Database on Nanomaterials

Objectives

To inform

- workers
- consumers
- indirectly exposed

To be informed

- risk management measures
- incident safety measures

Available legal instruments

Mandatory
Legislative decree

Voluntary base
Ministerial decree

Italian choice: ministerial decree

Project of ministerial decree

"Provisions relating to the establishment within the Ministry of Health, Directorate General of Health Prevention, of a national database on nanomaterials manufactured, imported and used on their own, in mixtures and in articles."

Whereas

the European Parliament in the resolution of 24 April 2009 on regulatory aspects of NMs

11. Calls on the COM to evaluate the need to review REACH concerning inter alia:
– simplified registration for NMs manufactured or imported below 1 tonn/year,
– consideration of all NMs as new substances,
– a CSR with exposure assessment for all registered NMs,
– notification requirements for all NMs placed on the market on their own, in preparations or in articles;
16. Calls on the COM to compile before June 2011 an inventory of the different types and uses of NMs on the EU market, while respecting justified commercial secrets, and to make this inventory publicly available; furthermore calls on the COM to report on the safety of these NMs at the same time.

EU Parliament call for action

National Database on NM creation

Data acquisition and inputs

- **Questionnaire will be made available on-line on a dedicated platform @ www.ministerosalute.it (Chemical Safety section)**
- **Input from manufacturers, importers, users of NM (including public and private research centers)**

Contents

General Part
Contains general information about the company/research center

Specific Part
for each NM manufactured, imported or used:
Contains information about
- market sector
- NM identity, physical state and dimensions
- extimated q of NM contained in the product
- identified uses
- foreseeable exposure conditions
- risk management measures in workplaces
- disposal

Data access

REACH CA administrates the archive. Information to all REACH implementation stakeholders, national and EU bodies involved in chemical legislation and workplace safety, and to consumers.

Outputs

- **Data reports**
- **Research project financing, prioritization within REACH evaluation process**

National database on NMs & REACH interface

The Database will be complementary to the REACH: it will complete data availability thus rising the knowledge of substances in nanoform

Key elements

- Knowledge of the market quicker available and more explicit
- Knowledge covers manufacture, import and placing on the market < 1 tonn/ year
- Input for CASG-Nano (assessment of the need to revise Reach in 2012)
- Awareness of industry about the need to care for its registration dossiers
- Help to prioritise registration dossiers and substances according to Title VI of Reach
- Help the authorities in charge of public health and environment to take action through REACH (SVHC, restrictions, …) to better manage the risk

Work in progress…
on Nanomaterials traceability

Common initiative of few EU Member States: harmonized NM database creation

Key feature: IUCLID 5.3

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FAQ