Update of current activities

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ECHA: Dir E & Task force on NMs

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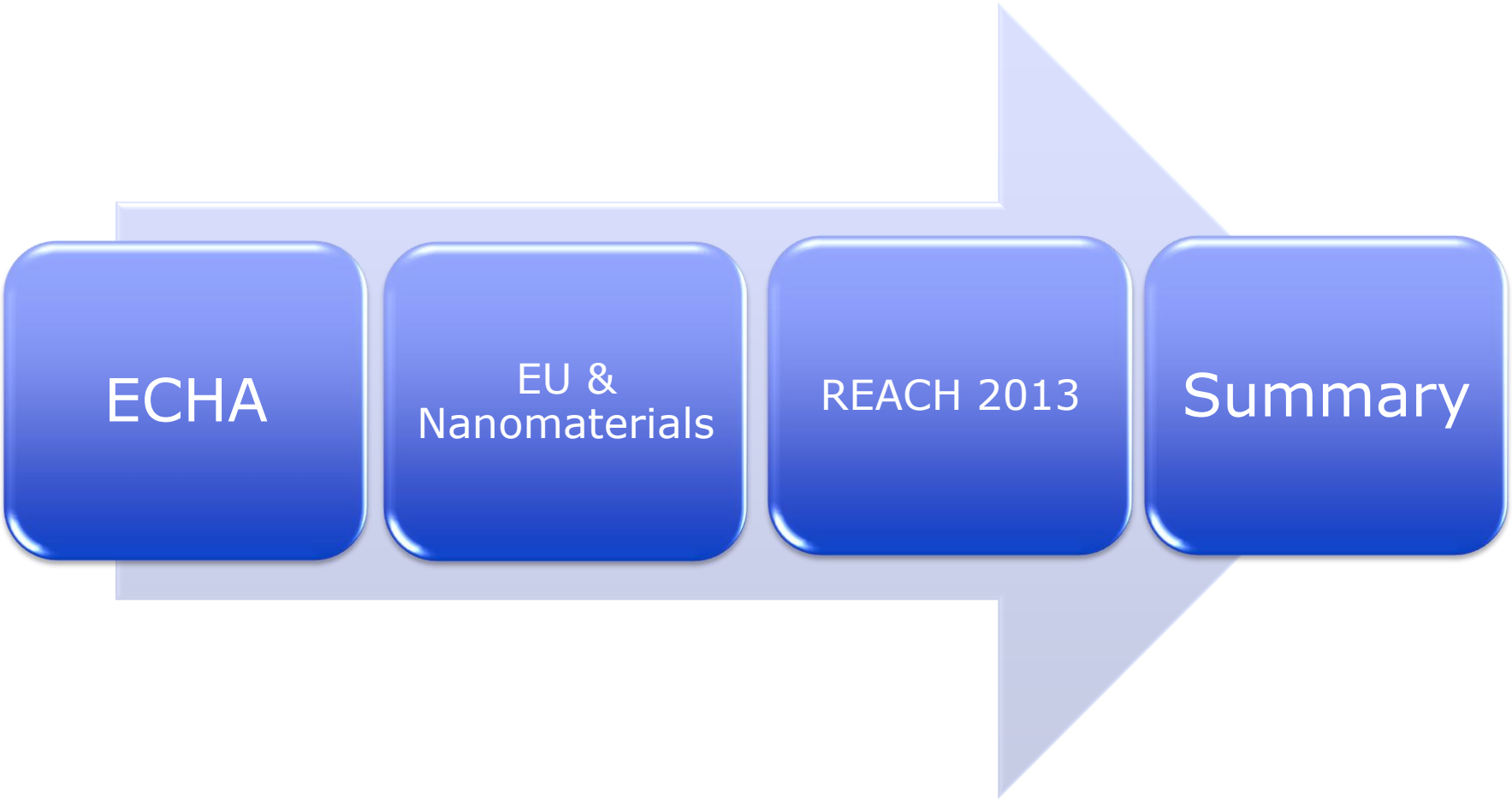
**Some slides are courtesy of ECHA*

Content



ECHA in numbers

- Over 500 staff from 27 European countries
- 4 legislative frameworks (REACH, CLP, BPR, PIC)
- 4 scientific committees with experts from all Member States
- 1 Forum of national enforcement authorities
- Over 6 000 substances registered
- Over five million C&L notifications for more than 100 000 substances

http://echa.europa.eu/documents/10162/13556/echa_general_leaflet_en.pdf

Short intro to REACH

Nanomaterials (NMs) under REACH

Where do nanomaterials fit under REACH?

No explicit reference to nanomaterials in REACH

- Considered as covered by the substance definition under REACH

Commission 2nd regulatory review on NMs (Oct 2012)

- Confirmed that nanomaterials can be either
  - substances on their own and thus registered as such substances
- nanoforms of a substance and included in the dossier of the corresponding bulk substance

Nanomaterial definition
(EU recommendation – 2011)

Nanomaterial when:

- 50% of particles by number <100 nm in one or more dimensions
- Volume specific surface area >60 m2/cm3
- *"Member States, the Union agencies and economic operators are invited to use the following definition of the term 'nanomaterial' in the adoption and implementation of legislation and policy and research programs concerning products of nanotechnologies."*

- No specific method indicated for measurements

- Number based distribution new, challenging

No standardized methods available

Nano inventory from the REACH/CLP registration/notification databases

A ”snapshot” of how nanomaterials have been registered under REACH after the 2010 deadline

2011: Request from the Commission to compile information on nanomaterial registered/notified

- REACH registration dossiers - three had explicitly selected “nanomaterial” as the form of the substance
- CLP notifications - 21 notifications referring to nanomaterials

Nanomaterials addressed through formal REACH processes

Testing proposals

– few TPs for nano

Compliance check

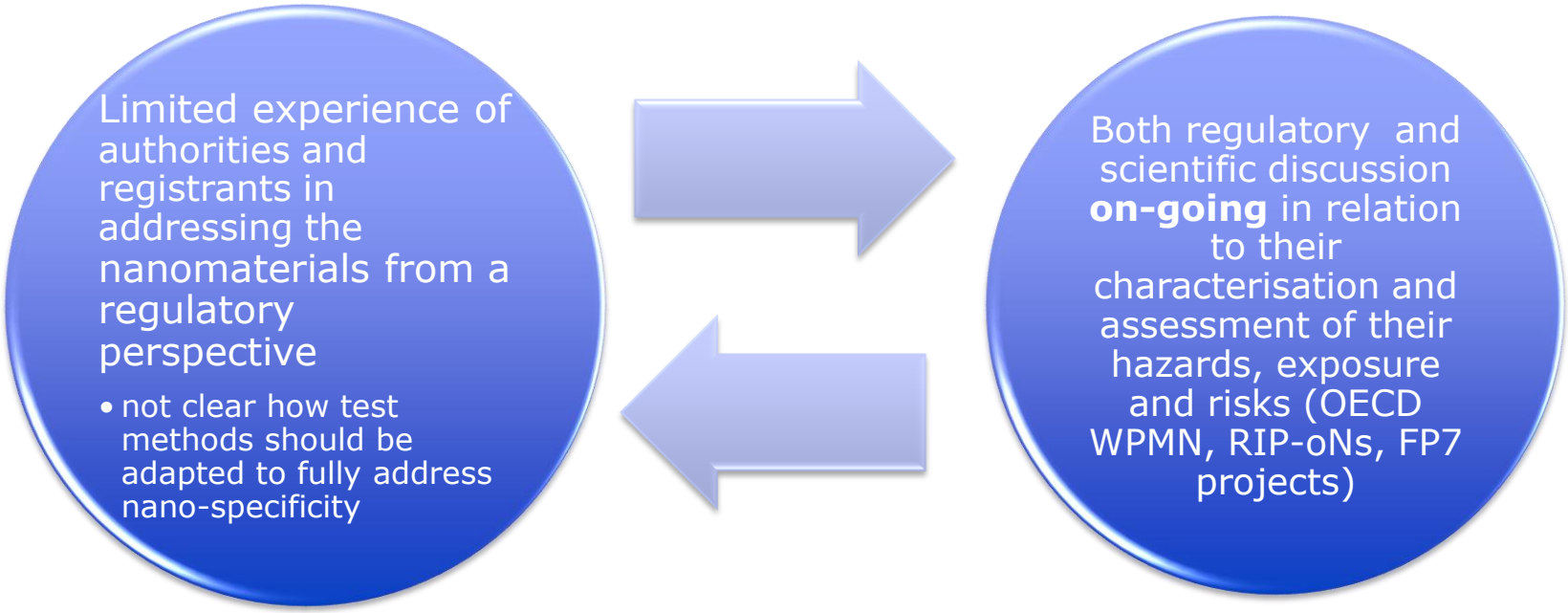
– to request more information on particle size

Substance evaluation

– on-going

- **2012: silicon dioxide**
- **2014: silver**
- **2014: titanium dioxide**

Specific challenges under REACH



ECHA has provided information and specific guidance concerning Information Requirements and Chemical Safety Assessment of NMs, to support the implementation of REACH:

http://echa.europa.eu/web/guest/view-article/-/journal_content/3df5b7b9-a36d-4e74-811b-3aeee23366f8

EU consultation on nanomaterials

The European Commission has launched a public consultation to clarify how NMs are addressed and safety is ensured.

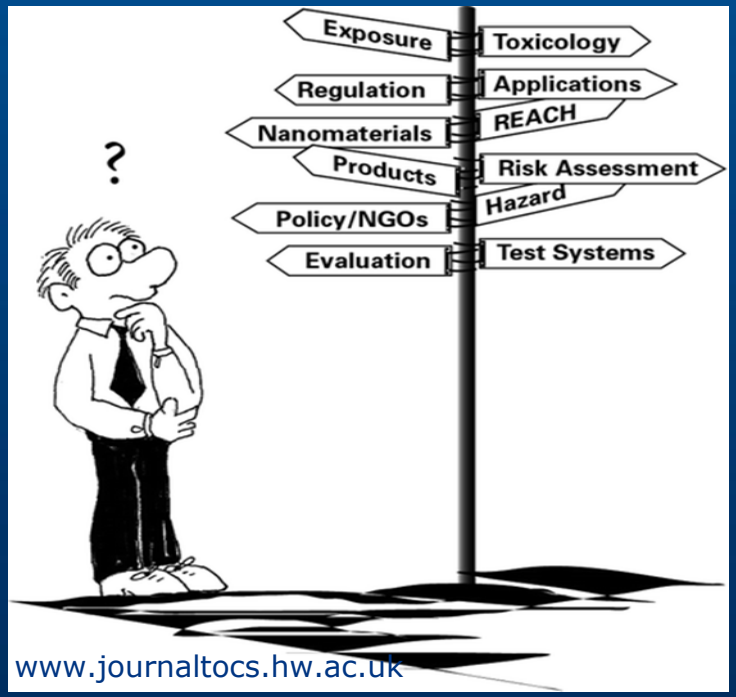
Scope of this consultation

- Taking into account the conclusions of the Second Regulatory Review on Nanomaterials and the General Review of REACH, the scope of this stakeholder consultation is focused on technical provisions in the Annexes to REACH.

- The Commission proposal of possible amendment of the REACH Annexes is promised to be made in 2013, and will be accompanied by an Impact Assessment.

- **Responses were accepted until 13 September 2013.**
- **http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=NanomaterialsREACH**

Update of current activities: Key messages

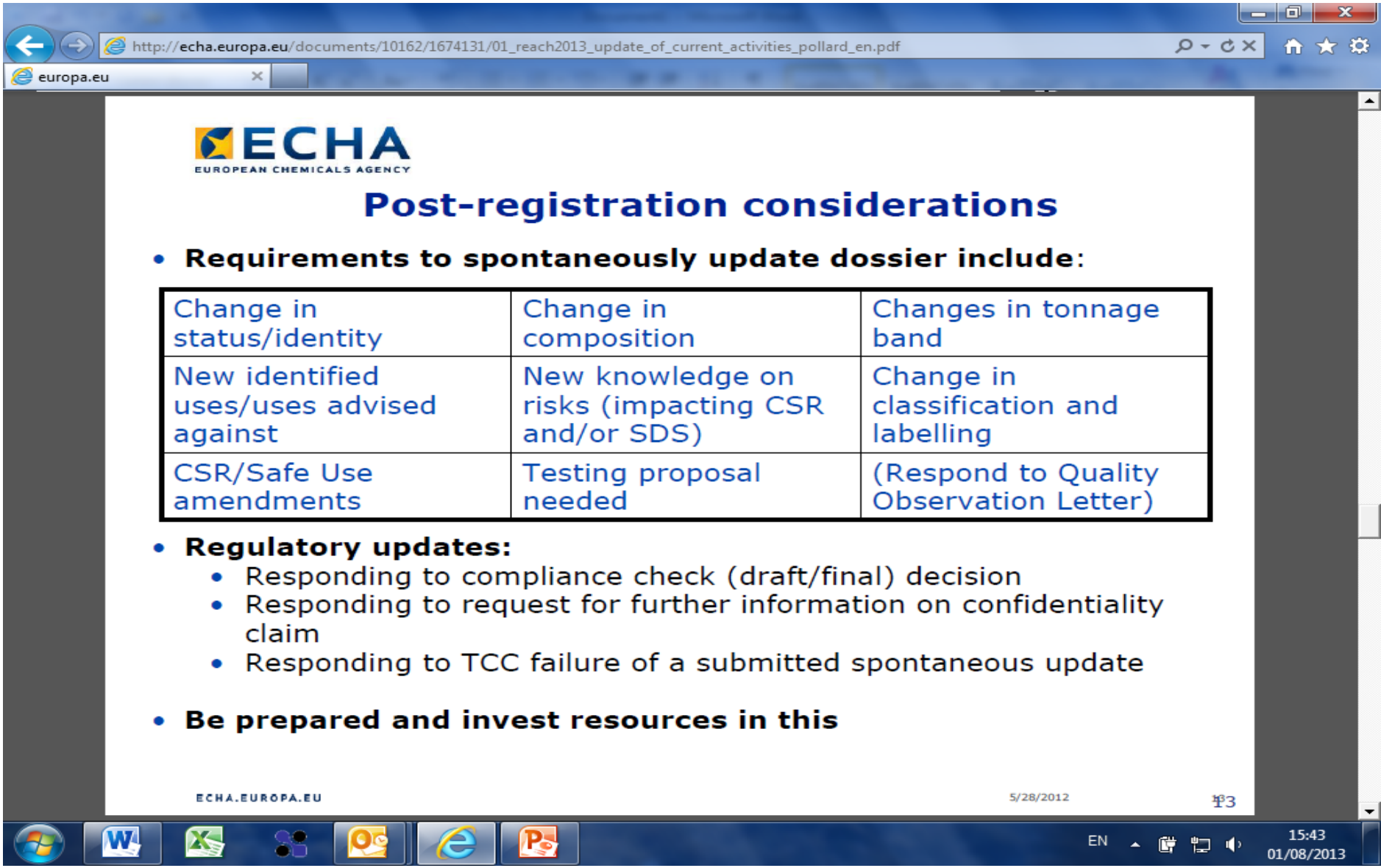


www.journaltocs.hw.ac.uk

2013 registrations

- Registration numbers have been granted to 9 030 dossiers that were submitted by the second REACH registration deadline;
- This corresponds to 2 998 more substances being registered under REACH;
- Companies submitted in total 770 testing proposals in 376 dossiers.
- 563 were proposals to test on animals in order to fulfil the REACH information requirements listed in Annex IX.
- The Agency will evaluate all dossiers which include testing proposals relevant to Annex IX by 1 June 2016.

http://echa.europa.eu/documents/10162/9941984/registration_statistics_2013DL_summary_en.pdf


http://echa.europa.eu/documents/10162/1674131/01_reach2013_update_of_current_activities_pollard_en.pdf
europa.eu
ECHA
EUROPEAN CHEMICALS AGENCY
Post-registration considerations
• Requirements to spontaneously update dossier include:
Change in status/identity
Change in composition
Changes in tonnage band
New identified uses/uses advised against
New knowledge on risks (impacting CSR and/or SDS)
Change in classification and labelling
CSR/Safe Use amendments
Testing proposal needed
(Respond to Quality Observation Letter)
• Regulatory updates:
Responding to compliance check (draft/final) decision
Responding to request for further information on confidentiality claim
Responding to TCC failure of a submitted spontaneous update
• Be prepared and invest resources in this
ECHA.EUROPA.EU
5/28/2012
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Spontaneous update

Based on experience; proactive spontaneous updates recommended in the following areas:

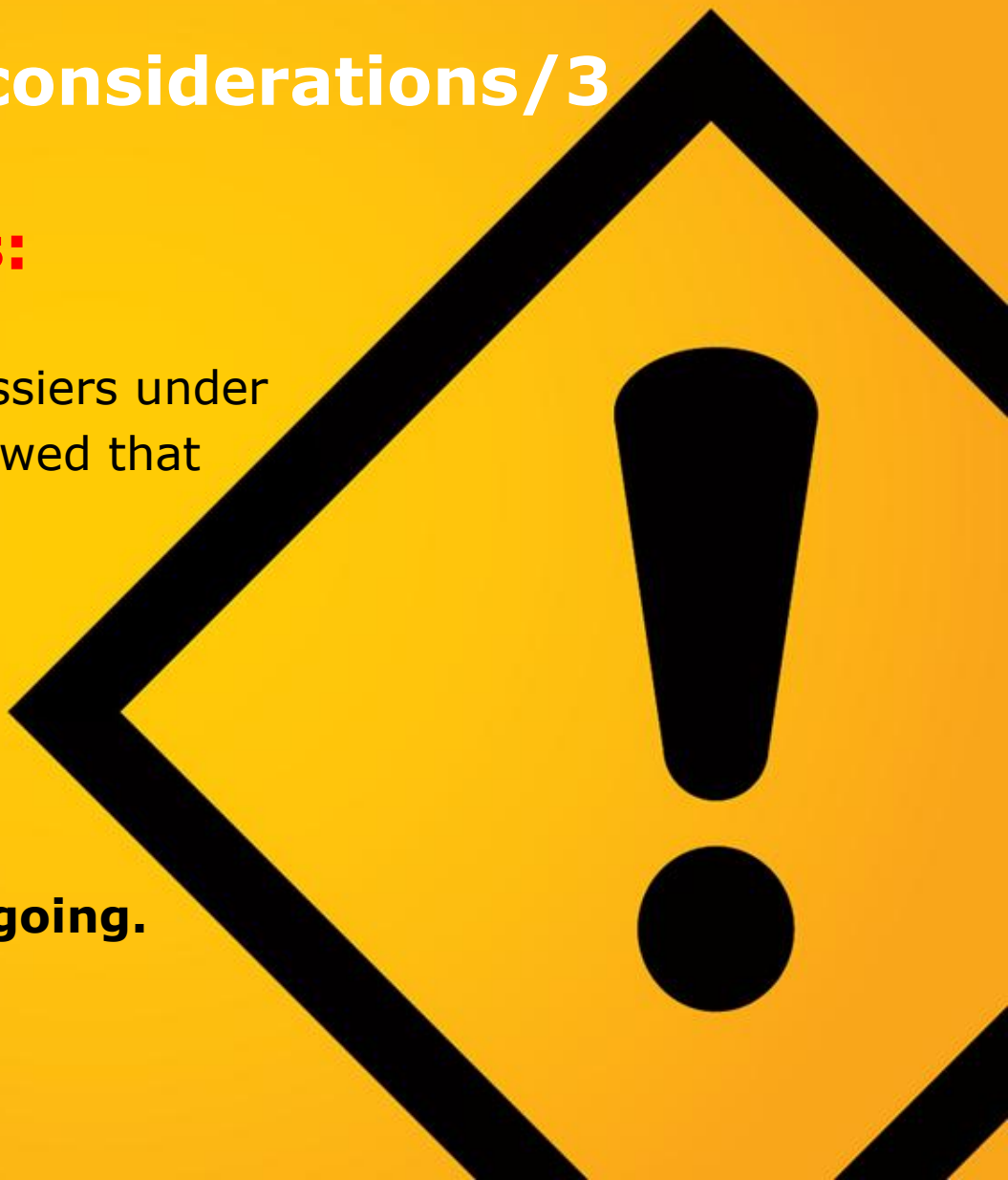
- Dossier evaluation: Completeness ≠ Compliance
- Read the Article 54 Evaluation Report and invest in a spontaneous update to address potential issues prior to compliance check
- Take care to correctly enter all testing proposals in the dossier.

Post-registration considerations/3

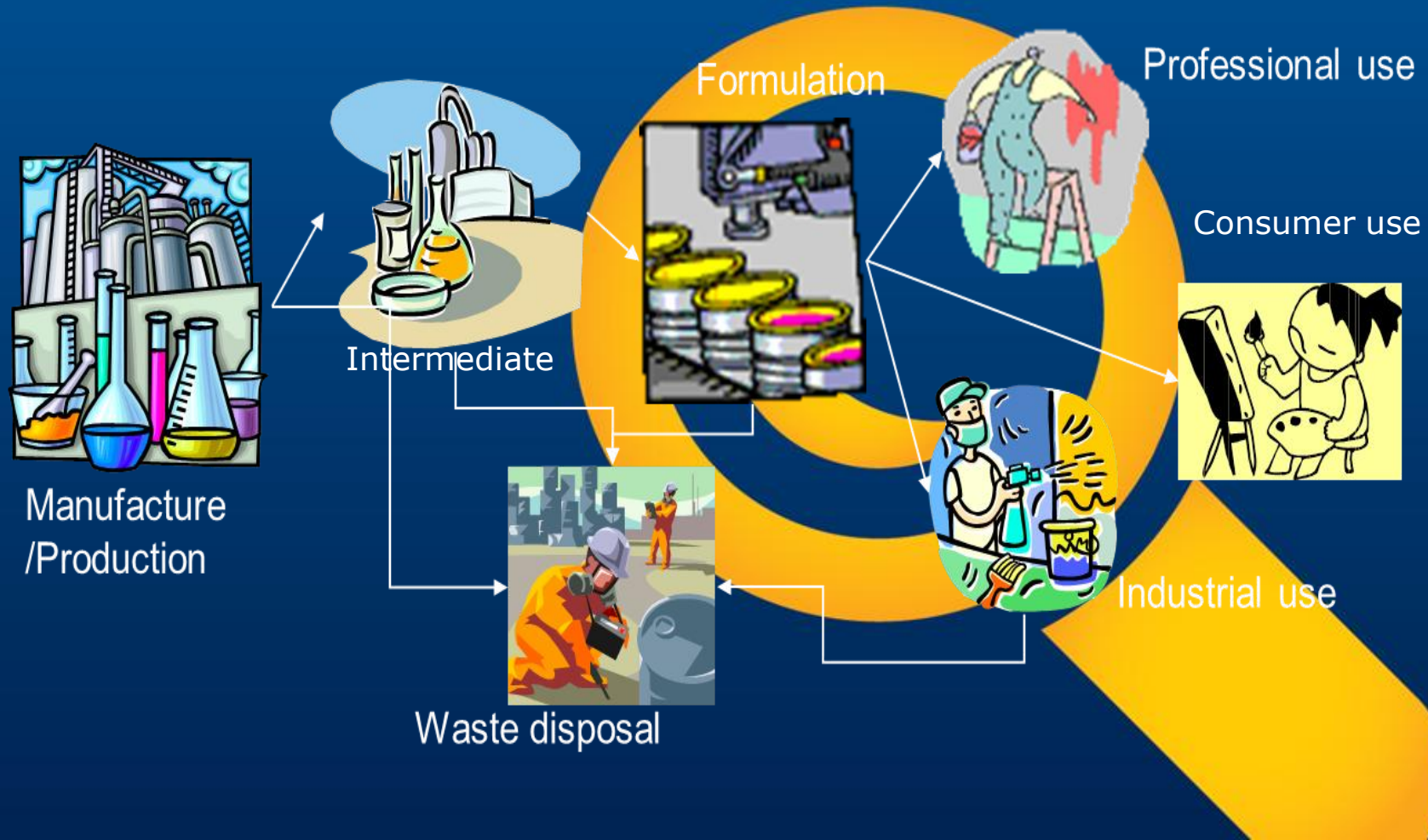
Intermediate status:

Screening of intermediate dossiers under **"Article 36" provisions** showed that 86% of dossiers screened had insufficient information to confirm intermediate status!!!!

Formal updates have been requested and work is on going.



What do exposure scenarios look like in reality?



Final report of the second REACH enforcement project/1

- **Final report of the second REACH enforcement project published**

- The ECHA Forum's second enforcement project (REF-2) focused on checking the compliance of downstream users – particularly formulators of mixtures – with the essential requirements of the REACH and CLP regulations.

- The project's operational phase was carried out in 29 Member States or EEA countries from May 2011 until March 2012.

Final report of the second REACH enforcement project/2

- The national enforcement authorities inspected 1 181 enterprises covering 6 900 substances, 4500 mixtures and 4500 safety data sheets (SDSs).

- The majority of the inspected companies were small or medium-sized. More than half of the inspected companies were not only active as downstream users but also in additional roles, e.g. as manufacturers, importers, distributors and only representatives.

- **In total, 67%** of the inspected companies were non-compliant with one or more provisions of REACH or CLP.
- Non-compliance was most commonly related to contraventions of (pre-)registration (REACH, 8%), notification (CLP, 15%), failure to keep information (20%) and having deficient risk management measures (12%).

- http://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

Exposure Scenarios/1

Qualitative risk assessment of local effects:

- When no DNEL can be derived for **irritation/corrosion**, a more qualitative approach to assessing and controlling these risks **is required by REACH**.

- This can be the case when only the following types of data are available: pH, in vitro data on skin and eye irritation/corrosion, in vivo data with no information on dose-response, or QSAR/read-across.

Exposure Scenarios/2

ECHA has issued Practical Guide15 on

"How to perform a qualitative human health assessment and report it in a Chemical Safety Report".

The guide supports registrants in performing a qualitative risk characterisation for human health effects where a threshold cannot be established.

http://echa.europa.eu/view-article/-/journal_content/ebefae2e-fbf6-46fb-94ca-4c3ac3146e87

Addressing Chemicals of Concern

Promoting substitution under REACH, CLP and the Biocidal Products Regulation

- On-going international work on substitution
- OECD established an ad hoc group on the substitution of harmful chemicals in June 2012.
- ECHA is co-chairing this group with the US Environmental Protection Agency. The group consists of representatives from governments, industry, academia, NGOs and trade unions.
- Currently, the group is working on an inventory of the available tools and methods which can be used to characterise and compare hazards and exposures/risks.
- The objective is to develop a toolbox that provides guidance on how to use priority tools and identify best practice. ECHA will contribute to this group to improve the knowledge on the costs of different substitution options. The first outcomes are planned to be ready in summer 2015.
- http://newsletter.echa.europa.eu/home/-/newsletter/entry/3_13_promoting_substitution

"User friendly" list of restrictions

- ECHA has published a user friendly Annex XVII table listing the restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixture and articles.

- The table also contains links to the latest Q&As connected to the specific entries.

http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions/list-of-restrictions-table

Summary

- Regulatory challenges of nanomaterials
- REACH 2013:

✓ Registration dossiers for 2013 deadline

✓ Post-registration considerations

✓ Exposure scenarios building

✓ Chemicals of concern

Thank you!