ECHA evaluations processes and recommendations on Dossier registration and Compliance

Precious Metals & Rhenium Consortium – Assembly meeting

14 June 2013

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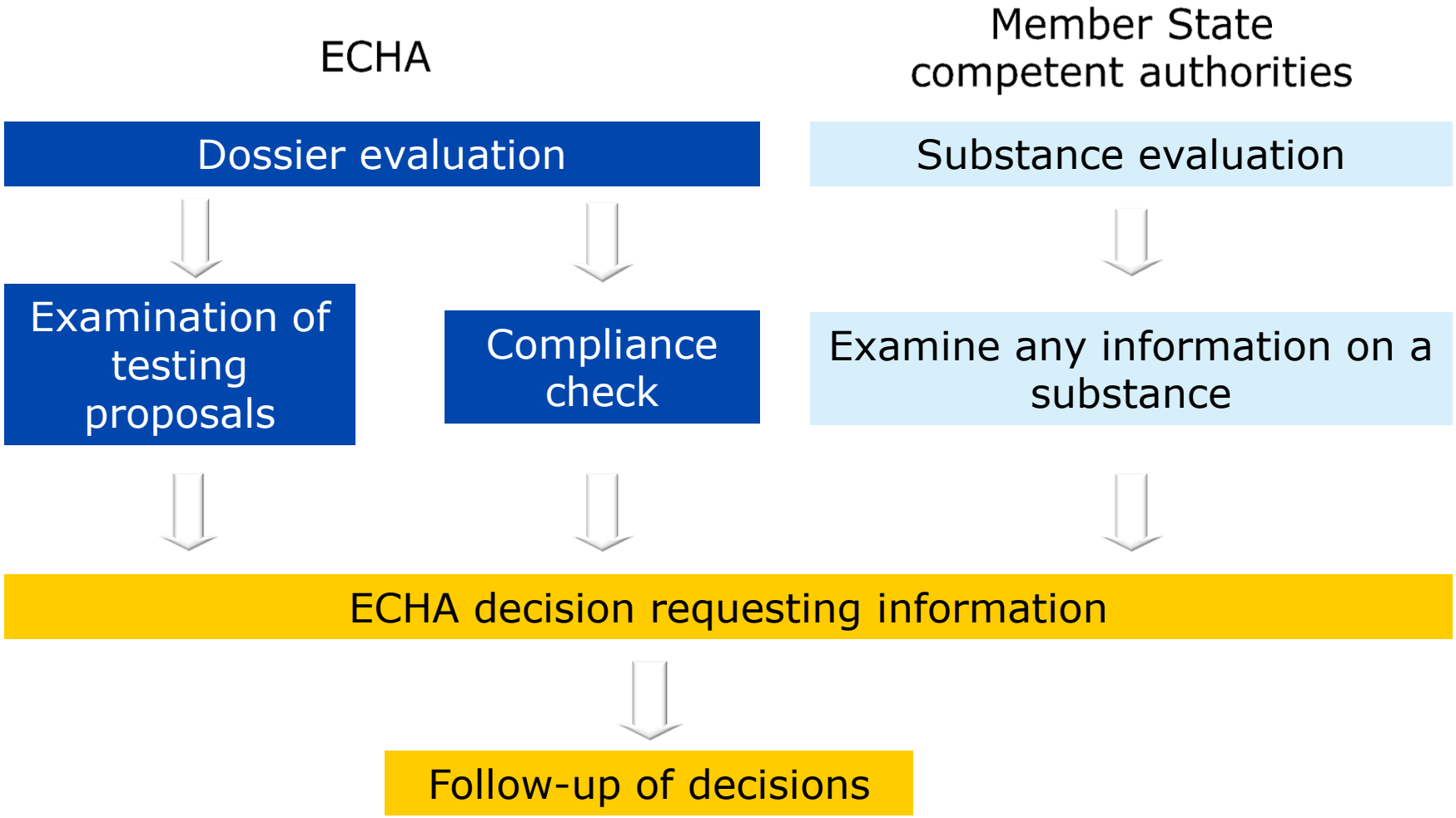
Outline

- Reminder on ECHA Evaluation processes
- General Recommendations
- Recommendations for nanomaterials

Reminder on ECHA Evaluation processes

Evaluation: overview



Follow-up of dossier evaluation decisions

After the deadline in the decision, ECHA looks at the latest dossier.

Requests not fulfilled: ECHA notifies Member States of non-compliance.
May lead to enforcement.

New information leads to further concerns: another compliance check.

Article 42(1) REACH

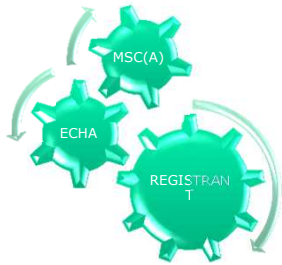
Requests fulfilled: ECHA notifies Commission and Member States.

Article 42(2) REACH

Scope, aim and outcome of dossier evaluation

Evaluation type	ECHA questions	ECHA examination conclusions	Numbers and timelines
Testing Proposal Examination (TPE)	Proposed test adequate and justified? Unnecessary animal testing avoided?	Article 40(3) draft decision: •Accept testing •Reject testing •Change test conditions •Request additional testing	All testing proposals •non phase-in: draft decision in 6 months •phase-in submitted by 1 June 2013: draft decision by June 2016.
Compliance Check (CCH)	Information requirements adequately fulfilled? Adaptations adequately justified?	Article 41(3) draft decision: •Request further information Other outcomes: •Quality Observation Letter – indicates elements to be improved •No further action	Select 5% of total received for each tonnage band •draft decision within 12 months of start CCH

Possibilities for comments on draft decisions



Key steps during the decision making process

Step 1: After receiving a draft decision

Registrant may comment and provide dossier updates within 30 days

Also possibility to informal interaction (e.g. teleconference)

ECHA may amend draft decision or decide no further action

Step 2: After MSCAs provide proposals for amendments

Registrant may comment within 30 days on proposals for amendments (and update dossier)

Step 3: During Member State Committee procedure

Case owner (registrant who received the draft decision) may participate in the MSC initial discussions on the draft decision

MSC result will be the final decision

General Recommendations

High quality information is required for REACH compliance

Recommendations on how to fulfil these REACH requirements:

- Identifying your substance clearly
- Making sure test material is representative
- Making intelligent use of all available information
- Providing clear use and exposure information

How to make use of ECHA support: Read the Evaluation progress report 2012

Recommendations for registrants

- Identity of the registered substance – describe it clearly
- Adaptation to the standard information requirements
  - must meet the conditions set out in Annex XI or in column 2 of Annexes VII – X of the REACH Regulation;
  - sufficient justification for any adaptation should be provided;
- Robust study summaries - sufficient level of detail required to allow an independent assessment of the information provided
- Classification and labelling - in line with the hazards identified or harmonized classification and labelling
- Testing proposal
  - submit for tests required under Annex IX and X before undertaking it
  - performing testing without an approving ECHA decision may lead to enforcement actions.

Recommendations for registrants (2)

- Check consistency
  - Between CSR and IUCLID file
  - Between different parts of the CSR
- Always provide justifications for
  - Omission or modification of a standard CSR element (see REACH Annex I) (e.g. if it is not possible to derive a DNEL or PNEC)
  - Deviations from guidance documents (e.g. if non-standard assessment factors are used in PNEC or DNEL derivation)
- Qualitative assessment and justifications are not just statements
  - Detailed reasoning and supporting data are required
- Ensure transparency
  - Give details on model assumptions, versions, input parameters

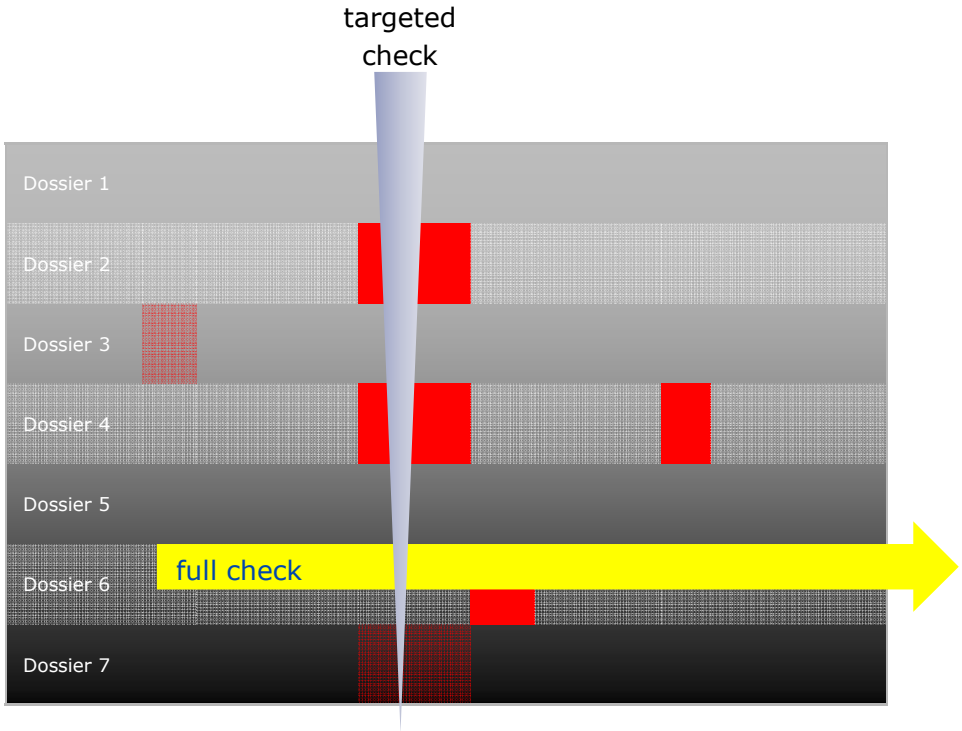
Key Messages for Registrants

- Do not consider your registration dossier a final product
- Take a pro-active approach and update your dossiers when new information on hazard or use becomes available
- Take into account the recommendations in the Article 54 report
- Do not await the outcome of potential compliance checks - improve the quality of the dossiers through updates on your own initiative.
- ECHA will further promote the quality of the registration dossiers through further (targeted and random) compliance checks in the coming years.

Targeted compliance checks to improve dossier quality

Targeted compliance checks

- Aimed at having **maximum impact on safe use** of chemicals
- ECHA will target compliance checks to specific dossier issues where safety matters



Targeted compliance checks to improve dossier quality

- ECHA scientists check dossiers more efficiently with data-mining tools
- **Poor entries will be caught**
- Complements other compliance check activities
- Most efficient use of ECHA evaluation resources

ECHA evaluation webinars

Old ones available for viewing on ECHA website:

- What should every registrant know about substance evaluation?
- Characterisation of nanoforms, Oct 2012
- Human health and environmental hazard assessment for Nanomaterials, May 2013
- Tips and Hints – How to bring your registration dossier in compliance with REACH (parts 1 and 2)
- Tips and Hints – How to bring your registration dossier in compliance with REACH (part 3)

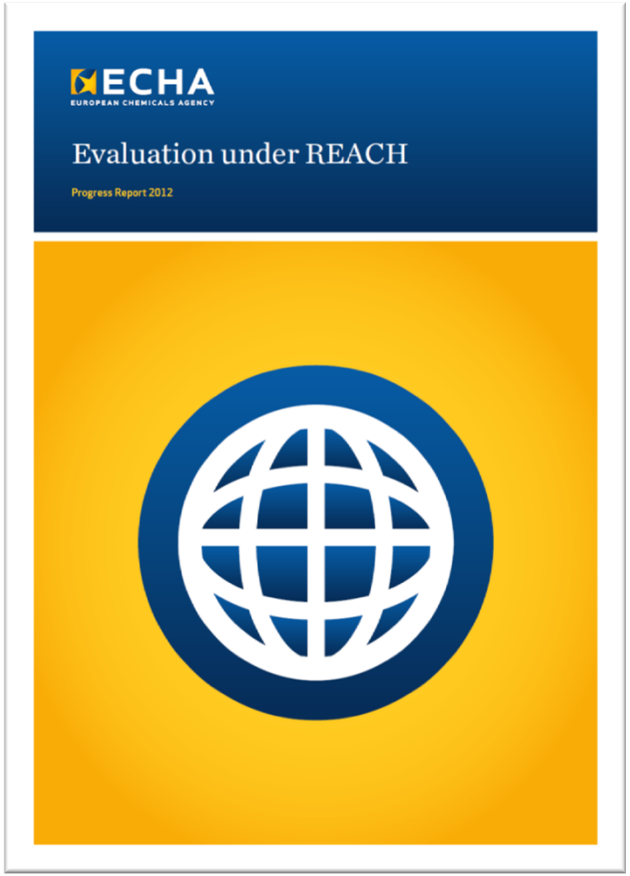
Ones to look forward to:

- Tips and Hints (part 4), September
- Tips and Hints (part 5), November

Evaluation progress report 2012

- Annual report
  - Maybe your yearly reminder?
- On ECHA website
- Progress in our activities
- Information on common pitfalls
- **Recommendations for you**

http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf



Recommendations for nanomaterials

Nanomaterials and REACH

- No explicit reference to nanomaterials in REACH
  - Considered as covered by the substance definition under REACH
  - Commission second regulatory review on nanomaterials

- Nanomaterials (NM) 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 form of the substance

Ensuring safety for nanomaterials

- Growing number of reliable references supporting regulatory action in order to ensure safety, e.g.
  - SCENHIR opinions recognising non-hypothetical hazards and risks specific to some nanomaterials - 2010
  - Definition of nanomaterials, EU Recommendation – Oct 2011
  - Commission second regulatory review of nanomaterials – Oct 2012
  - Increasing body of scientific literature
- Registrants need to demonstrate the safe use of their substance, whatever the form (also nanoform if the form of the substance falls under the definition of nanomaterials)

Characterisation of nanomaterials

Characterisation of nanomaterials

- The characterisation of nanoforms of a registered substance is a prerequisite to the proper determination of hazards and risks of the substance

- ECHA is thus concentrating on this characterisation:
  - when elements in a dossier indicate that the substance (may) fall under the definition of nanomaterial
  - when there is sufficient indication that the substance may be a nanomaterial in spite of the absence of reference in the dossier

ECHA's observations

- ECHA & DG JRC screened REACH dossiers for nano-specific information (*NanoSupport project*)
- General trends & recommendations
  - Limited information provided on nano-specific properties, studies and risk assessments
  - Room for improvement ➔ recommendations provided at http://echa.europa.eu/chemicals-in-our-life/nanomaterials
  - Nature of recommendations on dossier quality are in line with 'non-nano' specific recommendations (e.g. Art 54 report)
- Dossier submitted in 2010:
  - No agreed nano-definition; no nano-explicit reference to nano-materials in legal text; 'learning curve' effect

Nanomaterial definition

- A substance is considered a nanomaterial if:
  - 50% of particles by number 1-100 nm in one or more dimensions
  - Volume specific surface area >60 m^2/cm^3
- The definition also includes particles in agglomerates or aggregates whenever the constituent particles are in the size range 1 nm-100 nm
- In specific cases, the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

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
- It provides clarity on what is considered a nanomaterial
- Registrants should consider how they comply with the REACH information requirement if they have a nanomaterial
- Key question: does my dossier cover nanomaterial(s)?
  - Need sufficient information on particle size distribution and/or
  - Need sufficient information on surface area

Nanomaterials: characterising size

- REACH information requirement: granulometry: Annex VII, 7.14

- Granulometry can cover different information on particle size:
  - Particle size vs. particle size distribution
  - Number based vs. mass/volume based distribution
  - Constituent (primary) particle size
  - Aggregates: particles bound by strong forces
  - Agglomerates: particles bound by weak forces

Nanomaterials: characterising size (2)

- Information on constituent particle size distribution by number is needed
- Other information is also useful, and should be included:
  - e.g. information on aggregation/agglomeration may be useful for exposure assessment
  - Information on dustiness may be useful
- Particle size may vary significantly depending on manufacturing method/between different registrants

  Some registrants may manufacture a nanomaterial, while others might not. Which size should be submitted?

Nanomaterials: characterising size (3)

General recommendations:

- Include different information on particle size distribution (primary particle size by number, agglomeration, aggregation), as this information is complimentary. Different types of particle size may serve different functions
- As particle size may vary significantly by manufacturer, include information from different manufacturers (in case of joint submissions)
- Other properties may also vary significantly - registrants should consider if the available information on other forms is sufficient for their substance

Particle size: challenges (1)

- The EC recommendation for the definition of nanomaterials does not refer to any measurement method:

  Question: which method should I use?

  Answer: no single method can cover all size ranges-not unique to nanomaterials

- Particle size distribution is method specific

- Each method has advantages and pitfalls

Particle size: challenges (2)

- Registrants should tailor their particle size characterisation for their particular substance
  - In-house methods/industry developed methods can be used for characterisation
  - e.g. data that are generated for QC purposes for manufacturing of the NM
  - Use a variety of methods to characterise different aspects of particle size

Human health and environmental hazard assessment for nanomaterials

Use of non-testing data

- Supported for nanomaterials
- A solid scientific justification should be provided
- Insufficient to justify read-across based only on the chemical composition of a nanomaterial
  - aspect ratio, shape, form, solubility, surface area, charge, surface treatment, etc.
- A basis for grouping should be established using the similarity rules specified in Annex XI of REACH.

In vitro testing

- Despite their current limitations, *in vitro* methods can be useful as a supportive tool for *in vivo* testing.

- Many *in vitro* tests may need to be adapted before they can be applied directly for hazard assessment
  - appropriate sample preparation
  - adequate controls defined to monitor possible interferences

Reliability and use of existing data

- Peer-reviewed scientific studies should be considered and included in IUCLID dossier
  - to build multiple lines of evidence (e.g., Annex XI)
  - sufficient and unambiguous information on the physicochemical properties of the nanoform are reported in the peer-reviewed studies to make them useful for registration purposes under REACH
- The methodology used for sample preparation and dosimetry of exposure systems should also be well defined and reported
- Extensive literature reviews provide a good basis for determining the relevance of in vivo studies to be performed

Surface treated nanomaterials

- 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 toxicokinetics of nanomaterials
- Coated and uncoated nanomaterials should have separate IUCLID endpoint study records for the different hazard endpoints
- If an adaptation to the REACH information requirement is used, the registrant should ensure that it meets the requirements in Annex XI

Key messages

Key messages

- Like for any substance, REACH also applies to nanoforms
- Nano definition (Commission recommendation) is ECHA's benchmark
- The scope of the registration dossier should be clearly identified, in line with the current nanomaterial definition (2011/696/EU)
- Registrants need to demonstrate the safe use of their substance, whatever the form:
  - Update your dossier content proactively
  - Interact or consult ECHA (best practices, guidance, advice)
- GAARN, Workshop on Nanomaterials: to increase confidence and mutual understanding and set best practices
- ECHA Nanomaterial Working Group: to provide scientific and technical advice and support ECHA processes (REACH & CLP).
- Information available on ECHA nanomaterials webpage.

Key messages (2)

- The characterisation is a prerequisite to the proper assessment of hazards and risks of the substance
- Appropriate characterisation of nanomaterials is a starting point to understanding hazards
- Different nanomaterials require different characterisation techniques, registrants should tailor testing to their substance
- Information on particle size is multi-faceted (primary particle size, aggregate/agglomerate). Registrants should provide information on these different aspects
- Information on particle size is method dependent – therefore, registrants should provide a detailed description of applied method
- Information on surface area can be used to characterise nanomaterials and should be included

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Key messages (3)

- Read-across approach or use of existing data (e.g. weight of evidence) possible only when well-characterised nanoforms are reported in the dossier
- The use of grouping/read-across approach between different (forms of a) substance(s) should be adequately justified and documented
- Toxicokinetics data might also be considered
- Most standard biological endpoints used in regulatory hazard assessment remain appropriate for nanomaterials
  - Adaptations on sample preparation and dosimetry are foreseen for most of the tests
  - Parameters such as particle solubility and stability in the test media are essential parameters

Key messages (4)

- Use support documents available on ECHA website
  - Support http://echa.europa.eu/web/guest/support/
    → Guidance on REACH and CLP implementation
  - Publications http://echa.europa.eu/web/guest/publications
  - Nanomaterials http://echa.europa.eu/chemicals-in-our-life/nanomaterials

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Questions?

Thank you