Regulatory priorities/needs linked to Grouping (EU)

Celia Tanarro
ECHA
Scientific Workshop - Grouping of Nanomaterials

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Outline

- REACH and nanomaterials
- Read-across, grouping and categories under REACH
- Current ECHA Guidance for nanomaterials
- Conclusions

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 both substances and individual dossiers
- **Authorisation** – before a substance can be use or "placed on the market"
- **Restrictions** – banning of chemicals for specific uses such as e.g. consumers

Nanoforms and REACH (current framework)

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

- Nanomaterials and nanoforms 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

Nanoforms and REACH (upcoming framework) (i)

Nanoforms are explicitly mentioned in the revised REACH Annexes and there is an obligation to:

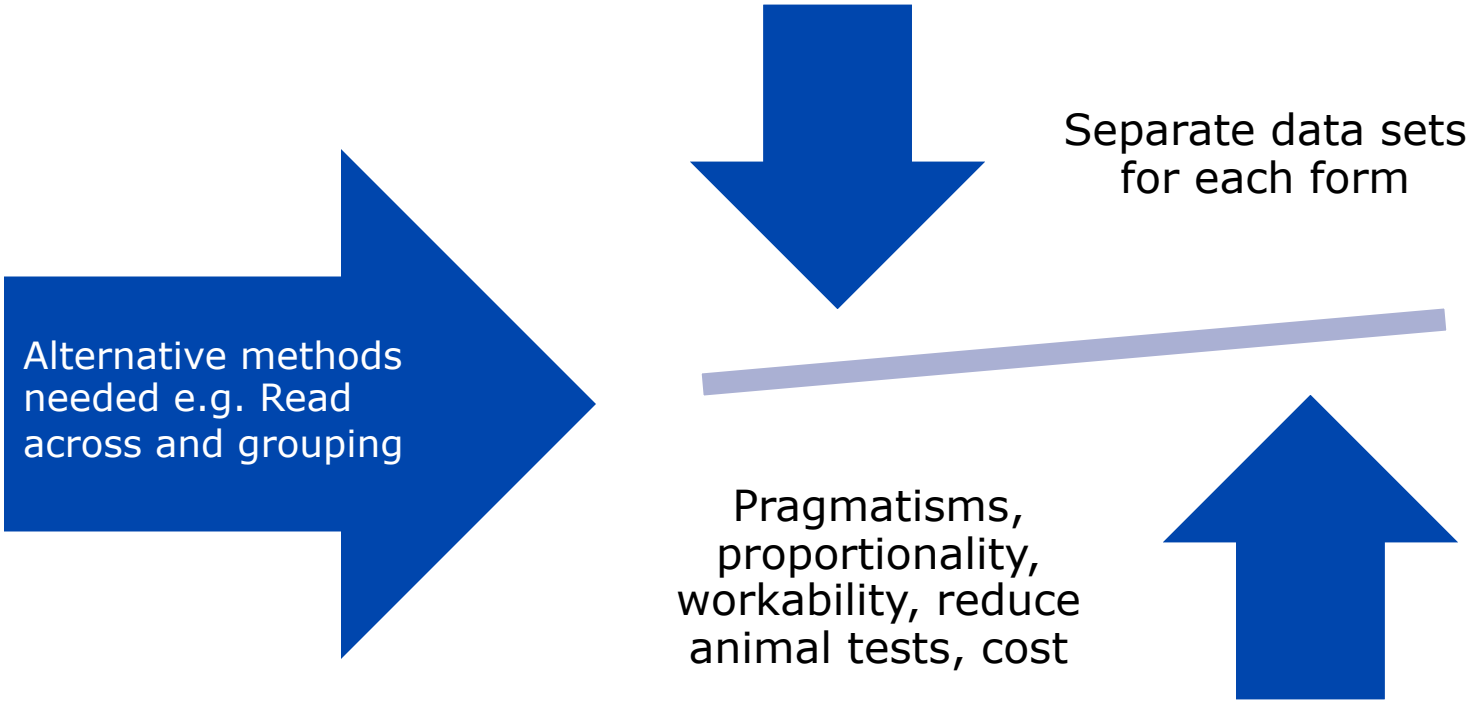
- Characterise the nanoforms or sets of similar nanoforms:
  - Size (number based PSD)
  - Shape, aspect ratio and other morphological characteristics
  - Surface functionalisation or treatment
  - Specific surface area

Nanoforms and REACH (upcoming framework) (ii)

- The registrant shall justify why the information provided, is adequate for assessing the nanoforms.
- More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties relevant for the hazard, exposure and risk assessment and management of nanoforms
- Methodologies set out in Annex XI.1.5 shall be used within a registration dossier when two or more forms of a substance are 'grouped' for the purposes the information requirements.

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

Numerous of potential nanoforms exist depending on modifications that may influence hazard properties such as e.g. surface treatments, shape and size



REACH information requirements
The starting point

- REACH **information requirements,** depend on the tonnage manufactured or imported substance per registrant
- Information requirements are **laid-down the annexes** of the REACH Regulation: Annex VII to Annex X
- The **default** way to meet these **information requirements** is to perform **standard tests**, according standardised guidelines and GLP
- REACH allows for and encourages the use of adaptation **as long as their results are on par with outcome from the use of standard methods**; it should not lead to an underestimation of hazard
- Important motivations: To reduce animal testing and costs

Grouping and read-across in the context of REACH

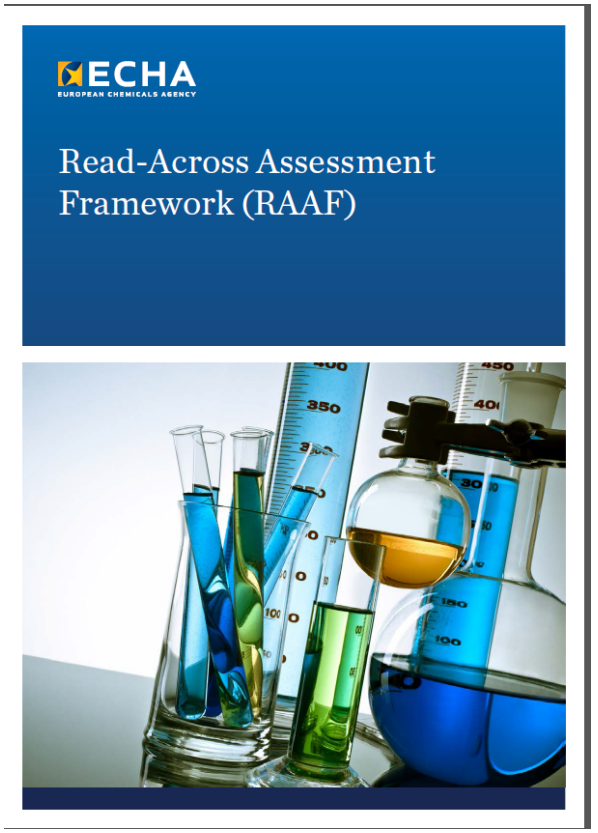
- Read-across and grouping is one of the adaptations of the 'standard testing regime' - 'rules' are laid down in Annex XI, 1.5 of the REACH Regulation
- The results of studies with one or more analogue substances are used to meet the information requirement of the registered substance by prediction, instead of measuring the property in a study using the registered substance
- Results from one or more substances (the 'sources') are used to 'read-across' to another substance (the 'target' or registered substance)
- Identify trends for a group of chemicals to clearly define boarders for an applicability domain of available hazard data

Legal basis: Annex XI, 1.5: Nanoforms (upcoming framework)

- When nanoforms are covered by the registration the approach shall address the nanoforms separately

- For grouping different nanoforms of the same substance the molecular structural similarities alone cannot serve as a justification

Guidance & Practical Guide



ECHA publishes **"Read Across Assessment Framework (RAAF)"** on its website ➔ how a grouping and read-across proposal can be justified. More guidance is foreseen in the short future relating to environmental aspects and complex substances.

Guidance for Nanoforms

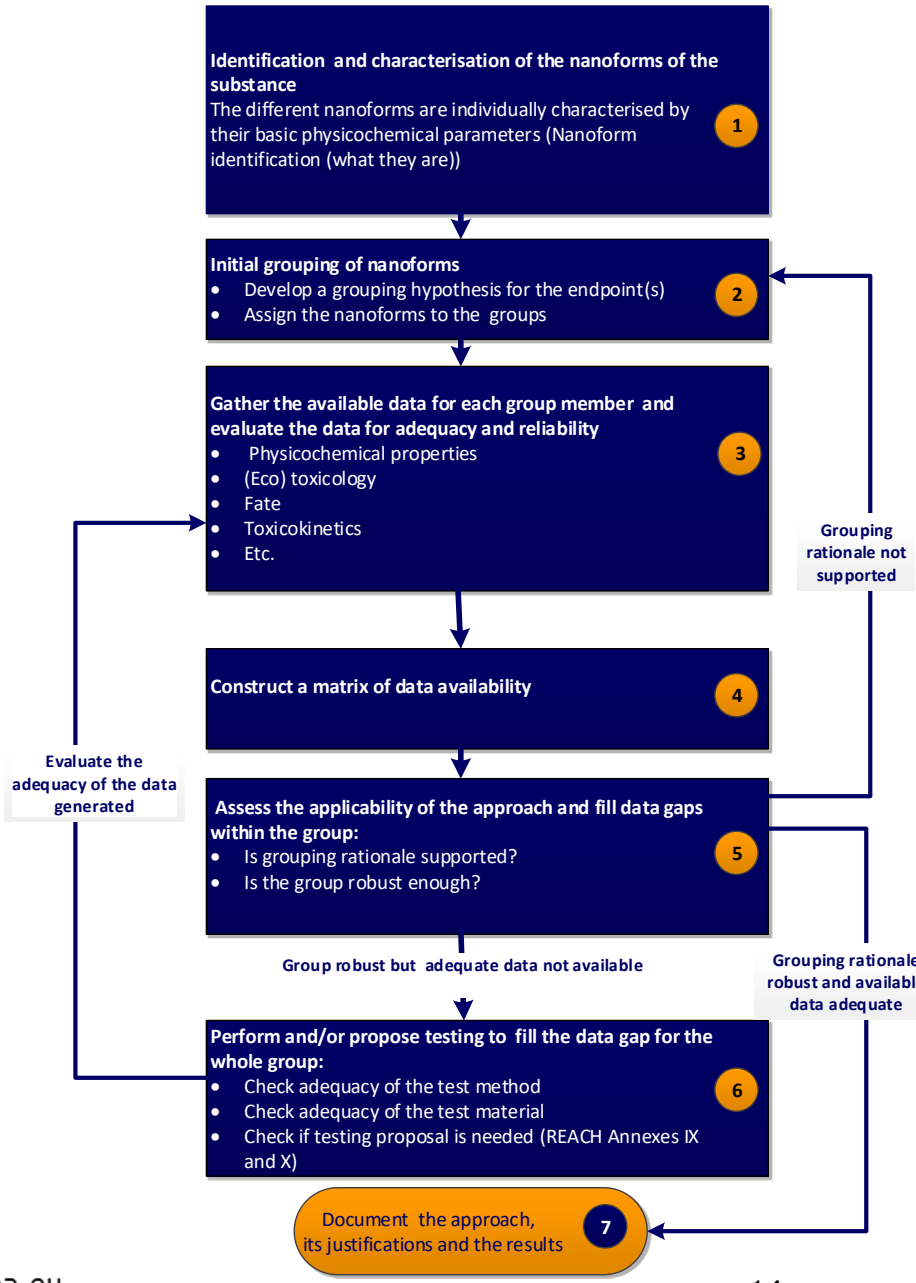
- Published in May 2017
- Considered still applicable in the upcoming regulatory framework - minor corrections needed: nanoforms characterization mandatory
- Starting point of the guidance was the: Report on usage of (eco)toxicological data for bridging data gaps between nanoforms of the same substance and grouping them (RIVM, JRC and ECHA)

Scope of the guidance

- Grouping and read-across between nano and non-nanoforms of the same substance
- Does not cover different substances directly. Information given may be useful when attempting to read-across between nanoforms of different substances
- No specific advice on QSARs for nanomaterials

Stepwise approach

- Alternative approaches possible
- Steps may overlap or order may vary
- Endpoint specific, but several endpoints can be addressed together if hypothesis supports it
- Follows principles of OECD No. 194: Guidance on grouping of chemicals



Conclusion

- Principles to be considered when doing grouping and read across are available in ECHA guidance
- Guidance remains general at the level of “principles” to allow flexibility
- Examples, case studies and more detailed methodology will be helpful to support the implementation of these principles by registrants

Questions?