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REACH 2018
webinars

Assess hazards and risks – How to do it?

20 July 2016

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Phase 4: Assess hazard and risk

Activities:

1. Understand your information requirements
2. Gather hazard data and fill data gaps
3. Agree classification and labelling in the SIEF
4. Gather information on uses
5. Assess risks and risk management measures

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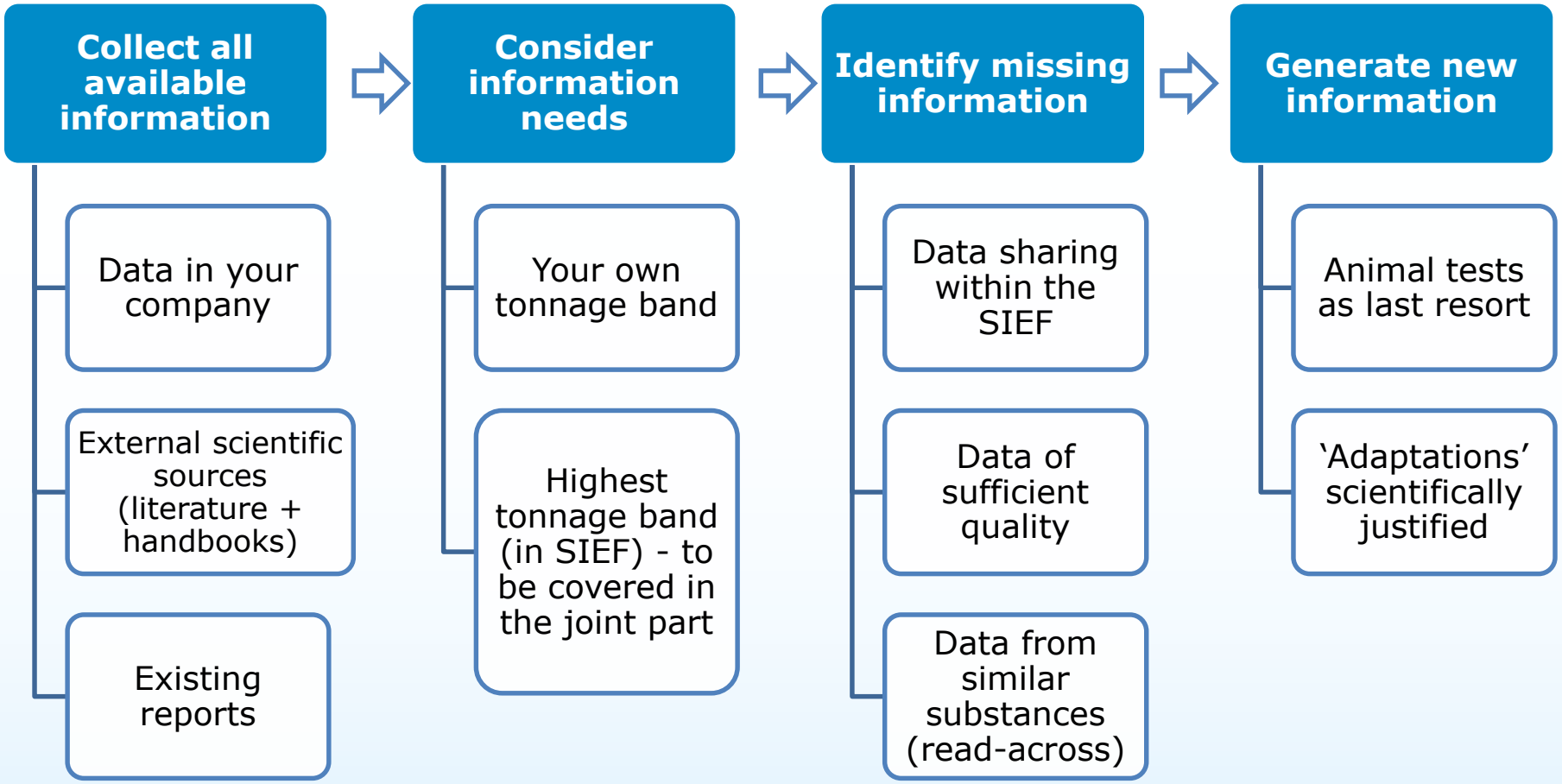
Gather hazard data and fill data gaps

Hazard information - overview



Animal testing as last resort

Avoid unnecessary animal testing by

- sharing data **and**
- using adaptations, based on general or specific rules

Justification to use an adaptation: crucial importance for acceptance

- E.g. explain in the dossier why the prediction obtained using a computer model is reliable for your substance

Adaptations under REACH

Specific rules

- Column 2 of Annexes VII-X
- Fulfil each criteria listed in column 2
- Example: No need for skin sensitisation test if the substance is corrosive to the skin (Cat. 1)

Gather hazard data and fill data gaps

Adaptations under REACH

General rules

- Testing not scientifically necessary
- Testing scientifically not possible
- Exposure-based adaptation (i.e. no exposure is demonstrated)

1. Use of existing data
2. Weight of evidence (WoE)
3. Qualitative or quantitative structure-activity relationship ((Q)SAR)
4. *In vitro* methods
5. Grouping of substances and read-across approach

Adaptations – WoE

What is it?

Weight of evidence is the use of several independent sources of information in combination

When can I use it?

- Useful when a single piece of evidence is not sufficient to fulfil the information requirement
- Useful when individual studies give conflicting results

Practical example:

Fulfil the requirement for a property by combining *in vitro*, read-across and (Q)SAR results – ensure you submit the justification and the evidence

Adaptations – (Q)SAR

What is it?

(Q)SAR - Qualitative or quantitative structure-activity relationship models are computational models that predict endpoints using chemical structures as input

When can I use it?

- Good results with simpler properties (e.g. physico-chemical properties)
- Less reliable for more complex properties (e.g. repeated dose toxicity)

Practical example:

Use a software to predict short term toxicity to fish – ensure you report the reliability of the model and of the prediction

Adaptations – *in vitro*

What is it?

In vitro tests (latin: in the glass) are experiments performed in a controlled environment, such as a test tube or Petri dish

When can I use it?

- Suitable *in vitro* methods can be used as adaptations
- For some properties, *in vitro* methods are now the standard information requirement (e.g skin/ eye irritation)

Practical example:

Neutral red uptake test: to give indications of mammalian acute toxicity, as part of weight of evidence considerations

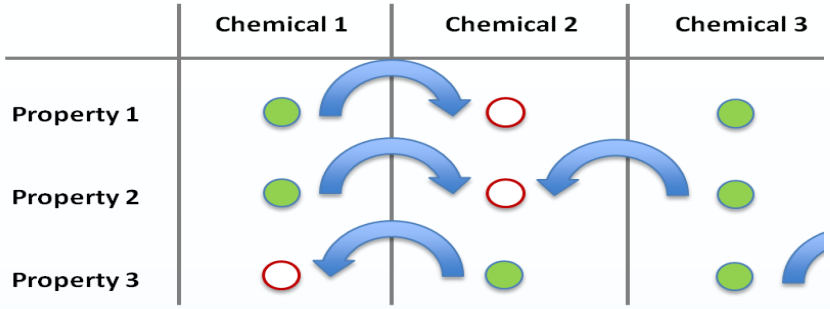
Adaptations – Grouping and read across

What is it?

Data from one or more substances ("source chemicals") are used to fill a data gap for a registered substance ("target chemical")

When can I use it?

Useful when you have good quality data from similar substances or other relevant substances



Practical example:

You do not have data for a specific endpoint for your substance, and you use good quality experimental data from a substance that is very similar to yours to fill the data gap

→ Ensure you **submit the justification**

Hazard information - tips

- Have a scientific expert to plan testing based on substance properties
  - Your substance is used in solutions + will break down rapidly in water

  → test the properties of breakdown products

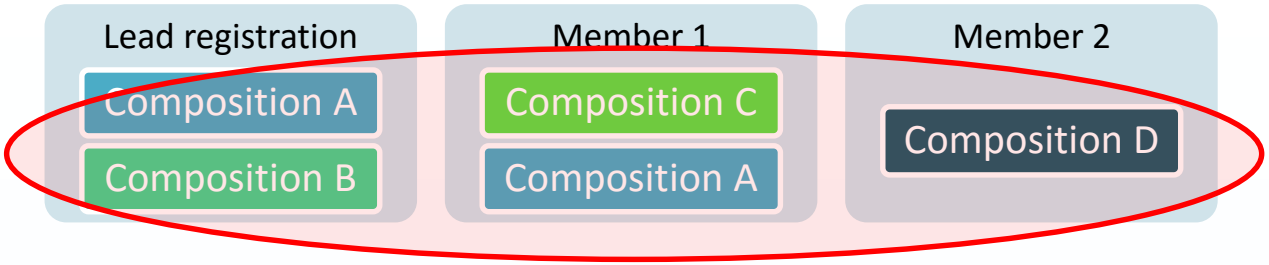
- Test relevant routes of exposure
  - Workers will be exposed to 'vapours' of your substance

    → test by inhalation route

Gather hazard data and fill data gaps

Hazard information - tips

- Hazard information has to cover all the compositions of the joint submission



- Use the **QSAR Toolbox** (free-of-charge software, co-developed by ECHA and OECD) to:
  - retrieve experimental data
  - find similar substance (analogues)
  - build categories of substances
  - predict properties using read across and QSARs

QSAR TOOLBOX

Classification and labelling

- If there is an harmonised classification for your substance, you must use it

- You may need to reconsider classification of your substance based on hazard information gathered for registration
  - Aim for agreement in the SIEF
  - Different impurity profiles may lead to a different classification

Gather information on uses

Uses and conditions of use

Collect information on how your substance is used in your supply chain

Sector use maps = first source for typical uses / conditions of use	Your company's internal data	Contact your customers

Prepare information for your registration

Cover only real uses relevant to your supply chain	In IUCLID 6, each use reported as separate record

Gather information on uses

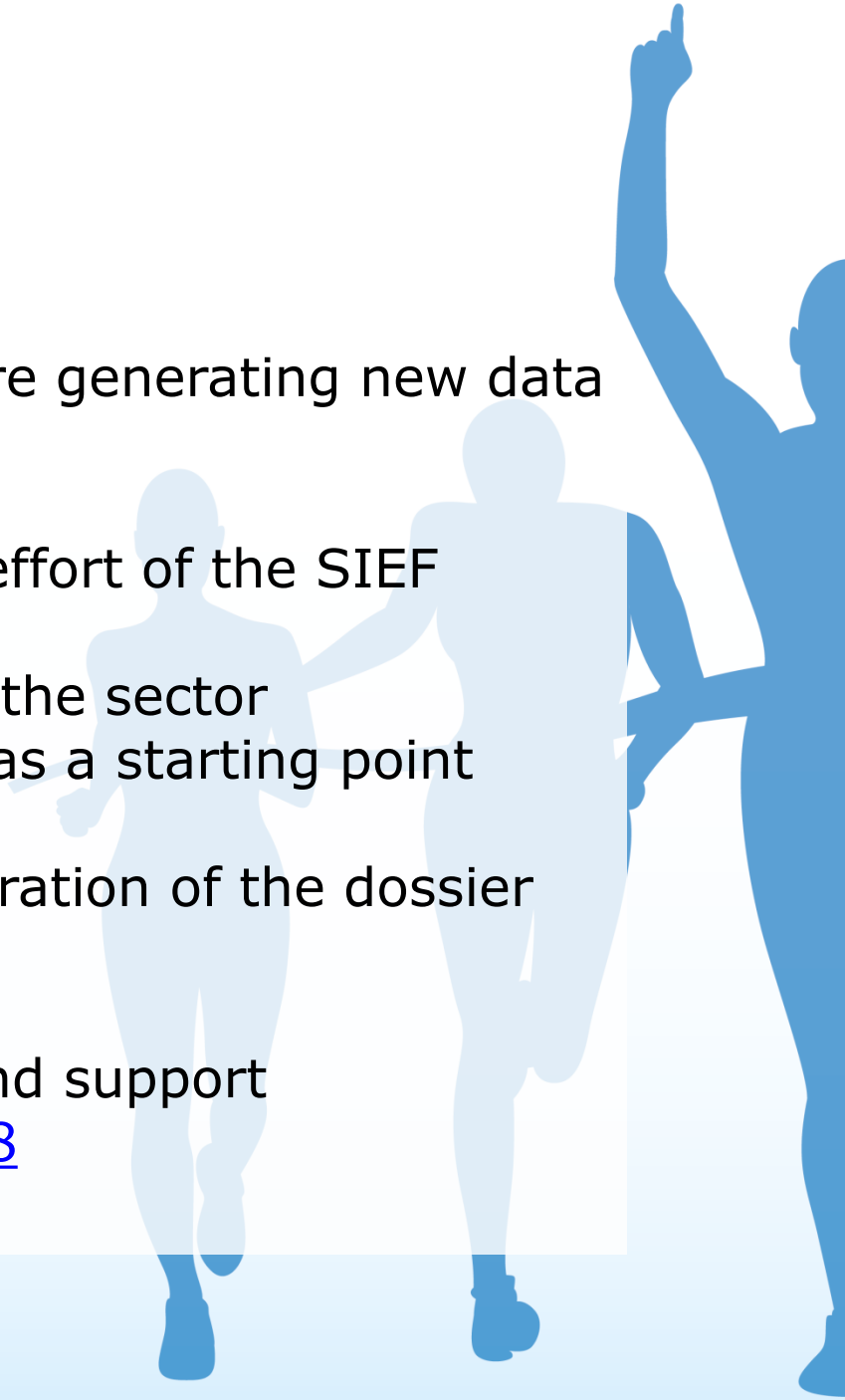
Chesar tool

- Functionalities
  - Carry out chemical safety assessments (CSA)
  - Prepare chemical safety reports (CSR)
  - Prepare exposure scenarios (ES) for registration and communication in the supply chain

- Benefits
  - Provided free of charge by ECHA
  - CSA according to standard workflow/ harmonised format
  - Data exchange with IUCLID: to ensure consistency and easier updates

Key messages

- ✓ Always consider alternatives before generating new data – various **adaptations** exist
- ✓ Generating information is a joint effort of the SIEF
- ✓ Collect information on uses, from the sector organisations of your customers, as a starting point
- ✓ Remember that testing and preparation of the dossier take time
- ✓ Take advantage of ECHA's tools and support http://echa.europa.eu/reach-2018



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