Missing data? How to get it

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  - 1-10 tonnes per year (REACH Annex VII)
    - Low risk substances
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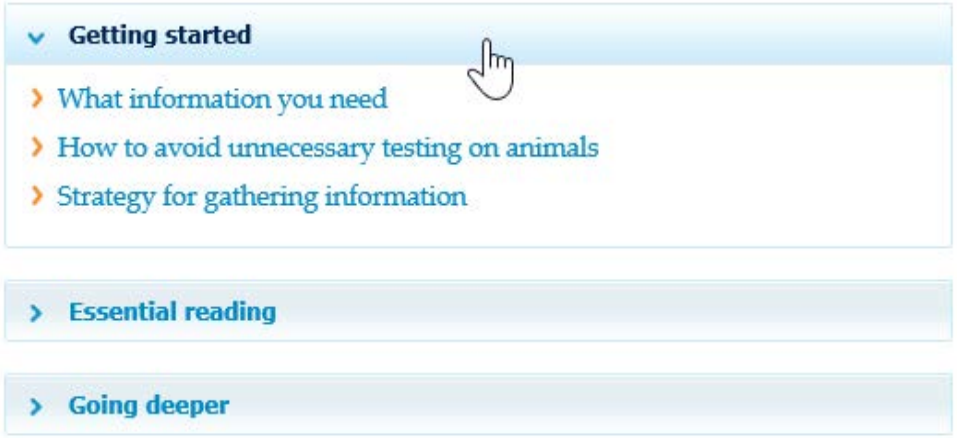
  - Animal testing as last resort
  - Regulatory alternatives
  - Cost and timelines

Support from ECHA

- ✓ Roadmap 2018: phase 4 support material



Tip Practical guide for SME managers and REACH coordinators: How to fulfil your information requirements

What data do I need?

- Depends on your type of registration
  - Intermediate, under strictly controlled conditions
    → all available data (independent of tonnage)
  - Standard registration → depends on your tonnage band

https://echa.europa.eu/support/registration/what-information-you-need

1-10 tonnes per year

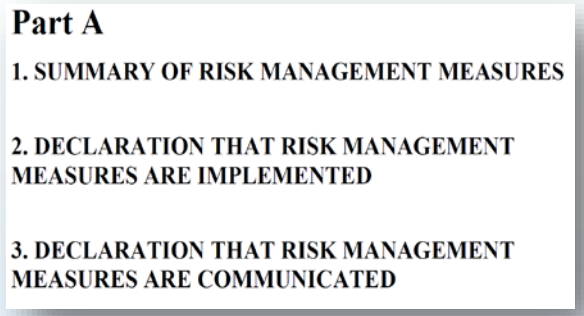
- ✓ Annex VII: physico-chemical, environmental and mammalian properties
- ✓ One test on an animal

Low risk substances

- If a **low risk** substance, reduced requirements = only physico-chemical properties
- Justification
- Criteria in Annex III
  - List of substances requiring a full data set

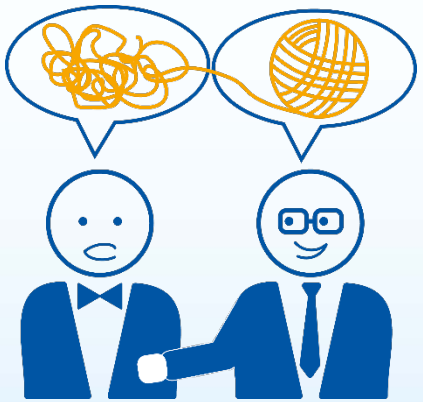
10-100 tonnes per year

- ✓ Annexes VII +VIII: physicochemical, environmental and mammalian properties
- ✓ Updated requirements
  - Irritation potential for skin and eye
  - Sensitising potential for skin
  - Accepted by ECHA
- ✓ Fewer tests on animals – only as last resort
  - If *in vitro* not allowing classification
  - If no acceptable alternative
  - Submit proposals for some tests
- ✓ Submit a chemical safety report



Tips

- ✓ Main tests should be there – your right to be on the market
- ✓ Good quality information – it will be reviewed by ECHA
  - Alternatives to be used – recommendations in ECHA's guide
  - Reduces future work and costs
  - Main aim is to use chemicals safely
- ✓ Support is here – ECHA and helpdesks



Overview

- What information do I need?
  - 1-10 tonnes per year (REACH Annex VII)
    - Low risk substances
  - 10-100 tonnes per year (REACH Annex VIII)

- How to fill in data gaps?
  - Strategy for testing
  - Animal testing as last resort
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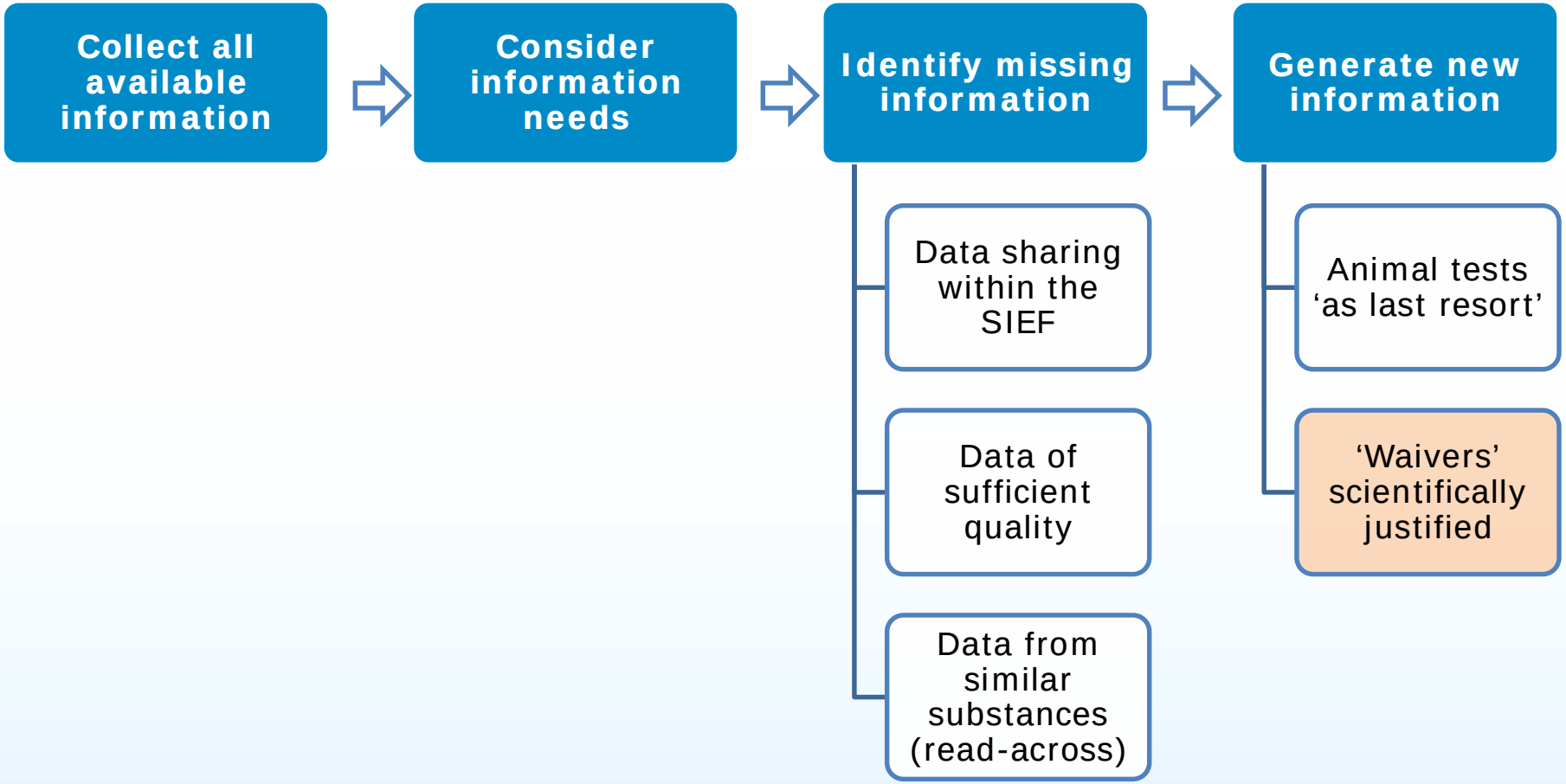
Best strategy forward



Avoid unnecessary animal testing

- Animal testing as last resort
  - Share existing and reliable data **and**
  - Use alternative information, i.e. “waivers”

- Ensure scientific and regulatory acceptance
  - Submit good and reliable information
  - Provide a robust justification for not running the test - crucial importance
    1. explain in the dossier why the prediction obtained using a computer model is reliable for your substance
    2. demonstrate that two existing studies cover the same criteria as what is required in a newly performed study

Tip

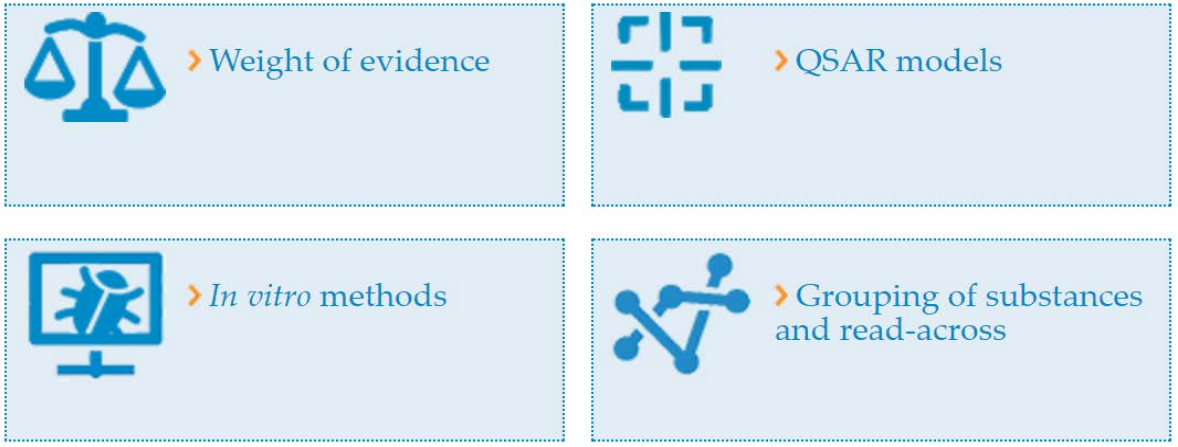
Practical guide: How to use alternatives to animal testing

Practical guide: How to use and report QSARs

Regulatory alternatives

- In Annexes, Column 2: Specific rules for each endpoint
  - ✓ Rely e.g. on substance's properties
  - ✓ When no need to perform a test if properly justified and meets all criteria e.g. C&L and/or risk assessment

- Annex XI – General rules
  - ✓ Rely on well-documented and science-based justification



+ other sections of Annex XI

Weight of evidence

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What is it?

= combination of several independent sources of information

When to use?

- ✓ If a single piece of evidence is not sufficient to fulfil the need
- ✓ If individual studies give conflicting results or are not of the highest quality

Example: Fulfil the requirement for a property by combining *in vitro*, read-across and (Q)SAR results

Tip Ensure you submit a justification and supporting data

(Q)SAR

QSAR TOOLBOX

REACH 2018

What is it?

= Computer models predicting property based on structures, qualitative or quantitative structure-activity relationship

When can I use it?

✓ For simpler properties (e.g. physico-chemical properties)

✗ For more complex properties (e.g. repeated dose toxicity)

Example: Use QSAR Toolbox to predict short term toxicity to fish

Tip

Always report the reliability and prediction of the model

Check our practical guide for SMEs to see which models are accepted

In vitro tests

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What is it?

= experiments performed in a controlled environment

When can I use it?

- ✓ If environment compatible with substance (e.g. solubility)
- ✓ If method is well described
- ✗ On its own

Example: For acute toxicity and as part of weight of evidence approach, neutral red uptake test can be used (see Guidance update)

Tip

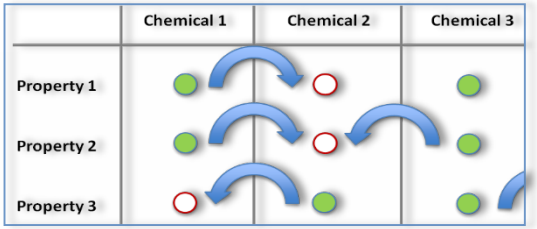
Always report correctly the information

Always justify the relevant classification

Grouping and read across

What is it?

= Predict a property of a substance (“target”) from data on one or more substances (“source”)



When can I use it?

- ✓ If data of good quality; if I can classify
- ✓ If “source” substances are similar/relevant to “target”
- × If data on source is not (yet) available

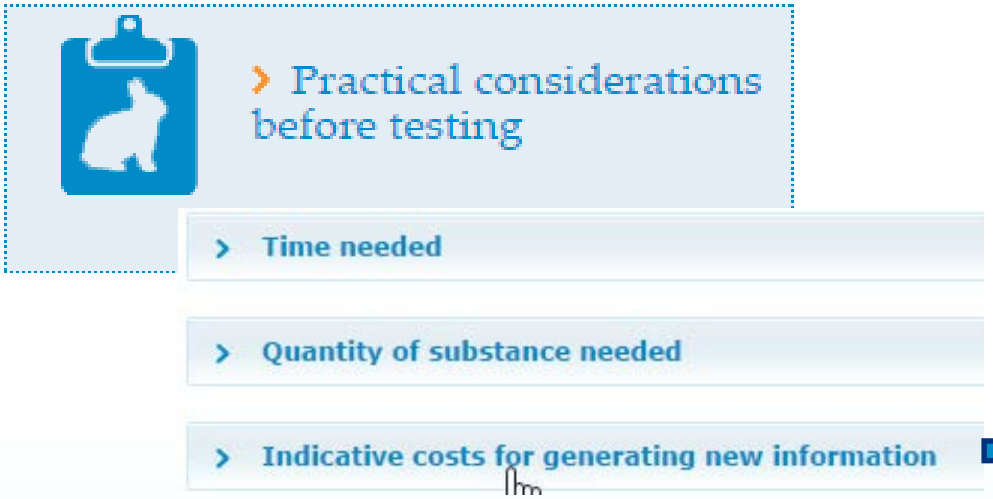
Tip

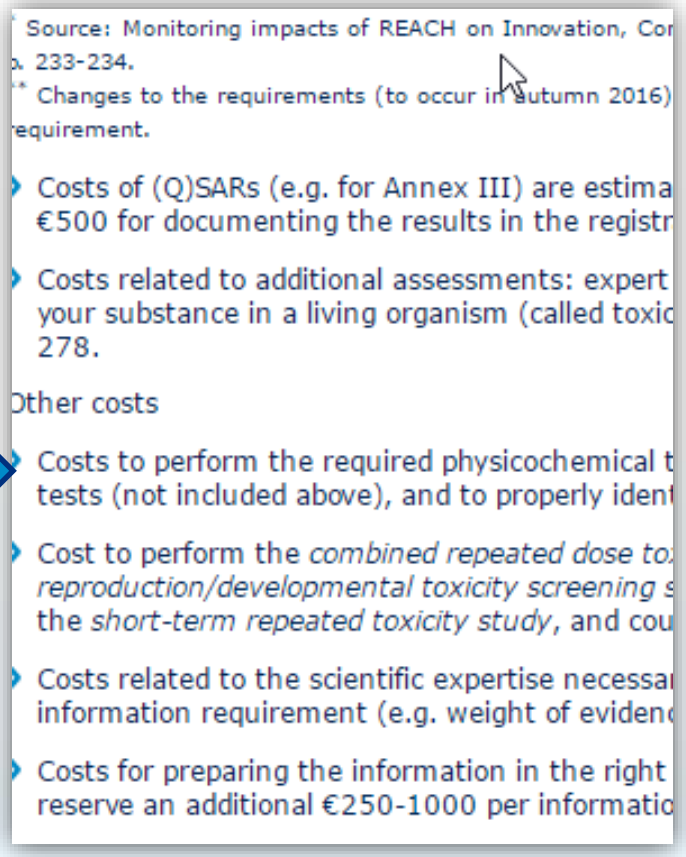
Always submit a scientifically well-documented justification

Always submit a data matrix and all supporting data

Costs and timelines

https://echa.europa.eu/support/registration/strategy-for-gathering-your-data





Tip

Often contracted out as package of tests – time and cost-efficient

Outcome of certain tests/waivers impact need to perform further tests

Take home…

- ✓ Have a clear strategy
- ✓ Animal testing as last resort: share data and consider waivers before testing
- ✓ Don’t hesitate to challenge your consultant: not all endpoints can be fulfilled with “easier” options
- ✓ Do a good job! It takes time and scientific input to fill in data gaps

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