

# Missing data? How to get it

**12<sup>th</sup> Stakeholders' day**  
5 April 2017, Helsinki

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  - 1-10 tonnes per year (REACH Annex VII)
    - Low risk substances
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- How to fill in data gaps?
  - Strategy for testing
  - Animal testing as last resort
  - Regulatory alternatives
  - Cost and timelines



# Support from ECHA

- ✓ Roadmap 2018: phase 4 support material

- ▼ **Getting started**
  - › What information you need
  - › How to avoid unnecessary testing on animals
  - › Strategy for gathering information
- › **Essential reading**
- › **Going deeper**

**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

**1**  
**10**

› Information requirements: 1 to 10 tonnes per year

**10**  
**100**

› Information requirements: 10 to 100 tonnes per year

<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**



## Part A

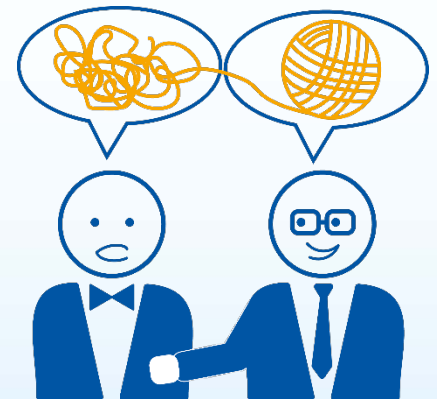
1. SUMMARY OF RISK MANAGEMENT MEASURES

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

## 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

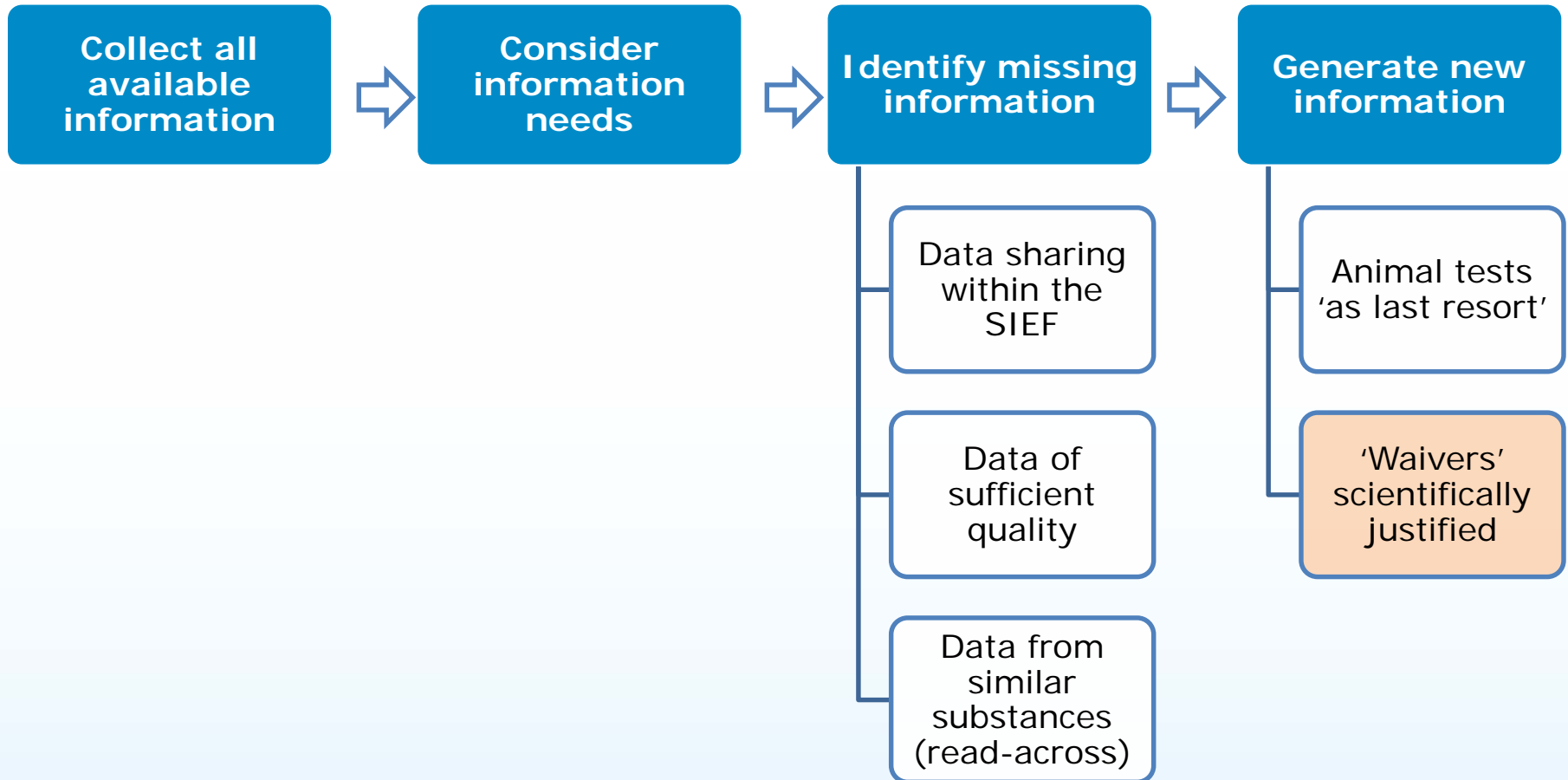


- What information do I need?
  - 1-10 tonnes per year (REACH Annex VII)
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# Best strategy forward



# 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

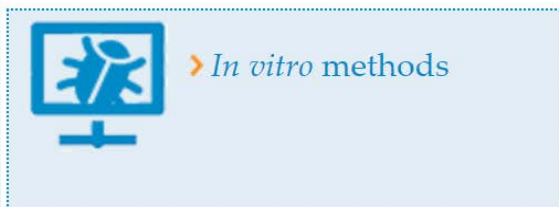
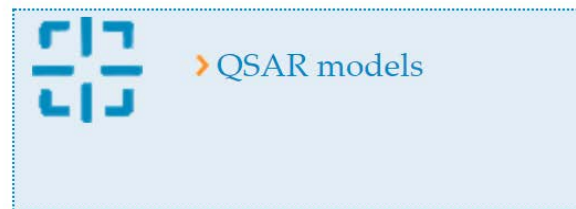
**Tip**

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



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# Weight of evidence

## 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

### 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

### 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

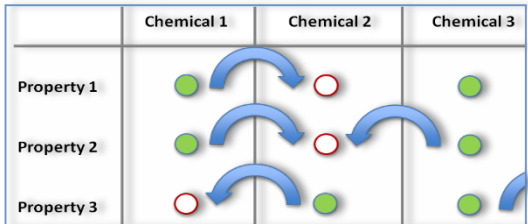
### What is it?

= **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

	Chemical 1	Chemical 2	Chemical 3
Property 1	●	○	●
Property 2	●	○	●
Property 3	○	●	●



### Tip

Always submit a scientifically well-documented justification

Always submit a data matrix and all supporting data



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# Costs and timelines

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



## > Practical considerations before testing

> Time needed

> Quantity of substance needed

> Indicative costs for generating new information

**Tip**

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

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

Source: Monitoring impacts of REACH on Innovation, Cor  
p. 233-234.

\* Changes to the requirements (to occur in Autumn 2016)  
requirement.

> Costs of (Q)SARs (e.g. for Annex III) are estima  
€500 for documenting the results in the registr

> Costs related to additional assessments: expert  
your substance in a living organism (called toxic  
278.

Other costs

> Costs to perform the required physicochemical t  
tests (not included above), and to properly ident

> Cost to perform the *combined repeated dose to  
reproduction/developmental toxicity screening s  
the short-term repeated toxicity study, and cou*

> Costs related to the scientific expertise necessar  
information requirement (e.g. weight of evidenc

> Costs for preparing the information in the right  
reserve an additional €250-1000 per informatio



## 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



# Thank you

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