

# Registration requirement under REACH - Feedback from evaluation

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## Overview

- Identify the information requirements
- Meet the information requirements
- Testing proposals
- Adaptations



# Identify the information requirements



# Identify information requirements

- Annex VI
  - Substance identity!
- Depending on tonnage, requirements in Annexes VII-X

Note exceptions, *e.g.*:

  - On-site isolated intermediates - Articles 17 + 49
  - Transported isolated intermediates - Article 18
  - Prior registration under NONS - Article 24

## Identify information requirements (2)

- Carefully consider Annex column 1 and 2 requirements
  - *e.g.* Annex IX, 9.2.1 - biotic degradation
    - The column 1 requirement is dependent upon whether the substance is readily biodegradable (column 2). Carefully document the rationale.
- Note interactions between Annexes
  - An adaptation may be available, depending on the results from other studies.
  - *e.g.* Annex VIII, 8.6.1. According to column 2, the 28-day study does not need to be performed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

# Meet the information requirements



## Step 1: Gather existing information

- Collect all relevant available information on the substance:
  - physical-chemical properties,
  - environmental toxicity and fate,
  - mammalian toxicity,
  - consider alternative information sources: *in vitro*, QSARs, read-across, etc.
- Manufacture and use
- Risk management measures
- Exposure
- Harmonised Classification and Labelling
- Available information from assessments carried out under other international and national programmes

## Step 1: Gather existing information (2)

- Evaluate the quality of data:
  - Is the data adequate for classification and labeling (C&L)?
  - ... for persistent, bioaccumulative and toxic (PBT) assessment?
  - ... for very persistent and very bioaccumulative (vPvB) assessment?
  - ... for risk assessment?
  - Is the data reliable?
  - Is the data relevant?

## Step 2: Information requirements

- Comply with Annex VI requirements, including substance identity
- Comply with tonnage band requirements (Annexes VII-X)
- Provide all available and relevant data irrespective of tonnage
- Consider potential options for adaptation found in:
  - Column 2 of Annexes VII-X
  - Annex XI

## Step 3: Identify information gaps

- If available information is insufficient:
  1. Check if data holders within SIEF have the relevant data
  2. (optional) Check if data holders in other SIEFs (i.e. for other substances) have the relevant data
  3. Apply risk management measures
- If sufficient information cannot be found, go to step 4.

## Step 4: Generate new information

- New data may be generated by alternative methodologies:
  - (Q)SARs
  - *in vitro* tests
  - weight of evidence, and
  - grouping approach
- Animal tests should be done as a last resort
- If adequate information is not available, then the test must be performed:
  - Generate new information (Annexes VII and VIII), or
  - Submit a testing proposal (Annexes IX and X)

# Testing proposals



## Testing proposals

- Required for Annex IX and X tests
- Must be flagged in IUCLID (and not just in Chemical Safety Report)
- IUCLID - flag as testing proposal
  - “study result type”>> menu>> “experimental study planned”
- Do not undertake testing while the TP is being evaluated

## Testing proposals (2)

- Substance identity must be clearly addressed
- Clearly identify test and provide all necessary information
  - e.g. a pre-natal developmental toxicity test (OECD 414), in the rat by the oral route
- Explain, and if necessary, justify
  - Why the test is necessary
    - e.g. it is an Annex IX requirement that must be fulfilled
    - concern for inhalation exposure in workers, hence do an inhalation study
  - Choice of test parameters
    - e.g. choice of test, choice of route of exposure, species etc.

# Adaptations



## Adaptation of standard info requirements

- Specific criteria in column 2 of Annexes VII-X
- General criteria for adaptation in Annex XI:
  1. Testing not scientifically necessary
  2. Testing not technically possible: e.g. for volatile, reactive, unstable, explosive substances
  3. Substance-tailored exposure-driven testing
- Necessary to directly address the legal requirements and to explain and justify

## Adaptation - Annex XI, 1

- XI, 1.1 Use of existing data
    - e.g. non-GLP data, historical human data
  - XI, 1.2 Weight of evidence
  - XI, 1.3 (Q)SARs
  - XI, 1.4 *In vitro* methods
  - XI, 1.5 Grouping/read-across
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- Necessary to provide “adequate and reliable documentation” to justify use of adaptation
    - Note the relevant guidance documents and practical guides
    - Practical guide on avoiding unnecessary testing:
      - [http://echa.europa.eu/documents/10162/17250/pg\\_avoid\\_animal\\_testing\\_en.pdf](http://echa.europa.eu/documents/10162/17250/pg_avoid_animal_testing_en.pdf)

## An example: Annex XI, 1.5; grouping and read-across

- Note requirements of legal text, especially for “adequate and reliable documentation”
- Standard for documentation is set out in the guidance
  - [http://echa.europa.eu/documents/10162/17224/information\\_requirements\\_r6\\_en.pdf](http://echa.europa.eu/documents/10162/17224/information_requirements_r6_en.pdf)
- Need to explain (provide a hypothesis) why, for a given endpoint the properties of the registered substance “may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).”
  - Chemical similarity is not necessarily sufficient to justify a read-across
  - Practical guide on read-across:  
[http://echa.europa.eu/documents/10162/17250/pg\\_report\\_readacross\\_en.pdf](http://echa.europa.eu/documents/10162/17250/pg_report_readacross_en.pdf)

## **Annex XI, 3; Exposure-based adaptation**

- Only for endpoints in Annexes IX-X and
  - section 8.6 (repeated dose toxicity) and
  - Section 8.7 (reproductive toxicity) in Annex VIII
- Needs exposure scenario(s) developed in the Chemical Safety Report
- Documentation that the specific criteria are met

## Links

- Webinar material
  - <http://echa.europa.eu/en/web/guest/support/training-material/webinars>
- Guidance
  - <http://echa.europa.eu/en/web/guest/support/guidance-on-reach-and-clp-implementation>
  - Guidance in a nutshell
    - <http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell>
  - Practical guides available from:
    - <http://echa.europa.eu/web/guest/support/information-toolkit>
    - <http://echa.europa.eu/web/guest/regulations/reach/evaluation>
- Evaluation Progress Reports
  - <http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports>

**Thank you**

**<http://echa.europa.eu/>**

