# REACH registration 2018

## Phase 3 activities

1. Agree on how to work together

2. Select the lead registrant

3. Gather the data

4. Share the costs

5. Prepare for newcomers

# SIEF

## Substance information exchange forum

- Cooperation of companies for joint registration of the same substance:
  - Increase knowledge on your substance
  - Reduce costs of registration for everyone
  - Avoid duplication of animal tests

- Joint registration is mandatory

- Share data on the substance and costs

- Pre-registration > pre-SIEF > SIEF

# Agree on how to work together

- Communication in the SIEF
  - Principle: all pre-registrants must be able to follow the SIEF discussions and progress
  - Use the facilitator's message field in pre-SIEF

- Cooperation
  - model SIEF agreements available from industry associations (optional)

# Agree on how to work together

- Responsibilities and tasks
  - sharing the work
  - hiring a consultant (checklist)?
  - forming a consortium?

- Financial aspects
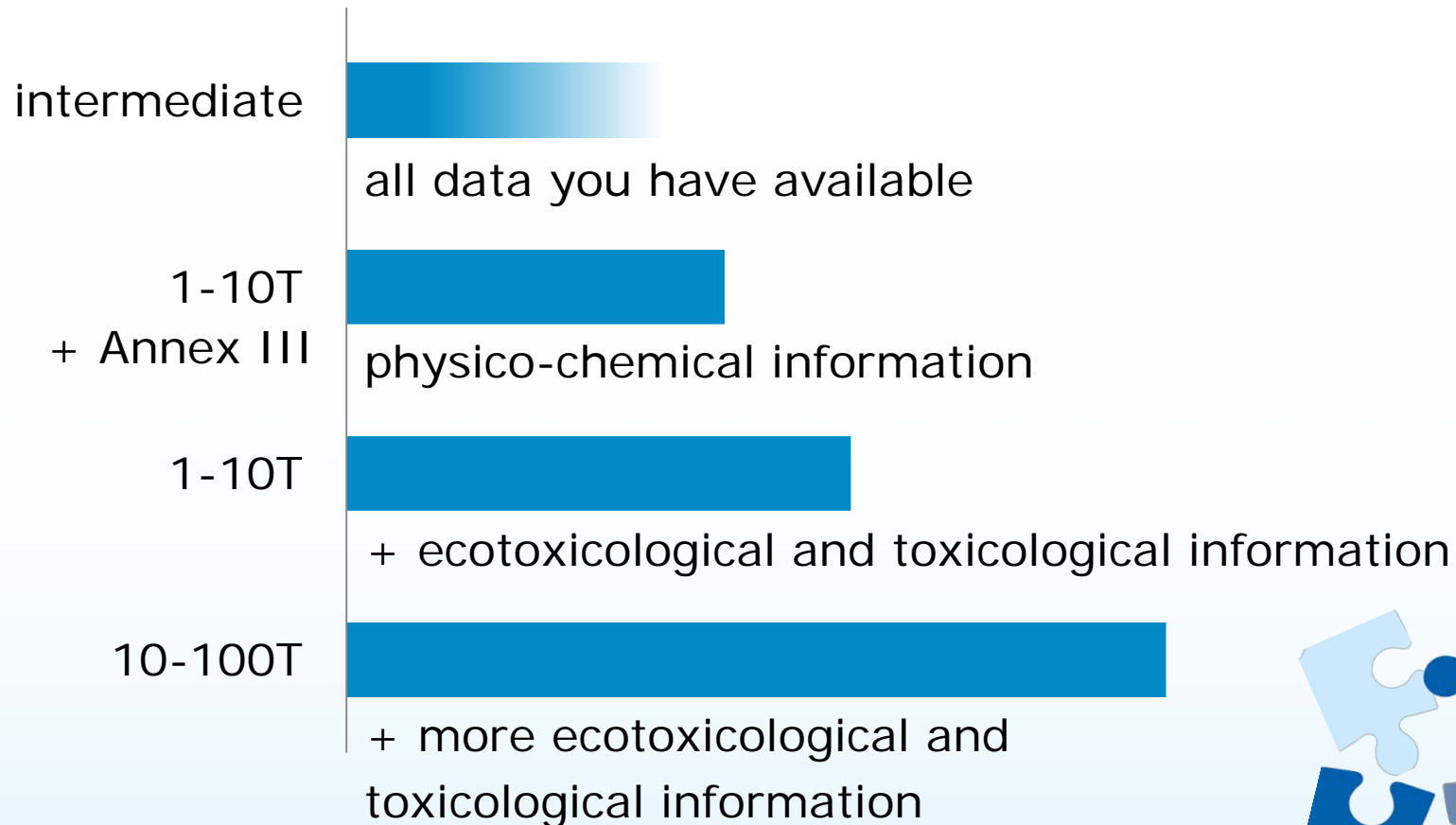  - invoicing and payment for work done

# Select the lead registrant

- All registrants are responsible for the progress in the SIEF and the content of the registration

- Lead registrant:
  - has a few specific tasks in REACH-IT related to managing the joint submission and submitting the joint part of the registration first
  - will act with the agreement of the co-registrants

- When to select the lead:
  - as early as possible; at the latest at the time of submission
  - do not let these discussions get in the way of the SIEF work

# Gather data

- Know what data you need

| | |
|---|---|
| intermediate | all data you have available |
| 1-10T + Annex III | physico-chemical information |
| 1-10T | + ecotoxicological and toxicological information |
| 10-100T | + more ecotoxicological and toxicological information |

# Gather data

- Know what data you need

- Make an inventory of the data you have in the SIEF
  - data on the substance
    - from own studies
    - from the literature
  - data on similar substances (for read-across)
  - data that can be waived (e.g. study not scientifically justified)
  - including the data ownership and copyright aspects

- Evaluate the data
  - relevance/reliability/adequacy

# Gather data

- Identify data gaps
  - is there information you need that you don't have?

- Fill in data gaps
  - buy from an owner outside the SIEF
  - generate new data
    - consider alternative methods (read-across, QSAR, ...)
    - new tests on vertebrates only as a last resort
  - including the data ownership and copyright aspects

- Consider preparing the CSR and guidance on safe use jointly

# Share costs

- Itemise, justify and set a price for
  - each of the data items
  - all other costs related to the joint registration

- Establish a cost-sharing model

- Cost-sharing principles:
  - all costs need to be shared in a fair, transparent and non-discriminatory way
  - registrants only need to pay for the data they need for their registration
  - under specified conditions, a registrant may submit certain data separately if justified

- Document in a data-sharing agreement

# Prepare for newcomers

- Cost-sharing model must be fair, transparent and non-discriminatory towards potential registrants

- Decide who will take care of questions by newcomers

- Include a reimbursement mechanism in your cost-sharing model

# Data sharing dispute

- If you and your co-registrants cannot reach an agreement on data sharing:
  - make sure you can demonstrate that you have made all efforts in the negotiations (asking and replying)
  - file a data-sharing dispute with ECHA as a last resort
  - will still need to submit in a joint registration

# Take away messages

- Many new SIEFs will need to be formed for 2018

- Get active in your SIEF (or pre-SIEF)
  - share the information you have on your substance
  - preparing for registration and in particular generating new information takes time

- Be fair, transparent and non-discriminatory in
  - your communication with your co-registrants
  - sharing the work
  - setting prices for data and work done

- Support material is available
  http://echa.europa.eu/support/registration/working-together/practical-advice-for-new-siefs

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