ECHA
EUROPEAN CHEMICALS AGENCY

# Taking action to ensure compliance

## Safer chemicals – ECHA conference

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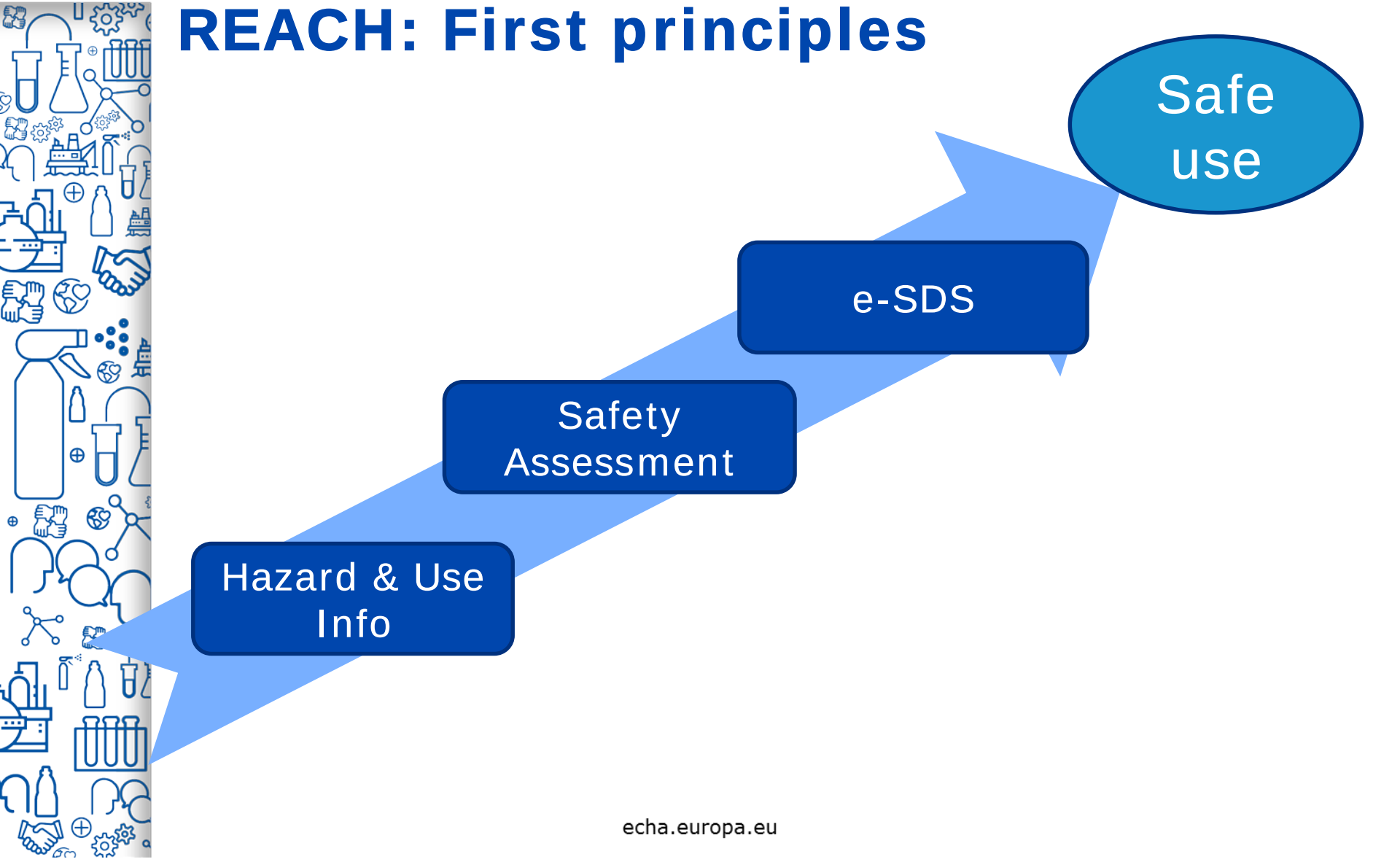
#SAFERCHEMICALS

# REACH: First principles



# More than 10 years of evaluation – what we achieved so far?

- ✓ More than **2700** dossiers checked for compliance (to various degrees)
  - Non-compliance in one or more endpoints identified in more than two thirds of the dossiers checked
- ✓ About **25 %** of substances registered above 1 000 tonnes checked
- ✓ Improved knowledge on chemicals
  - Generation of information to clarify CMR and PBT properties for more than **1 000** substances
- ✓ Support to other processes
  - **96** substances flagged for harmonised classification and 3 for substance evaluation after data generation
- ✓ Improving safe use
  - Substance no longer produced after generating information which led to Carc 1B classification

https://echa.europa.eu/overall-progress-in-evaluation

# Main reasons for non-compliance

- Waiving of data requirements not correctly justified
- Adaptations (read-across, QSAR, WoE) failing due to incorrect justification or lack of documentation – leading to data gaps for higher tier information requirements
- Documentation insufficient - e.g. insuficient level of detail in robust study summaries to allow for an independent assessment

# Feedback on compliance

- Annual evaluation reports (2010-2018) - advice on how to improve compliance
- Evaluation decisions available on ECHA website
- Workshops, MSC meetings
- Reports on the use of animal tests

# Increase impact and transparency

- ✓ Address substances in **groups**
  - Coordinate with on-going processes on analogue substances
- ✓ **Expand** dossier evaluation to the whole joint submission
  - As of 2019, dossier evaluation decisions sent to all co-registrants that are not compliant with their respective information requirements, incl. opt-out members
- ✓ Dossier evaluation **progress visible** on ECHA's website
  - Progress tracked from draft to final decision
  - Tool for registrants… but also to the public at large

# ECHA-Commission joint action plan

# Why an action plan?

- Despite efforts, still major compliance and quality issues with registration dossiers
- REACH review by Commission (2017)
  - “REACH is effective but not efficient”
  - “Significantly improve evaluation procedures…”
- Study by German Federal Institute for Risk Assessment:
  - Data gaps and inappropriate waiving/adaptations identified
  - ≥1000 tpa: 12-61% of the examined endpoints “non-compliant”
- Media and stakeholder attention

# REACH compliance – a priority

- Direct impact on ensuring that REACH delivers its objectives
- Commitment to take action: joint ECHA-Commission action plan
  - To be finalised by June
  - Will propose concrete actions to improve compliance

# Objectives

- ✓ Address all substances
- ✓ Improve clarity of legal provisions
- ✓ Accelerate decision making
- ✓ Improve follow-up and enforcement of evaluation decisions

# Address all substances

- 16 500 substances registered in full in 66 000 dossiers as of end 2018

## IT screening → Grouping → Regulatory pools

  - Put all substances above 100 tonnes in regulatory pools by end of 2020
  - Develop a plan to enable similar conclusions for lower tonnage bands

- Preliminary timelines as market is dynamic
  - New registered substances, tonnage down(up)grades, cease of manufacture

# Regulatory pools

**priority for regulatory risk management**

- in the process of being regulated
- pending action

**low priority**

- already regulated
- concluded as low priority in the assessment

**priority for data generation**

- Need more data for a judgement to be made on the need for risk management or low priority

  Candidates for compliance check and substance evaluation

# New compliance check targets

- Currently 5 % of dossiers per tonnage band – REACH Article 41(5)
- **Proposed new target: 20 % of dossiers**
  - corresponding to ~30 % of substances
    - ~ 35-40 % - above 100 tonnes
    - ~ 20 % - below 100 tonnes
- Commission Regulation to modify the target

# Other actions to improve compliance

- Improve clarity of **legal text**
  - Revise information requirements and adaptations; no new requirements added
- Accelerate the **decision making** process
  - Simplify compliance check decisions
  - Resolve different views among Member States to reduce the number of proposals for amendments
  - Better integrate substance evaluation and compliance check
- Improve **enforcement**
  - Harmonisation

# Last, but not least

- **Industry takes on the compliance challenge**
  - Companies with large portfolio to consider programmes for addressing multiple substances
  - Optimise testing strategies
  - Refine information on use and exposure

  - Working arrangements between ECHA and big industry associations
    - To facilitate action plans by industry for addressing compliance

# What to expect from now on?

# Increasing the number of compliance checks

- Chances to receive a CCH decision increase
  - As all substances will be addressed
  - …and two thirds are non-compliant
- How to get prepared?
  - Consider regular updates, remove information which is no longer relevant
  - Update is a legal obligation – this is the law but also the proof for safe use of chemicals
  - Implementing Act on dossier updates – to stimulate updates

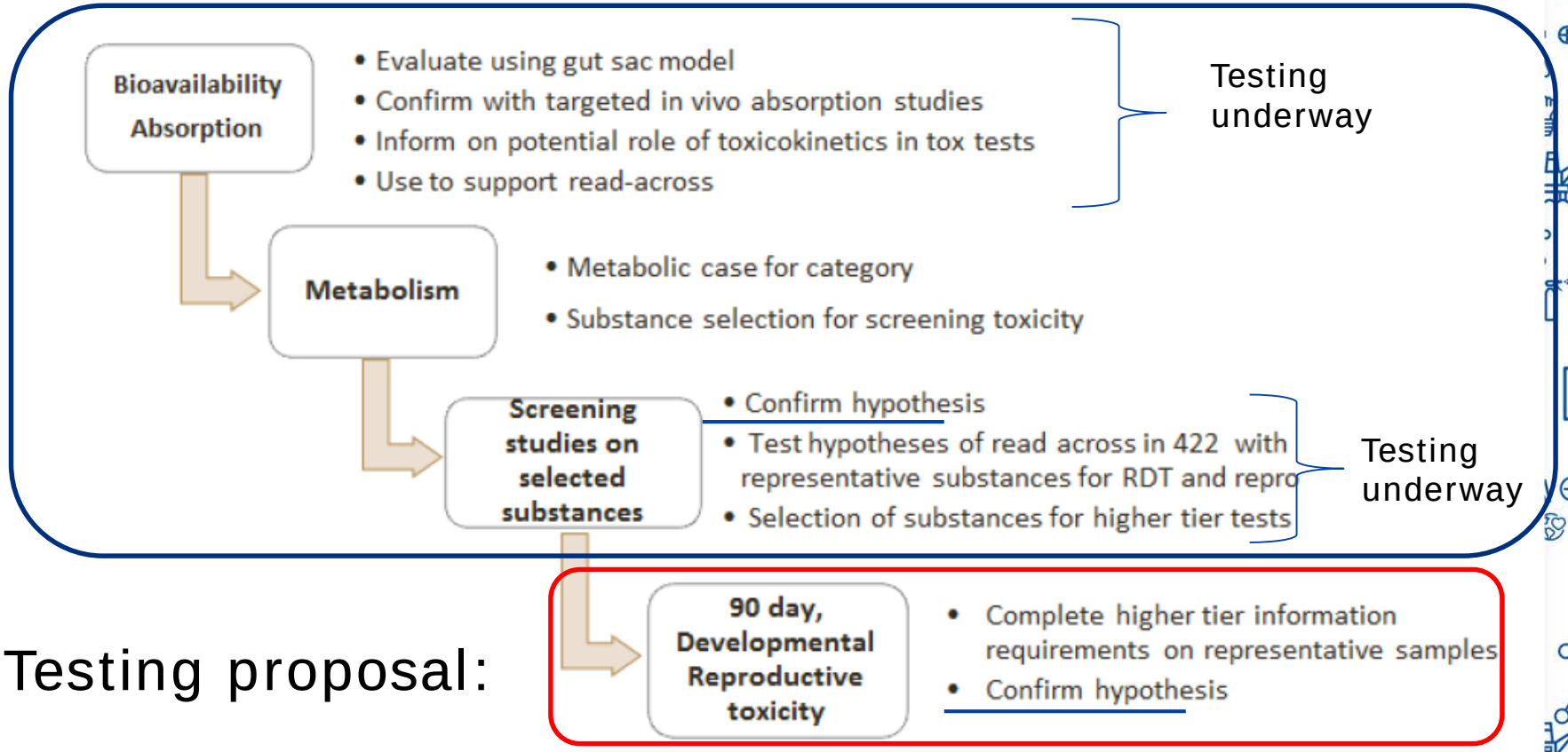
# Be pro-active

- Most likely, you will need to generate further information
- Consider submitting testing proposals
  - Especially when using read-across/category approaches

# Compliance checks vs testing proposals

- **If category / read-across fails, ECHA will reject the category and request data for each substance**
  - Less possibility to refine/incorporate strategy during process
- Testing proposals
  - Can incorporate a strategy
    - Sequence of tests for a substance, and within a category
    - Some tests could be initiated immediately (e.g. toxicokinetics)
  - You will save money and perform less animal tests
  - Need to be realistic with regard to how compliance could be achieved within reasonable timelines

# Real example – registrant's testing plan to build read across




Testing proposal:

# In summary

- A lot has been achieved… still many challenges ahead for all players
- Being compliant with REACH is not only an obligation but also an act of social responsibility to use chemicals safely
- To instil confidence of citizens, we all (ECHA, MSCAs, registrants) need to play our role properly

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# Thank you!

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