The results of REACH

REACH, the impacts along the supply chain

13 November 2019, Milano

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European Chemicals Agency

Content

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- ECHA – Commission joint action plan on evaluation
- What to expect from now on
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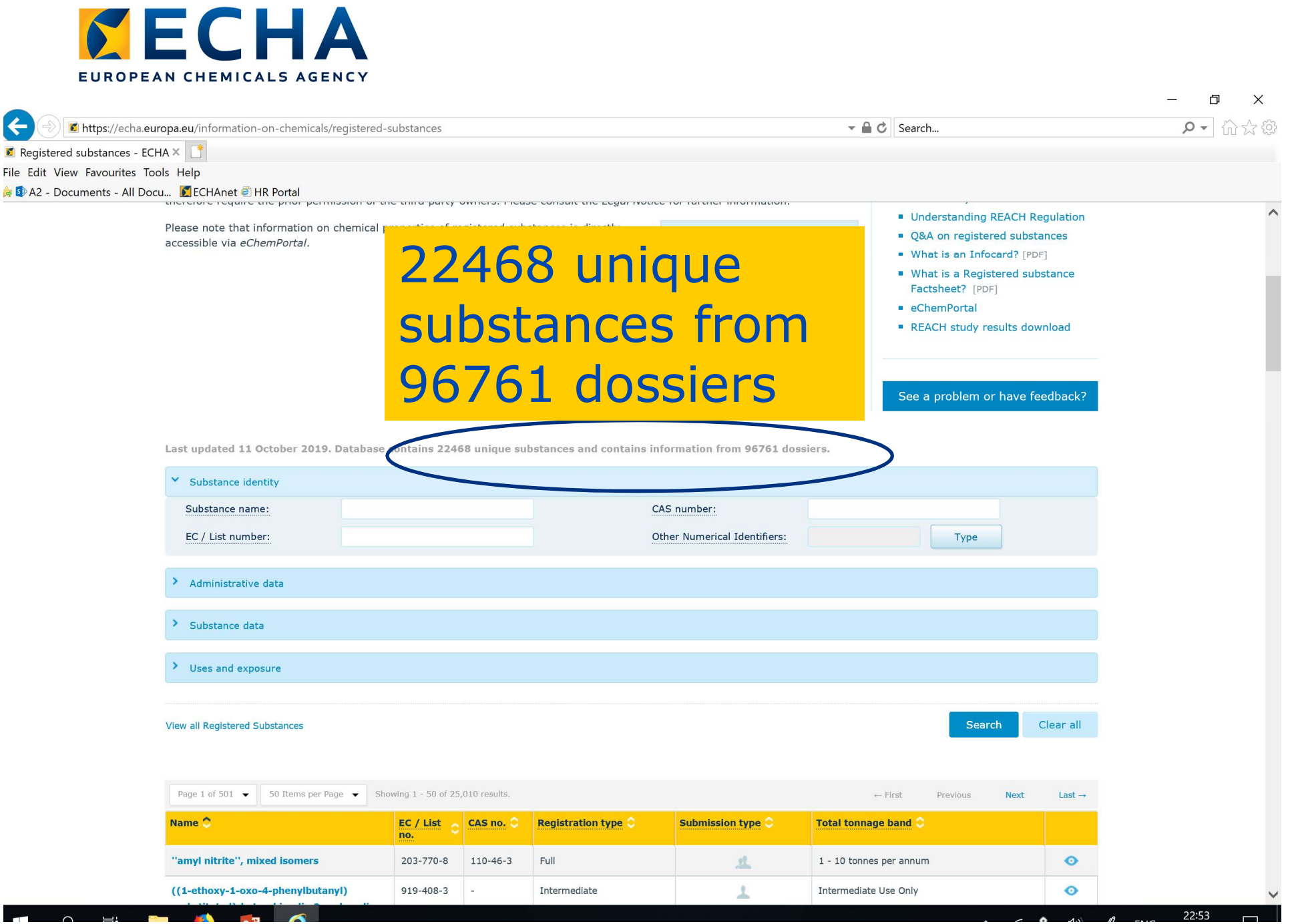
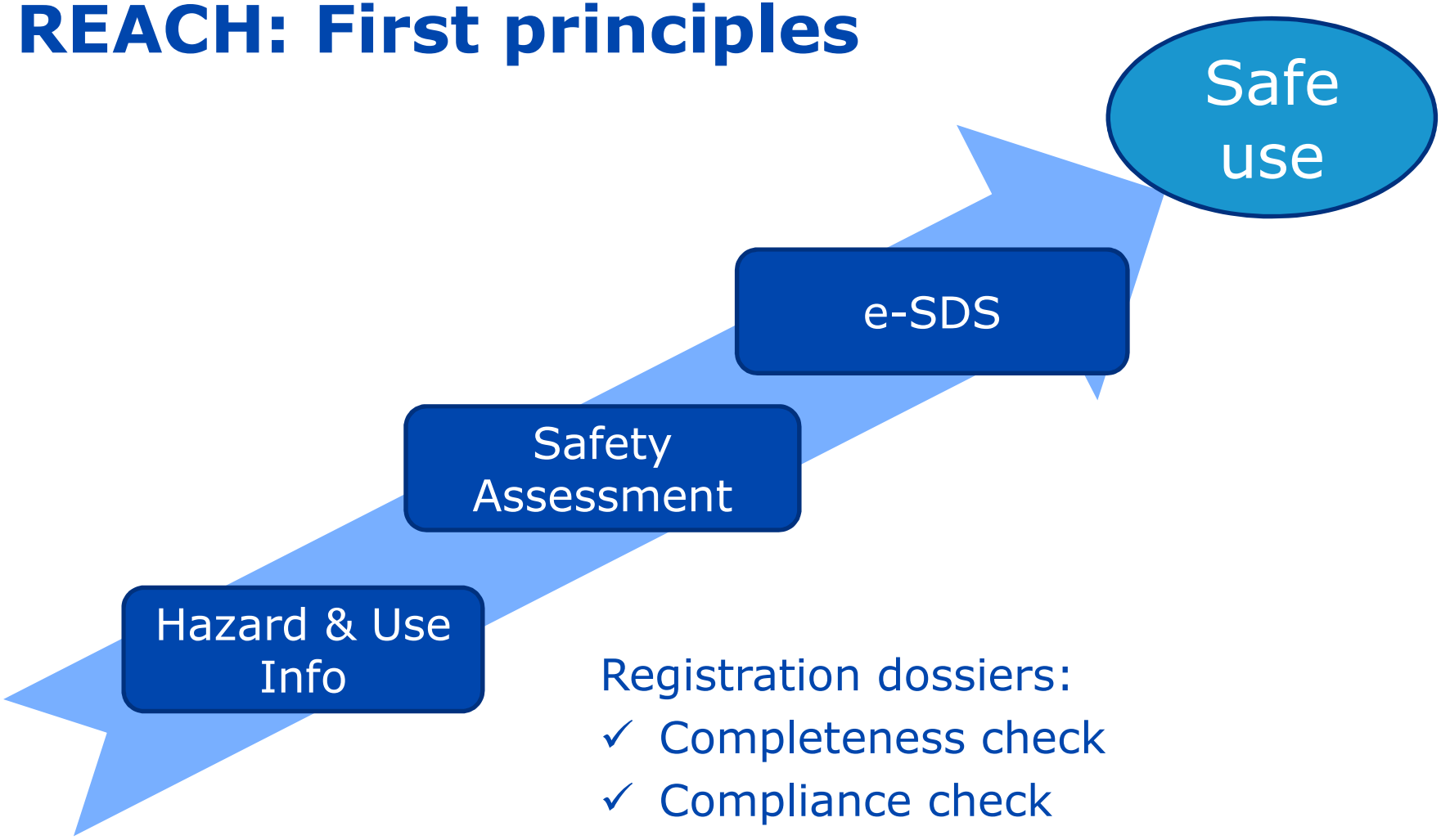

ECHA
EUROPEAN CHEMICALS AGENCY
https://echa.europa.eu/information-on-chemicals/registered-substances
Search...
Registered substances - ECHA
File Edit View Favourites Tools Help
A2 - Documents - All Docu... ECHAnet HR Portal
Please note that information on chemical
accessible via eChemPortal.
22468 unique substances from 96761 dossiers
Understanding REACH Regulation
Q&A on registered substances
What is an Infocard? [PDF]
What is a Registered substance Factsheet? [PDF]
eChemPortal
REACH study results download
See a problem or have feedback?
Last updated 11 October 2019. Database contains 22468 unique substances and contains information from 96761 dossiers.
Substance identity
Substance name:
CAS number:
EC / List number:
Other Numerical Identifiers:
Type
Administrative data
Substance data
Uses and exposure
View all Registered Substances
Search
Clear all
Page 1 of 501
50 Items per Page
Showing 1 - 50 of 25,010 results.
← First
Previous
Next
Last →
Name
EC / List no.
CAS no.
Registration type
Submission type
Total tonnage band
"amyl nitrite", mixed isomers
203-770-8
110-46-3
Full
1 - 10 tonnes per annum
((1-ethoxy-1-oxo-4-phenylbutanyl)
919-408-3
-
Intermediate
Intermediate Use Only
22:53

REACH: First principles



Registration dossiers:

- ✓ Completeness check
- ✓ Compliance check

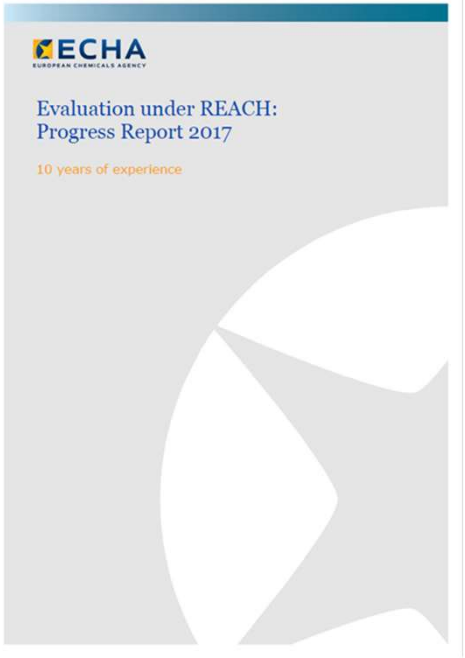
More than 10 years of evaluation

- ✓ More than 2700 dossiers checked for compliance
  - Non-compliance in one or more endpoints identified in more than two thirds of the dossiers checked
- ✓ About 25% of substances registered >1000T checked
- ✓ Improved knowledge on chemicals
  - Generation of information to clarify CMR and PBT properties for more than 1000 substances
- ✓ Improving safe use
  - Substance no longer produced after generating information which led to Carc 1B classification

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

However…

- Despite efforts made, still major compliance issues with registration dossiers

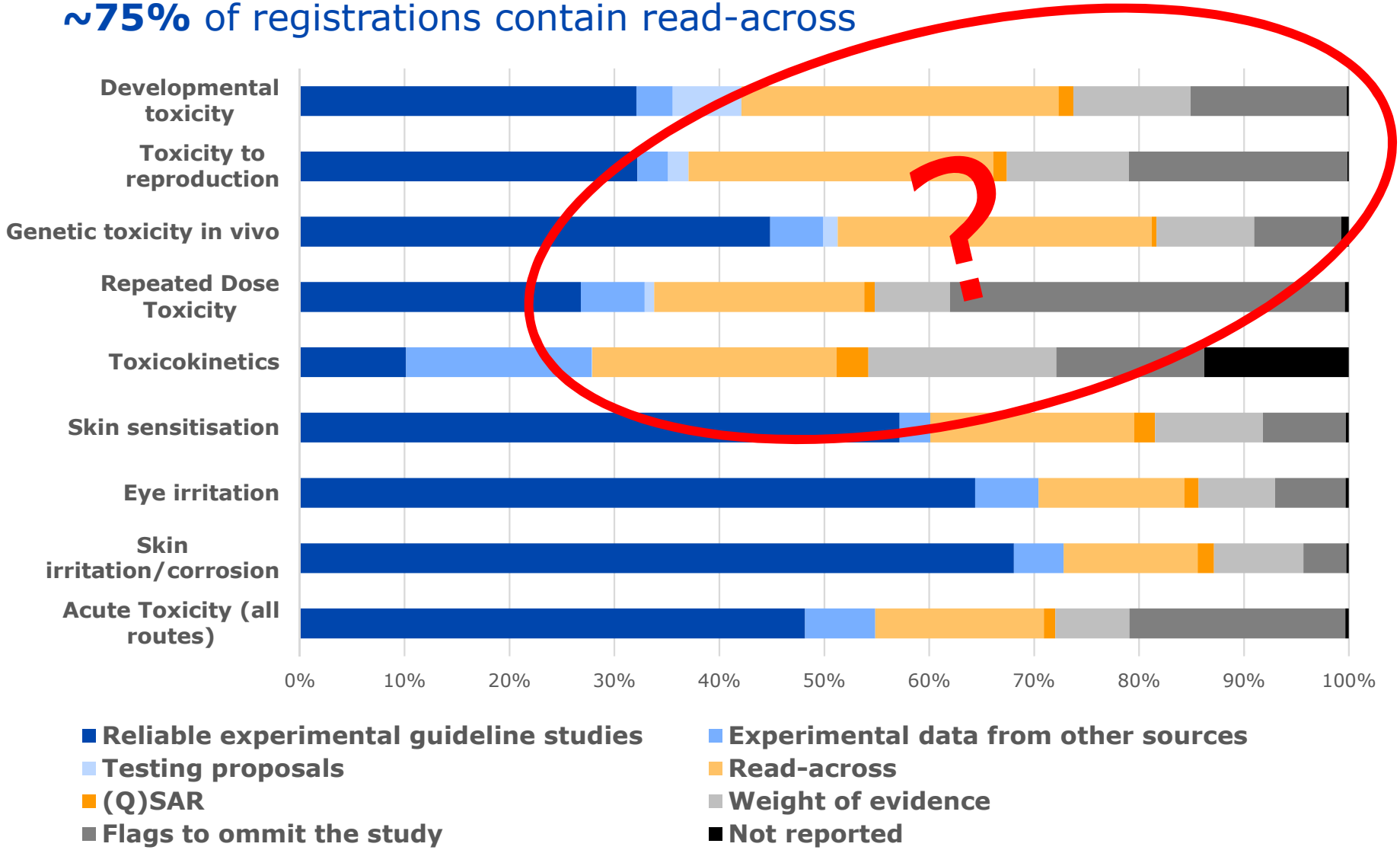


Main reasons for non-compliance

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

Options used to meet the information requirements

~75% of registrations contain read-across



Why does read across fail?

Main reasons for rejection based on analysis of 50 decisions

Reason for rejection	Out of 50
Unclear substance identity, not possible to ascertain structural similarity – significant issue for UVCBs	**48**
Lack of sufficient evidence to substantiate assumptions – including lack of data on analogues provided	**43**
Lack of scientific plausibility – disagreement with hypothesis, data not supportive of arguments presented	**20**
Read-across to inappropriate data – e.g. read-across to a reproductive screening study to address higher tier information requirements for reproductive toxicity	**5**

How to improve compliance

→ Where possible, improve your read-across adaptations using the Read-Across Assessment Framework

- Aims to organise criteria for expert opinions
- Structures and codifies expert judgement of complex scientific questions on the critical aspects of read-across

echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

How to improve compliance

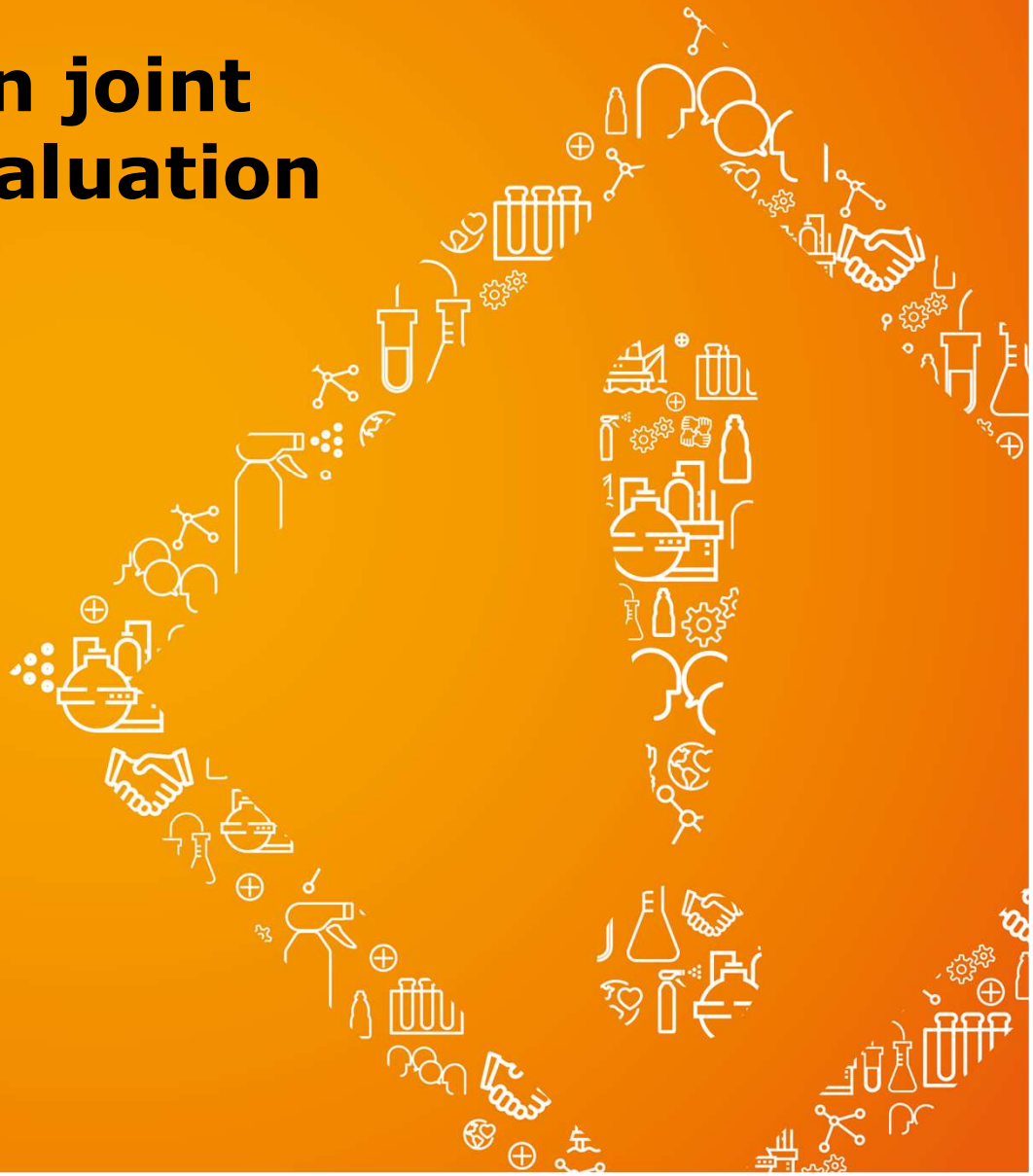
- If read-across fails, you will have data gaps, and in compliance check ECHA will request data for each substance

→ Testing required

→ Submit proactively a testing proposal (for Annex IX and X)

- Greater possibility to refine strategy during process
  - Possibility for more interaction prior to draft decision
- Can incorporate a strategy
  - Sequence of tests for a substance, and within a category

ECHA-Commission joint action plan on Evaluation



REACH compliance – a priority

- Direct impact on ensuring that REACH delivers its objectives
- **Commitment to take action**:
  joint ECHA-Commission action plan
  - Adopted by Management Board in June 2019
  - Concrete actions to improve compliance, engaging all stakeholders

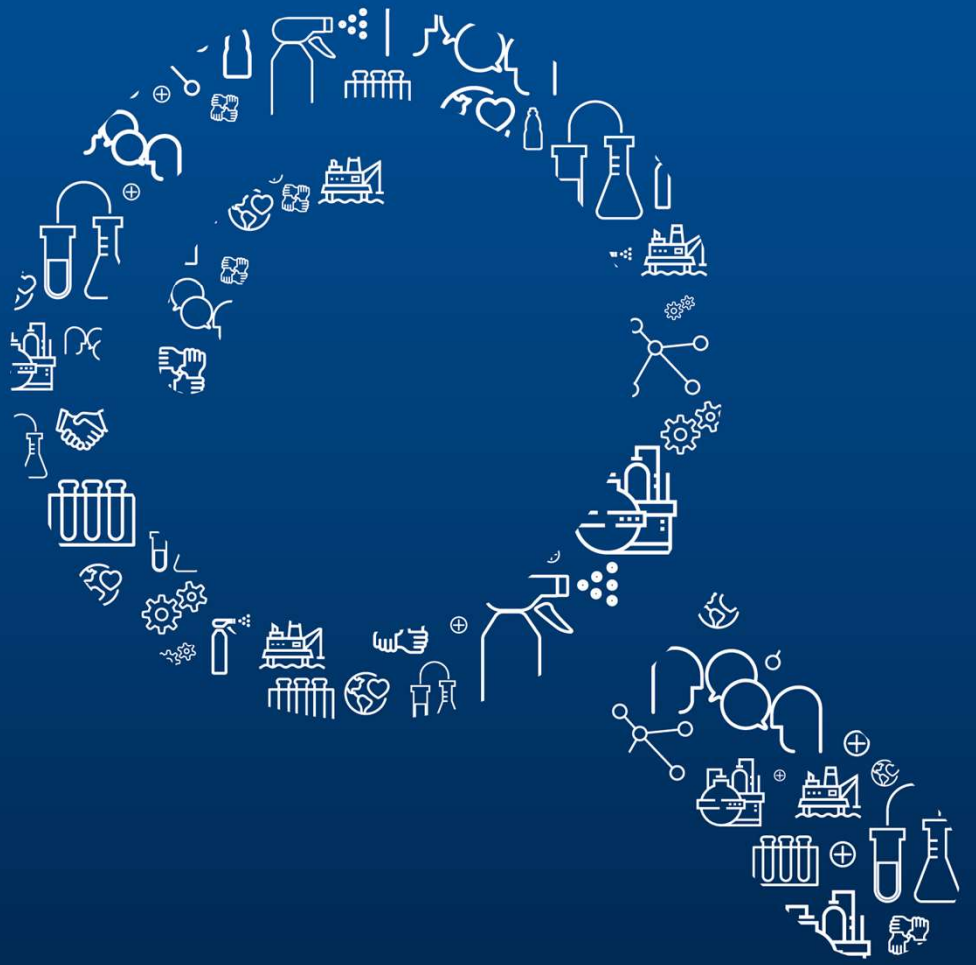
https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

Joint action plan: objectives

1. Address all substances
   - 16500 substances registered in full in 66000 dossiers (2018)
   - By end 2020: put all substances >100T in 'regulatory pools'
     i) of priority for regulatory risk management,
     ii) currently of low priority for further regulatory action, or
     iii) need more data for a judgement to be made → candidates for CCH
   - By 2023: info requested for registrations >100T needing CCH
   - By 2027: info requested for registrations 1-100T needing CCH
2. Improve clarity of legal provisions
3. Accelerate decision making
4. Improve follow-up and enforcement of decisions
5. Industry takes on the compliance challenge

https://www.echa.europa.eu/-/echa-to-scrutinise-all-reach-registrations-by-2027

What to expect from now on?



Increasing the number of CCHs

- Chances to receive a compliance check decision increase
  - As all substances will be addressed
  - …and two thirds are non-compliant
- ECHA expects that all dossiers are up-to-date when the CCH starts
- How to get prepared?
  - Consider regular updates, add new information, remove information which is no longer relevant (uses, unjustified read-across, …)
  - Updating is a legal obligation

Member registrants impacted too

- Since January 2019, ECHA checks compliance of all dossiers for a substance
  - Focus still on the 8 "super-endpoints"
  - Ensure that lower tonnages are compliant
- Decisions sent to all non-compliant registrants, and having obligations to comply with respective testing or required information
  - Not necessarily only the lead
  - Not necessarily all registrants of a joint submission
  - Can include a registrant with opt-out
  - Can include a registrant at any tonnage

https://echa.europa.eu/-/member-registrants-will-start-receiving-dossier-evaluation-decisions-in-2019

What you should do

- ✓ Know the dossier evaluation process and the responsibilities of registrants
- ✓ Be prepared that you or your OR will need to work together with the co-registrants to improve and make the registration dossiers compliant

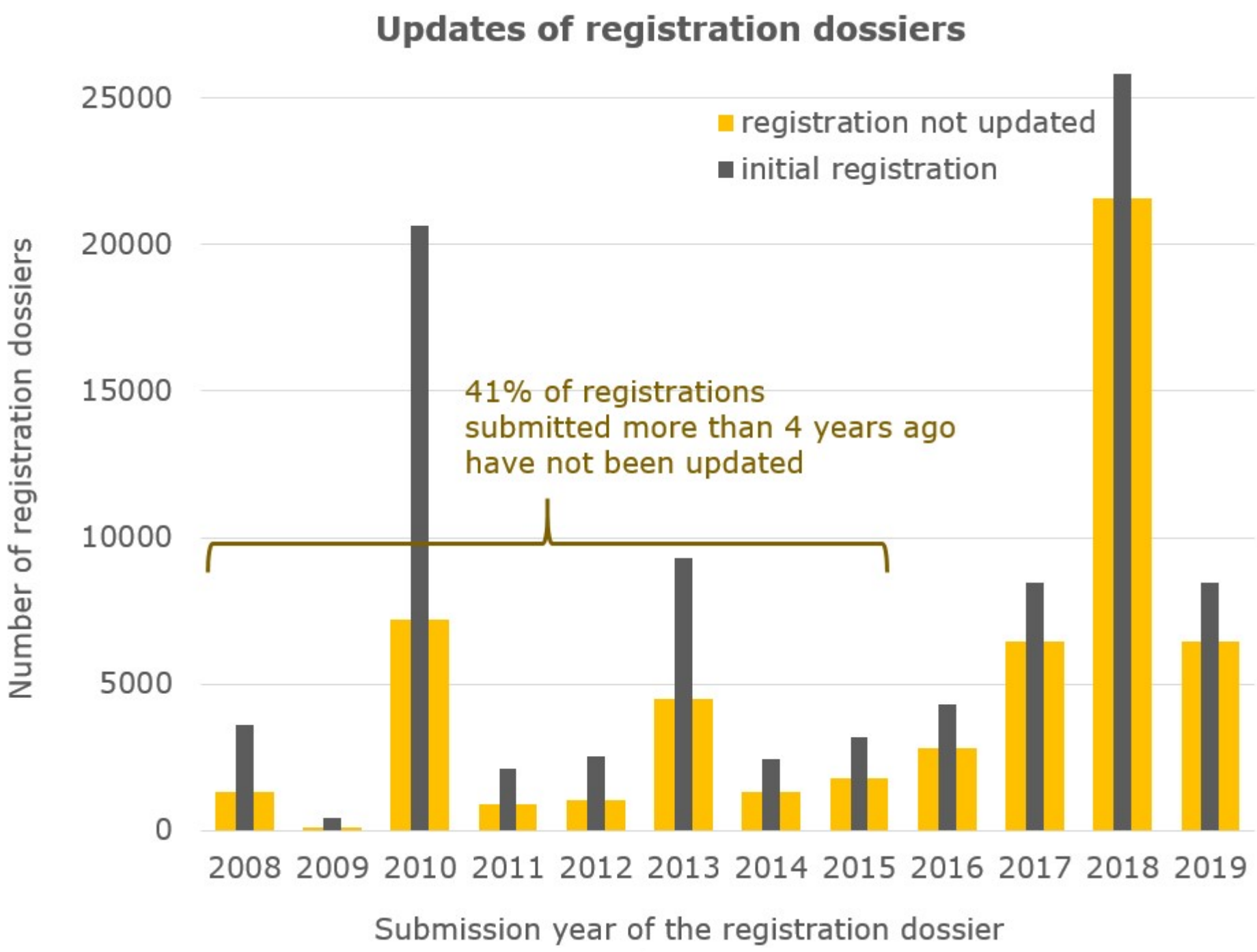
Know responsibilities of registrants

- How to act during dossier evaluation
  - Read the practical guide
  - Keep your contact details in REACH-IT up to date
  - Check Dossier Evaluation Status page: if substance listed, get in touch with your co-registrants to get organised. Substances are listed here before a draft decision is sent.
- Tonnage band downgrades
  - Dossiers are expected to be up-to-date on tonnages and uses
- Ceasing manufacture or import
  - If between draft decision and final decision: registration becomes invalid
  - If after final decision: need to comply with requests in the decision

Data and cost sharing continues

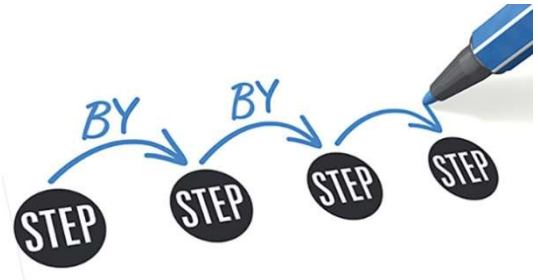
- REACH is not a one-time exercise
  - Joint submission and data-sharing agreements should be reviewed/updated to include steps after the initial registration
- Co-registrants should prepare to work together to improve their dossiers and make them compliant, before receiving a decision from ECHA
  - You will need to contribute to the review of the JS information
  - Most likely, you will need to contribute to generating further information
- Where necessary, you will need to accept a review of strategy and submission of testing proposals
  - Especially when using read-across/category approaches

Dossier update experiences


Updates of registration dossiers
25000
20000
15000
10000
5000
0
Number of registration dossiers
registration not updated
initial registration
41% of registrations
submitted more than 4 years ago
have not been updated
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
Submission year of the registration dossier

Updating is a legal obligation (Art. 22)

- On your own initiative, without undue delay, after changes in:
  - company status
  - tonnage band
  - new risks of the substance to human health and/or the environment
  - composition of the substance
  - new identified uses
  - classification and labelling
  - …
- When the Agency requests an update of the registration after a dossier or substance evaluation decision
- After an authorisation or a restriction for the substance



Keep dossiers up-to-date!

- Updating is a legal obligation
  - Implementing Regulation on dossier updates (expected in 2020) will clarify timing of 'without undue delay'
- Registrants needs to ensure that advice on safe use is based on up-to-date and reliable data
- Allows authorities to make decisions on the basis of most current and relevant data
- Registrants should include dossier updating in their internal quality processes!

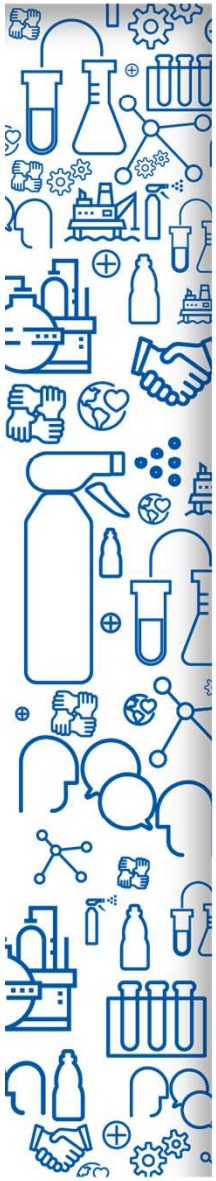
What with SME's under REACH

- According to Commission studies, REACH costs are proportionally more important for SME's
- Before REACH entered info force, highest cost estimation from testing
- After 2010 and 2013 deadline, highest cost from consortia and SIEF management
- And tests to come…

SME's under the REACH Review

- **Action 3:** *Improving the workability and quality of extended Safety Data Sheets*
- **Action 14:** *Support compliance by SMEs*

  ECHA and Member States are requested to step up efforts to develop, with input from voluntary actions by industry organisations, tailored guidance and support instruments focused on the needs of SMEs. Such instruments may include collection of best practice, generation of sector specific solutions and publication of documents in national languages.



Take-home messages

- The REACH journey is not over…
- Evaluation becomes even more important!
- Be ready to play your part in the compliance challenge
- You have the obligation to:
  - Review and update your dossiers
  - Contribute to the review and update of the jointly submitted part of your dossiers
  - Act on Evaluation decisions (together with your co-registrants)

Thank you

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