Registration-dossiers: shortcomings and possible improvements by updates - experiences so far

WKÖ Workshop

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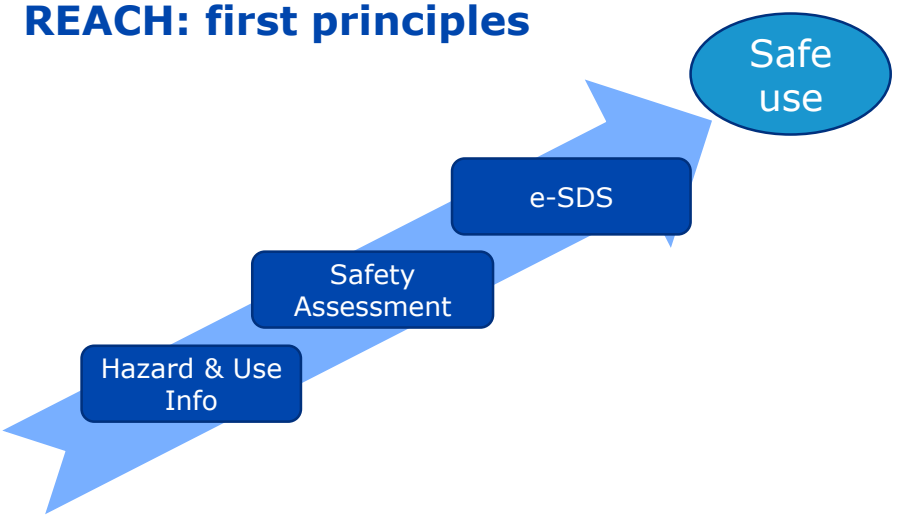
REACH: first principles



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Phase-in period successfully over!

Some figures

21 600	Chemicals registered
>90 000	Registration dossiers from chemical companies
145 000	Chemicals classified and labelled 
>6 million	Classification notifications sent by chemical companies
>2 million	Study summaries on properties and effects of chemicals

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However…….

- Despite efforts made, still major compliance issues with registration dossiers
- Use information often incomplete, either too broad or too narrow
- Waiving of data requirements and adaptations (read-across, QSAR, WoE) failing due to incorrect justification or lack of documentation
- Quality of Chemical Safety Reports not adequate to understand advice on safe use

Some observed shortcomings in compliance

- Joint submission
- Post-2016 completeness check rules
- Wrong or vague information on uses
- Compliance check: read-across

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Joint submission

- One substance, one registration principle (OSOR)
- 'Individual' dossiers cannot be submitted nor updated if a joint submission exists (since 2016), also for NONS
- Project on checking older dossiers for fulfilling OSOR:
  - Of ~200 registrations addressed, mostly registrants manage to join the joint submission (sometimes with opting-out)

→ Ensure all your registrations are in a joint submission, so you are in a position to update them when needed
→ Lead dossiers have to pass full completeness check, also for NONS
→ NONS lead registrants can start by creating a joint submission in the 1-10T band, and put their higher tonnage data in opt-out

Post-2016 completeness check

- Technical Completeness check (TCC) was enhanced in 2016:
  - Automatic checks improved
  - Manual checks of certain information introduced
    - ~21% of submitted dossiers are currently stopped for manual verification by ECHA staff
- Requirements did not change (except where Regulation was changed)
- Each submitted dossier is fully checked for completeness, not only the updated sections

→ Proactively run the IUCLID validation assistant on your older dossiers and correct failures

Areas of verification by ECHA staff

- Substance identification
  - Deviations in identification of well-defined substances.
  - UVCB substances: manufacturing process description and composition breakdown. Most common failure!
- Justification for data waiving
  - Must be based on Column 2 or Annex XI
  - Must be supported by other information if applicable
- Justification for no CSR
  - Must be based on Article 14(2)
- Considerations for alternatives for testing proposals
- Justification for opting-out of joint submission of data

→ Use the document describing the areas of verification by ECHA staff at echa.europa.eu/manuals

Wrong or vague information on uses

Frequently occurring issues identified by ECHA and Member States:

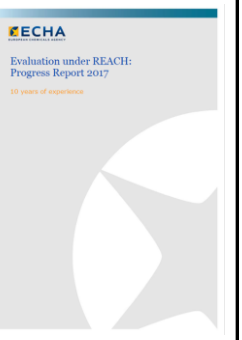
- Description of assessed uses is too vague, so that DUs cannot understand whether or not their use is covered → utilize information from DU sector use-maps
- "Uses advised against" not spelled out → be specific
- Uses reported in the registration dossier are not covered in the CSR → keep the use descriptions aligned
- Over-reporting: Widespread uses (consumer, professional) reported although not relevant in practice → remove not relevant uses

10 years of evaluation (2008-2017)

- 1780 dossiers checked, to various degrees, for compliance
  - **non-compliance** in one or more endpoints identified in more than **two thirds** of the dossiers checked
- 2 586 information requests made
  - 420 (16 %) - targeted substance identification,
  - 178 (7 %) - physico-chemical properties,
  - **955 (37 %) - human health hazards**
  - **662 (26 %) - ecotoxicity and fate**
  - 367 (14 %) – exposure and other CSR issues

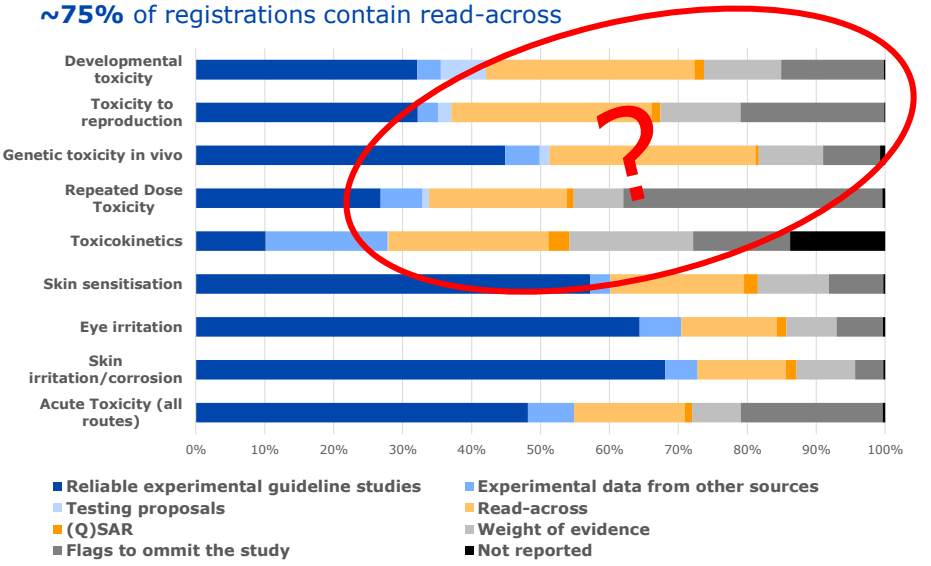
Main reasons for non-compliance

- 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. insufficient level of detail in robust study summaries to allow for an independent assessment

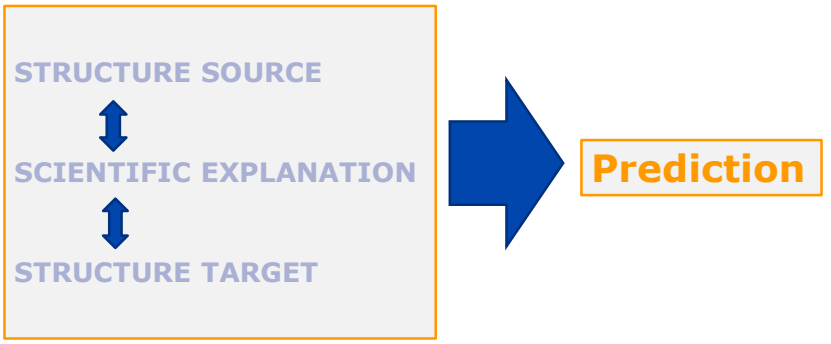


Options used to meet the information requirements

~75% of registrations contain read-across



A definition of 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

Dossier update experiences

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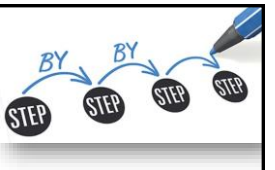
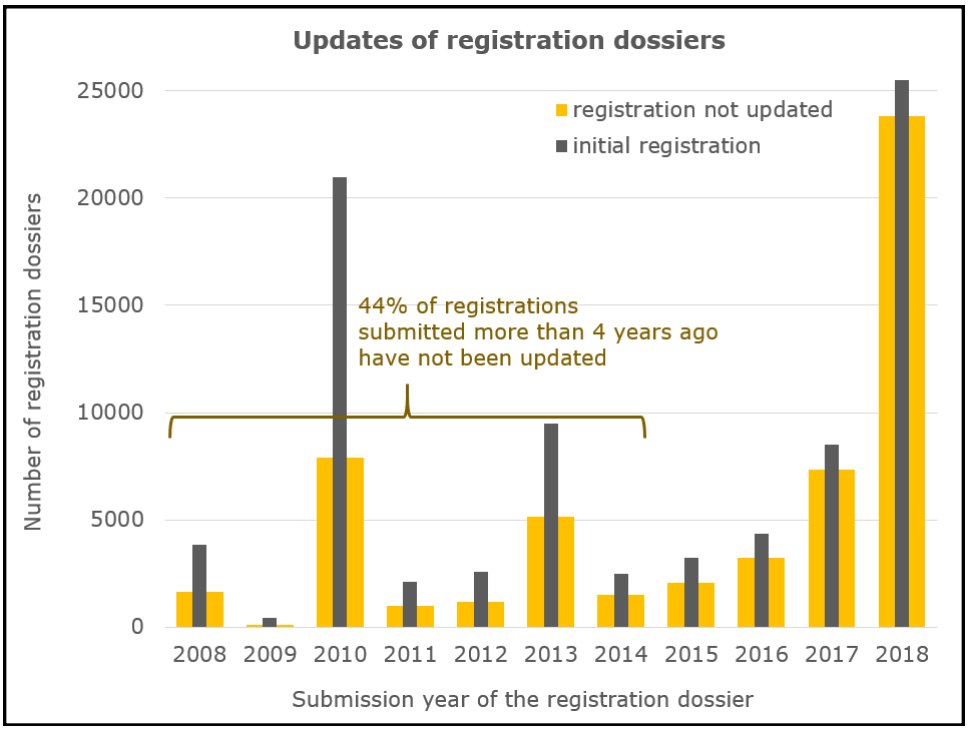


Keep dossiers up-to-date!

- The reality:
  - 67% of all dossiers have never been updated
  - Lead dossiers better off: over 50% updated
  - 45% of dossiers older than 4 years old were never updated
  - Registrants survey: 85% of the companies are familiar with the update process, but only 55% have already discussed how to handle future updates
  - Most updates follow a request by ECHA (dossier or substance evaluation) or letter campaign; few spontaneous updates



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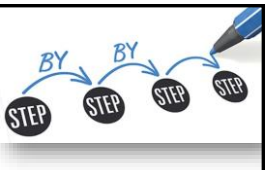

Keep dossiers up-to-date!

- Updating is a legal obligation (Article 22)!
- 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!

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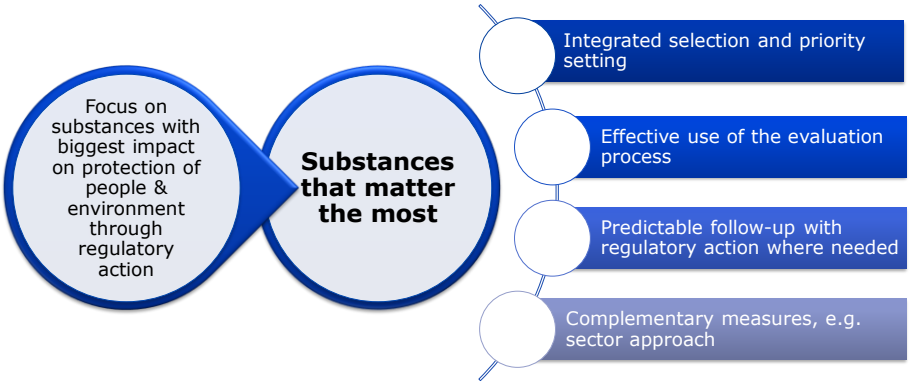
A Regulatory Strategy for "substances that matter most"



Stepping up our efforts:

More efficiency and impact!

Let's acknowledge success

- Tremendous collective effort from companies and authorities
- Largest database worldwide on properties and effects of chemicals
- Information is available…

to industry for a better management of their portfolio of substances

to authorities for proposing risk management measures at EU level

to the public at large to get informed on the risks from the chemicals to which they may be exposed

REACH evaluation by the Commission in 2017

- REACH is fully operational and delivering results
- Progress lacks behind initial expectations in some areas: dossier quality is one!
- Actions on improving dossier compliance
  - Action 1: Encourage updating of registration dossiers
  - Action 2: Improve evaluation procedures
- Actions to improve supply chain communication
  - Action 3: Improving the workability and quality of Safety Data Sheets
  - Action 4: Tracking substances of concern in the supply chain

Increase impact

- Address substances in groups
  - Coordinate with on-going processes on analogue substances
  - Avoid regrettable substitution
  - Avoid unnecessary testing and achieve compliance within reasonable timelines
  - Scrutiny until the group is considered as low priority: sufficiently regulated or low concern based on solid information
- Address all co-registrants of the joint submission
  - From January 2019, evaluation decisions are sent to all co-registrants that are not compliant with their respective information requirements, incl. opt-out members echa.europa.eu/-/member-registrants-will-start-receiving-dossier-evaluation-decisions-in-2019

Increase transparency

- Dossier evaluation progress visible on ECHA's website: echa.europa.eu/information-on-chemicals/dossier-evaluation-status
  - Tool for registrants … but also to the public at large
  - Information on scope and status of the assessment
  - Searchable
  - Progress tracked from draft to final decision
  - Publication of the non-confidential version of the decision
  - Link to the registration dossiers
- More information on authorities activities (assessments, risk management and regulatory management options) in the Public Activities Coordination Tool: echa.europa.eu/pact

Enforcement by national authorities

- REF-7 project on registration in 2019 (reporting in 2020)
- All EU countries participating
- Scope:
  - Registration obligations in cooperation with customs authorities
  - This includes verification of strictly controlled conditions applicable to substances registered as intermediates
  - Dossier update obligation

In summary

- REACH journey is not over…
- Evaluation kicks in!
- Lack of compliance has raised attention – this is not over
- You need to update your dossiers – this is the law, and also the proof that you take safe use of chemicals seriously

- Contact us for support on specific matters: http://echa.europa.eu/contact

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Questions, comments, experiences, good practices or case studies to share?

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