

REACH 2018

How to ensure a successful submission

12th Stakeholders' day

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Completeness check

- Dossiers have to be complete to get a registration number
- “Technical completeness check rules” in place to know what information needs to be provided
 - Used by us to verify completeness
 - By industry to check before submission
- Completeness check enhanced in 2016 to improve availability of data



Enhanced completeness check

- Since new IUCLID format in 2016
- Well ahead of 2018 registration deadline
- Based on our experience and stakeholder feedback
 - Automatic rules reviewed
 - New manual verification steps



Manual verification

- Automatic rules have free text field limitations
- Prevents from bypassing the system
- Still in the scope of completeness check (no assessment of quality)



Manual verification: areas of attention

- Unclear substance identity
- Information requirements waived by registrants
- Dossiers include testing proposals
- Chemical safety report missing



Manual verification: first results

- **33%** of all incoming dossiers manually verified
- **20%** of verified dossiers failed first check
- **95%** of failed dossiers successfully updated
- If new submissions fail, no registration number issued



Retrospective checks

- Ensure level playing field for existing and upcoming registrations
- Pilot campaigns in 2016
 - Study claimed 'on-going' for long time
 - 'Placeholder' lead dossiers
- First results show registrants are able to fulfil information requirements, e.g. provide a missing study

Enforcing OSOR principle

- **One Substance One Registration:** joint submission and data sharing a legal obligation in REACH
 - Avoid duplication of animal studies
 - Reduce costs
 - Increase consistency of safe advice



Enforcing OSOR principle

- Regulation in force since 2016 → ECHA to ensure joint submissions
 - No submissions outside joint submission possible
 - Leads acting without SIEF agreement can be demoted
 - Contact us with a dispute in case of a difficult situation



Make sure your dossier is complete

- Run the validation assistant tool in IUCLID: a 'must' before submitting
- Consult our help: tips on manual verification
- Follow our webinar on 20 April
- Contact our helpdesk



Take-home messages

- We are taking action to increase availability of data
- Dossiers checked manually
- Actions address both existing and upcoming dossiers
- Joint submission mandatory
- Make use of available help to ensure a successful registration



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