

US Clients
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Registration dossiers – how to
make use of IUCLID and how
to avoid the pitfalls; the master
dossier concept

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What this presentation is and isn't

- What it is
 - An overview of the registration process
 - A few tips on IUCLID
- What it is not
 - A IUCLID training seminar!

What is a registration dossier?

- The concept: one substance one registration (OSOR)
 - Not what it actually is!
 - One substance one **dossier**
 - If you manufacture/import a substance it must be registered in accordance with the registration deadlines
 - Your registration is yours!
 - Must be in IUCLID 5
 - ECHA doesn't want study reports
 - So... all endpoints have to be entered into form fields

Reducing registration costs

- So... registration is costly in every way!
 - Management time
 - Consultancy time
 - Registration fees
 - Data costs
- How can it be reduced?
 - Reduce data costs by
 - Substance grouping, read across and use of surrogate data
 - Data waivers
 - (Q)SARs

The master dossier concept

- Use IUCLID template
 - One dossier aggregates all data for a group of substances
 - Pull down data from IUCLID 4 files
 - Used for HPV, ICCA etc.
 - Used for EU ESR
 - Create a lead substance dossier from template
 - Upload substance dossier to REACH IT

The master dossier concept

- Advantages
 - Only have to parse data and fill out form fields in IUCLID **once**
 - Some data is already aggregated by group for other reporting programmes
 - Use it as it is!
- Issues?
 - Not ideal for all substances/groups
 - Difficulty in converting IUCLID data 4 to 5

Data waivers

- Exposure based waivers
 - Need downstream use information
 - May be able to argue that a dossier does not need a certain endpoint that is in the lead dossier
 - No need to but letter of access for that study
- Studies not required because of properties, e.g.
 - Granulometry not needed for liquids
 - FP waived for high BP
 - Oxidative properties waived based on structure

Data waivers

- Endpoints not required because of results from other studies
 - Environmental data waived if substance is readily biodegradable
 - Beware old data!
 - May be inadmissible for arguing waivers for other endpoints
 - Old protocols not to REACH specification

The (Q)SAR

- Prediction of a hazard property based on chemical structure
 - Well-established scientific principle, but...
 - We don't know how ECHA will receive SARs
 - REACH is not 100% clear on acceptability of SARs
 - Conclusion: use with caution