

Planning: generation new registration dossier

	week 1	week 2	week 3 to 6	week 7	week 8	week 9	week 10	week 11	week 12/13	week 14/15	week 16	week 17	week 18	week 19	week 20/21	week 22	week 23	week 24	week 25	week 26	week 27	week 28	week 29	week 30/31	week 32	week 33	week 34	week 35	week 36	week 37	week 38	week 39	week 40	week 41	week 42	week 43	week 44	week 45	week 46	week 47		
start process: legal docs																																										
contact SEF																																										
strategic analysis																																										
budget preparation																																										
kick-off meeting																																										
buy legitimate access to existing studies for read across																																										
start new testing: blind labs + define protocols																																										
start new testing: collect money																																										
start new testing: determine representative sample																																										
start new testing: get sample to the lab(s)																																										
start new testing: perform testing																																										
start new testing: draft reporting																																										
start new testing: review results / finalize testing																																										
transfer test results in robust study summaries																																										
if needed: Tier 2 testing																																										
determine uses / exposure scenarios																																										
gather analytical information (substance ID and quantification)																																										
CS																																										
analysis																																										
CS																																										
submit IUCLID																																										
prepare CSR (if needed)																																										
review of IUCLID / CSR by clients																																										
registration by LR																																										
registration by Co registrants																																										

~1 year if new studies are needed (in tiered approach)

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Anybody can be lead registrant

- Lead registrant (LR):
 - Open joint submission
 - Forward info to and from ECHA
 - ⇒ Communicator role
 - ⇒ Not time-consuming
 - ⇒ No extra resources needed

LR position is manageable also for small companies!

Especially IF

most of LR work is done by consortium like ROSC!

BUT

Don't take this position lightly if you do this alone!

Pitfalls – bottle necks - challenges

- ❑ Get your pre-registrations sorted out
 - Contact details ok in existing ones?
 - Need new ones (late pre-registration till 31 May 2017)?
 - Answer to emails you receive from the SIEF
- ❑ When to decide on the need of registration?
 - Registration cost vs added value
 - Get datagap analysis done and find out!
 - Define cost vs added value
- ❑ Analytics (substance ID and quantification)
 - May be difficult to analyze / unstable or reactive
 - Start early!
- ❑ Availability of labs!!
- ❑ Availability of representative sample



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Pitfalls – bottle necks - challenges

- ❑ High cost
 - REACH is very expensive
 - LoA cost can vary between few 100€ to several 100.000€
 - Ask for LoA cost breakdown! ECHA guidance available!
 - Find co-registrants! Work together!
- ❑ How to choose a good, reliable consultant?
https://echa.europa.eu/documents/10162/13559/dcg_consultant_checklist_en.pdf
- ❑ LR role: be prepared! Get help (e.g.ROSC)!
- ❑ IUCLID 6
 - Extra fields need entry compared to IUCLID 5
 - Data bought via LoA need update to IUCLID 6
- ❑ May 2018 = deadline for registration - NOT for REACH!

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Summary

- ❑ Make your REACH 2018 inventory now!
- ❑ Find out if you have orphans + get budget estimate!
- ❑ Go for a stepwise approach
- ❑ If you don't have time / personel: hire help!
- ❑ LR role is not unmanageable
- ❑ Decide on your level of involvement
- ❑ Choose your consultant wisely: cost efficient solutions do exist!



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Useful websites

- ❑ <http://wko.at/reach>
- ❑ <http://www.hse.gov.uk/reach/>
- ❑ <http://echa.europa.eu/reach-2018>

- ❑ <http://www.arche-consulting.be/>
- ❑ <http://www.chemservice-group.com/home.html>
- ❑ <http://www.kvconsultings.com/>
- ❑ <http://www.ROSconsortium.eu>



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Abbreviations used

□ CSR	Chemical Safety Report
□ ECHA	European Chemicals agency
□ GLP	Good laboratory practice
□ ID	Identification
□ Intl	International
□ IUCLID	Intl Uniform Chemical Information Database
□ LoA	Letter of Access
□ LR	Lead Registrant
□ LtU	License to Use
□ ROSC	REACH Orphan Substances consortium
□ SIEF	Substance information exchange forum
□ SVHC	Substance of very high concern
□ T	Tonne

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