Planning: generation new registration dossier

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

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

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!

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!

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

Karine Van de Velde
ROSC, Secretary General
Tel: +32 3 297 60 92
Mobile: +32 478 327 562
karine@ROSconsortium.eu
http://www.ROSconsortium.eu

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