REACH Orphan Substances Consortium

ROSC

Registration dossiers /data-collection /testing - SME with hands-on experience

9 March 2017 – REACH 2018 SME workshop

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REACH 2018

- Registration deadline: 31 May 2018
- All substances > 1 T / year / company
- 25.000 substances (60 to 70.000 dossiers?) relevant for 2018 deadline??? (ECHA 2018 roadmap)
- http://echa.europa.eu/reach-2018

448 days before the deadline

~55 substances per day???

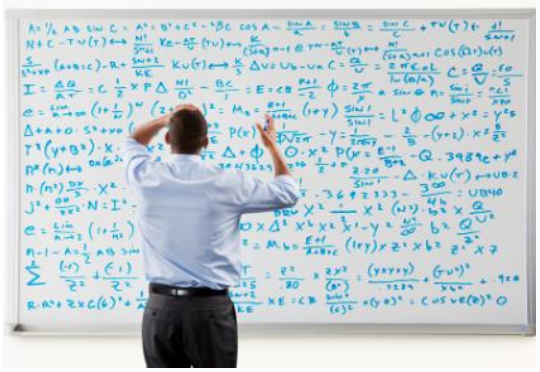
REACH 2018

Help out the SME's!

- Focus on **SME's**:
  - 25 to 40% of registrants by 2018?
  - Help them step by step through the process together

Potential hurdles for SMEs

- Regulatory people in house?
- How to prepare the REACH inventory?
- How to decide on benefit versus cost?
- Small tonnages / market changes
- How to decide on LoA versus consortium membership?
- Lots of consortia
  - Need people to attend meetings (often sales people)
  - Scientific discussions to listen to
  - Yearlong membership / commitment needed
  - How deep do you need to be involved?
  - REACH = only 1 of regulatory topics followed



Potential hurdles for SMEs

- SIEF communication - languages
- “Orphans” – how to start?
- What if you are the only company interested?
- Some consultants expect you to:
  - Take the lead (lead registrant) and prepare the dossier
  - Pay the entire dossier
  - Try to sell LoA later on
  - Highly resource demanding!

Orphan = a REACH 2018 eligible substance not covered by any organisation. Orphans can be metals / organics / inorganics

Lead registrant responsabilities

- Gather existing data / perform datagap analysis
- Missing endpoints: new studies or read across?
- Negotiate with labs
- Studies acceptable for regulators (GLP etc.)?
- Uses / exposure scenarios if required
- IUCLID / CSR
- Communicate with SIEF / ECHA / member states
- Open Joint Submission
- LoA management
- Keep dossier up to date
- Be transparent, fair and non-discriminatory

⇒ Not to be taken lightly
⇒ Time and resource demanding
⇒ Need good preparation

ARE THERE MANAGEABLE SOLUTIONS?

YES!

Example: ROSC

- REACH Orphan Substances Consortium (ROSC)
- Created mid 2015 to help SMEs comply with REACH in a resource efficient way
- ROSC = over arching, horizontal consortium
  - Grouping substances (organic/inorganic/metals)
  - Minimize lab / admin cost
  - Stepwise approach (datagap/budget calculation/prepare dossier)
  - LR position = manageable (everybody can take first step!)
  - YOU decide your level of involvement!

= REACH Orphan Substances Consortium

= strategic partnership

ARCHE

Ir. Patrick Van Sprang

KV Consulting Services bvba

M. Sc. Karine Van De Velde

CHEMSERVICE

Dr. Dieter Drohmann

Where to start?

MAKE YOUR REACH INVENTORY NOW!!

- What do you manufacture / import?
  substances / preparations / articles
- Which raw materials do you need?
- Which tonnages?
- Did you pre-register? => May 2017!!
- Phase-in or non phase-in substances?
- What do you want to register?

Make informed decisions

- Substances under regulatory pressure => not worth investing in?
- Substances affected by restrictions / authorisations?
- What about SVHC? Do you use them? Import them?
- What are your REACH obligations?
- **What will this cost you?**

⇒ Make informed decisions!!!

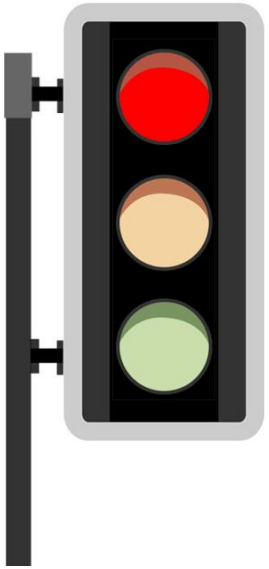
⇒ Don’t wait any longer!!!

⇒ Get / hire help if needed

If you want /need to register:

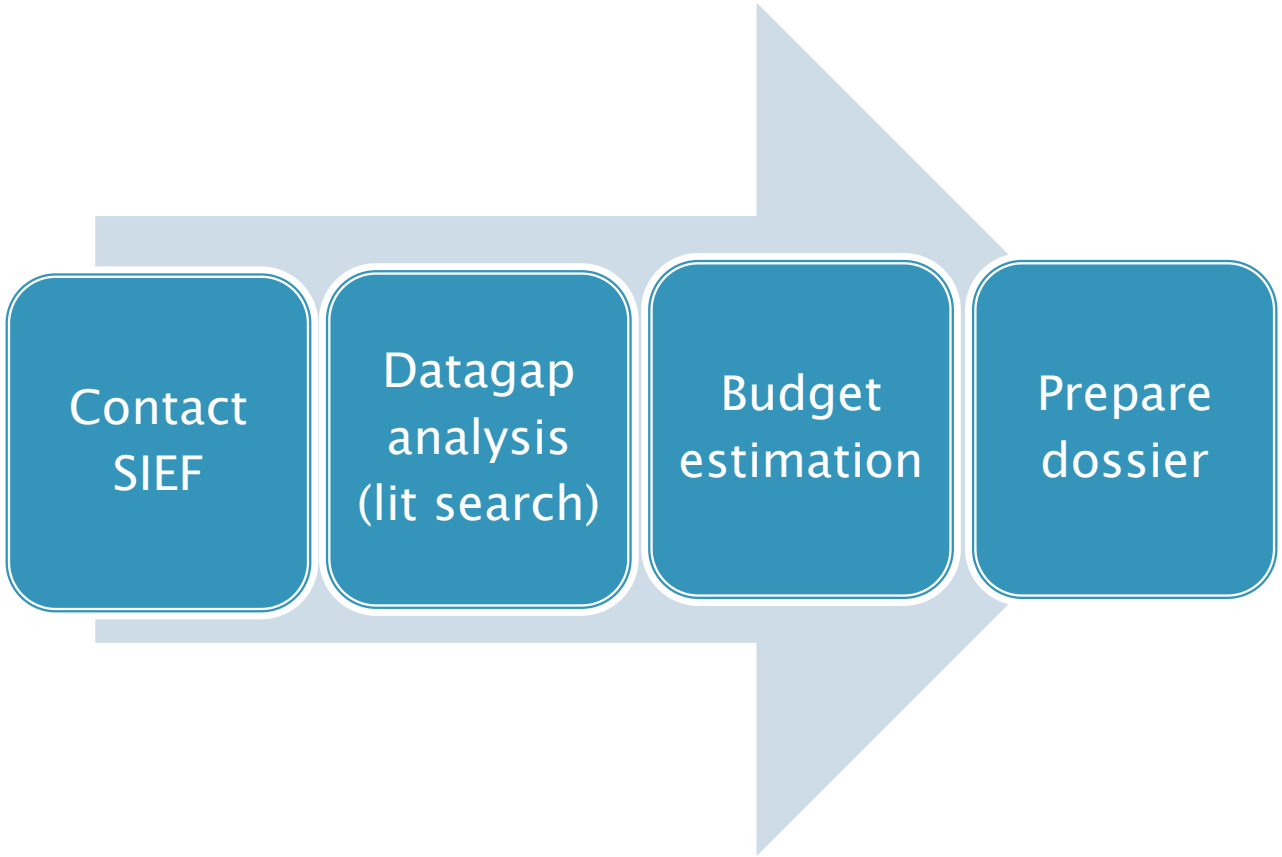
3 options

- Substance = REACH registered – buy LoA
- Substance = being worked on – join or buy LoA
- Substance = orphan substance – act now!



HOW TO DEAL WITH YOUR ORPHANS?

Go for stepwise approach



How does it work in practice?

- Legal docs – start cooperation
- Contact SIEF – data and cost sharing
- Datagap analysis (incl lit. search) per endpoint
- New testing vs read across
- Budget estimation for full dossier
- Kick-off meeting: continue or stop?

Step 1

- Decide on way forward + working group agreement
- Start testing and/or buy LtU for read across approach
- Work on exposure scenarios (if needed)
- Prepare IUCLID /CSR
- Register

Step 2

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 /26	week 27	week 28	week 29	week 30/40	week 41	week 42	week 43	week 44	week 45	week 46	week 47
start process: legal docs																					
contact SIEF																					
datagap analysis																					
budget preparation																					
kick-off meeting																					
buy legitimate access to existing studies for read across					2 months																
start new testing: find 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						ES									finalze ES						
gather analytical information (substance ID and quantification)							analytics														
C&L																					
fill in 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)

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

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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