



REACH Orphan Substances Consortium

ROSC

# Support for SME's

31 Jan 2018 – ECHA Stakeholder day

Karine Van de Velde

REACH Orphan Substances Consortium

Secretary General

# REACH 2018

- ❑ Registration deadline: 31 May 2018
- ❑ Clock is ticking...
- ❑ <http://echa.europa.eu/reach-2018>



120 days before the deadline

**REACH 2018**



# What is an SME?

▶ DEFINITION:

[http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition\\_en](http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en)

<b>Company category</b>	<b>Staff headcount</b>	<b>Turnover</b>	<b>or</b>	<b>Balance sheet total</b>
Medium-sized	< 250	≤ € 50 m		≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m
Micro	< 10	≤ € 2 m		≤ € 2 m

▶ DO the test!

<https://smetest.uwe.be/>

# 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?



# 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 responsibilities

- ❑ 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**



Ir. Patrick  
Van Sprang



M. Sc. Karine  
Van De Velde



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

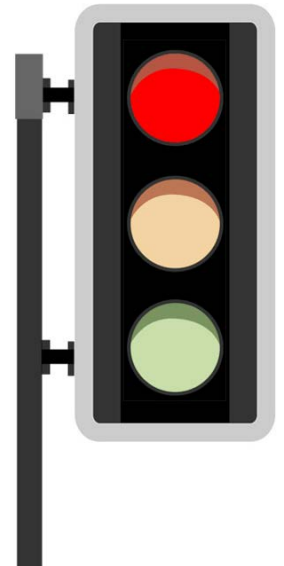
- ❑ Substances under regulatory pressure => not worth investing in?
  - ❑ Substances affected by restrictions / authorisations?
  - ❑ What about SVHC? Do you use them? Import them?
  - ❑ What are your REACH obligations?
  - ❑ **What will this cost you?**
- ⇒ Make informed decisions!!!
- ⇒ Don't wait any longer!!!
- ⇒ Get / hire help if needed



# If you want /need to register:

## 3 options

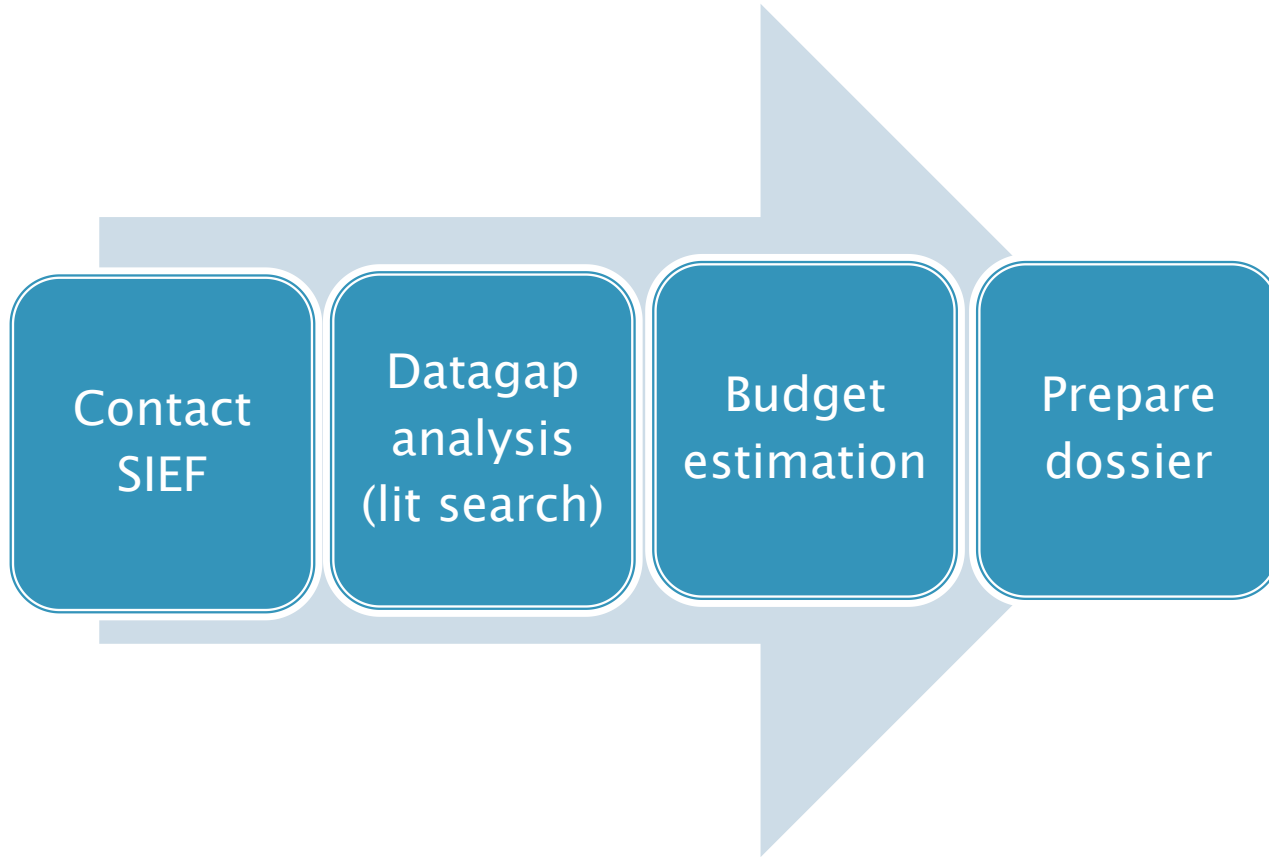
- ❑ Substance = REACH registered – buy LoA
- ❑ Substance = being worked on – join or buy LoA
- ❑ Substance = orphan substance – act now!



# 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  
(timing!!)

# 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!

**WHAT DOES REACH  
COST?**



# SME: what does REACH cost?

- ▶ 3 parts:
  - Pay the data
    - As lead registrant
      - Perform new studies
      - Read across from existing data
      - Buy literature data
    - As co-registrant – buy LoA
  - Pay the consultant
  - Pay ECHA – registration fee

# ECHA registration fees

- ▶ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0864&from=EN>

	Medium enterprise (Individual submission)	Medium enterprise (Joint submission)	Small enterprise (Individual submission)	Small enterprise (Joint submission)	Micro enterprise (Individual submission)	Micro enterprise (Joint submission)
Fee for substances in the range of 1 to 10 tonnes	EUR 1 131	EUR 848	EUR 609	EUR 457	EUR 87	EUR 65
Fee for substances in the range 10 to 100 tonnes	EUR 3 038	EUR 2 279	EUR 1 636	EUR 1 227	EUR 234	EUR 175
Fee for substances in the range 100 to 1 000 tonnes	EUR 8 126	EUR 6 094	EUR 4 375	EUR 3 282	EUR 625	EUR 469
Fee for substances above 1 000 tonnes	EUR 21 904	EUR 16 428	EUR 11 795	EUR 8 846	EUR 1 685	EUR 1 264

Large enterprise	
Individual submission	Joint submission
EUR 1 739	EUR 1 304
EUR 4 674	EUR 3 506
EUR 12 501	EUR 9 376
EUR 33 699	EUR 25 274

# Check for financial help (grants)

- ▶ National level
  - E.g. ministry of Economy of the Slovak republic
- ▶ Regional level
  - E.g. MRBC (Brussels region)
    - [http://werk-economie-emploi.brussels/documents/16195/64792/Formulaire\\_Personnel\\_gestion.pdf/22d18d9f-bcbd-44a5-b82d-2a54602e4ffe](http://werk-economie-emploi.brussels/documents/16195/64792/Formulaire_Personnel_gestion.pdf/22d18d9f-bcbd-44a5-b82d-2a54602e4ffe)
    - [www.sprb.irisnet.be/economie-emploi](http://www.sprb.irisnet.be/economie-emploi)

# CONCLUSIONS — ADVICE

# Advice – best practice

- ❑ Communication
  - Contact details ok in REACH IT?
  - Answer to emails you receive from the SIEF
- ❑ Decide NOW on the need for 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!
- ❑ Timing!!!
  - Availability of labs and consultants!!
  - Availability of representative sample



# Advice – best practice

- ❑ 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](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://echa.europa.eu/reach-2018>
- ❑ <http://www.hse.gov.uk/reach/>
- ❑ <http://www.arche-consulting.be/>
- ❑ <http://www.chemservice-group.com/home.html>
- ❑ <http://www.ROSconsortium.eu>







Karine Van de Velde  
ROSC, Secretary General  
Tel: +32 3 297 60 92  
Mobile: +32 478 327 562  
[karine@ROSCconsortium.eu](mailto:karine@ROSCconsortium.eu)  
<http://www.ROSCconsortium.eu>