



REACH Orphan Substances Consortium

ROSC

# REACH ORPHAN SUBSTANCES CONSORTIUM “ROSC”

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# What is ROSC?

= REACH Orphan Substances Consortium bvba  
= strategic partnership



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# ROSC services: registration

- ❑ SIEF communication
- ❑ Data and test gap analysis
- ❑ Exposure scenarios
- ❑ Risk assessment
- ❑ Preparation of REACH dossier: chemical safety report / IUCLID
- ❑ Review and / or preparation of safety data sheets
- ❑ Consortium formation / management
- ❑ Letter of access management
- ❑ (temporary) REACH help in general
- ❑ Classification and labeling (CLP)

# ROSC services: authorisation

- ❑ Socio-economic analysis (SEA)
- ❑ Analysis of alternatives (AoA)
- ❑ Risk management options analysis (RMOA)
- ❑ Cross industry consortium formation – horizontal approach starting from the use of the substance

# ROSC: a horizontal consortium

## ❑ Why 'consortium'?

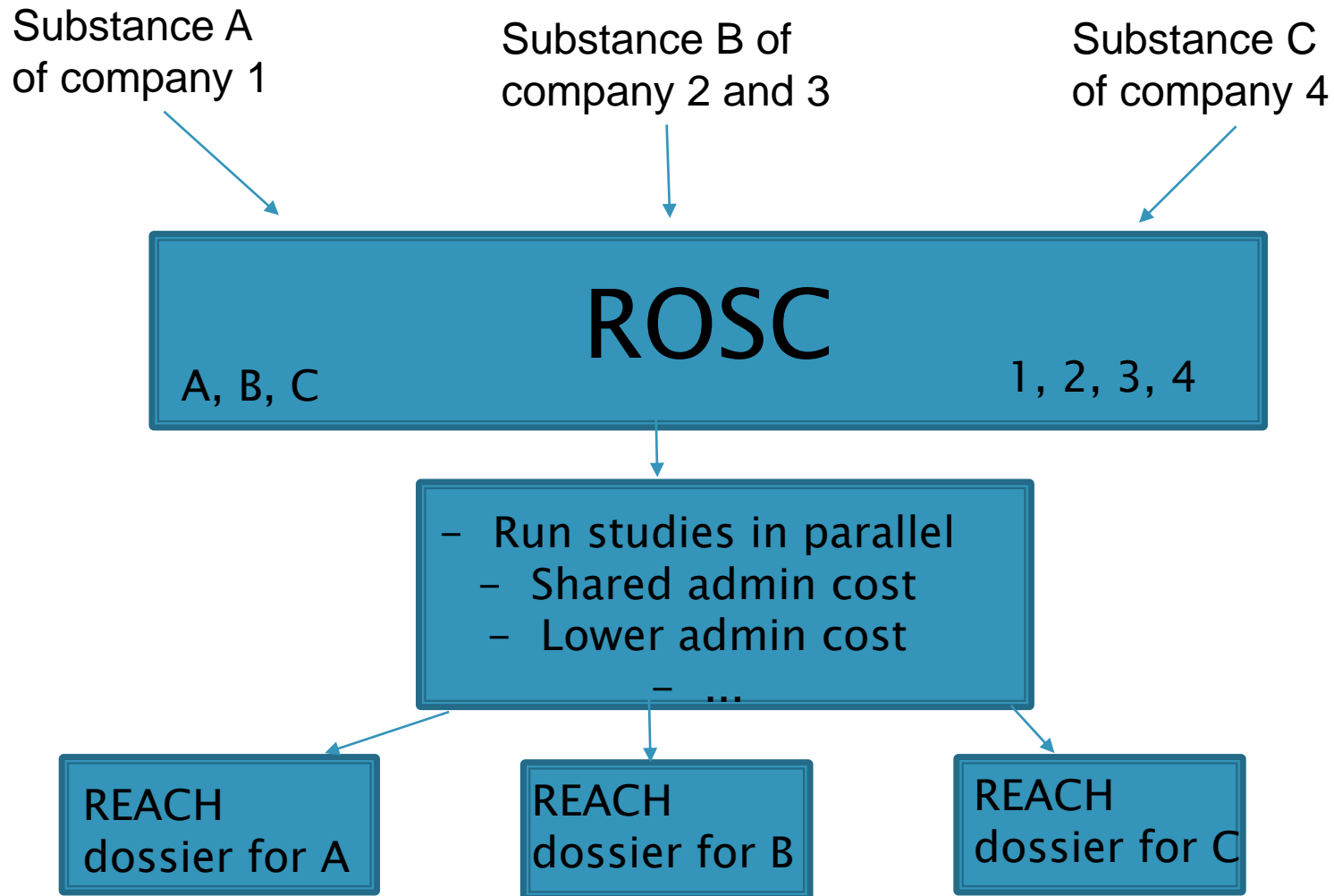
*A consortium is an association of two or more companies with the objective of participating in a common activity or pooling their resources for achieving a common goal.*

## ❑ Common goal = comply with REACH in a cost effective way!

## ❑ How can a consortium be more cost effective?

- Group metals / organics / inorganics
- Test substances in parallel => reduced lab cost
- Shared admin costs
- Create docs (legal and admin) – useable for all substances
- Run by experienced people – no expensive lawyers

# ROSC as horizontal consortium



# ROSC and registration

‘orphan’ = a REACH 2018  
eligible substance  
not covered  
by any organisation

Orphans can be metals / organics /  
inorganics



# How do you know if you have 'orphans'?

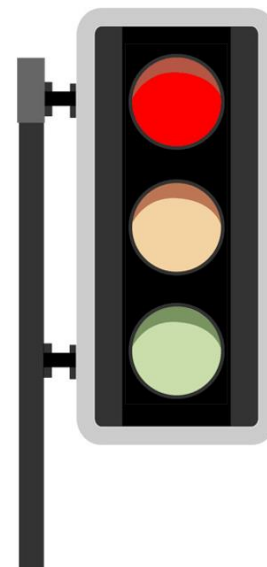
MAKE YOUR REACH INVENTORY NOW!!

- ❑ What do you manufacture / import?
- ❑ Which raw materials do you need?
- ❑ Which tonnages?
- ❑ Did you pre-register?
- ❑ Phase-in or non phase-in substances?
- ❑ What do you want to register?
- ❑ Substances under regulatory pressure => not worth investing in?



# Make your REACH 2018 inventory NOW!

- ❑ Substance = REACH registered
- ❑ Substance = being worked on
- ❑ Substance = orphan substance
  - Will your supplier register?
  - Do you have alternative suppliers or substances?
  - Do you need to register?



**BE PREPARED !!**

# Don't wait! Act now!

- ❑ 'orphans': START NOW!
- ❑ Contact the SIEF: Are there co-registrants? Somebody to share cost with?
- ❑ Do a scientific data gap analysis
- ❑ Will you need external help?

⇒ **Take a few hours to find out now!!!**

# Why start now?

- ❑ Spread costs over 2016-2018
  - Keep more substances on the EU market
  - Manageable for both SME's and multinationals
- ❑ Takes time to coordinate cooperation
- ❑ Avoid multiple initiatives
- ❑ Respect OSOR principle!!
- ❑ Availability of labs!
- ❑ Availability of consultants

=> Take informed and cost efficient decision!



# Help out the SME's!

- ❑ Focus on **SME's**:
  - 25% of registrants by 2018?
  - Help them step by step through the process together
  - Even if they don't have regulatory people in-house
  - We know their worries.
  - We speak their language!



# Advantages ROSC structure

- ❑ No membership needed
- ❑ No hassle:
  - No lengthy meetings to attend
  - No scientific discussions to listen to
- ❑ **Stepwise** approach:
  - REACH inventory
  - Co-registrants?
  - data gap analysis
  - Prepare REACH dossier (CSR / IUCLID)



**Anyone can take  
the first step!**

# Anybody can be lead registrant

- ❑ REACH work is done by ROSC
- ❑ 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!**



# ROSC structure – tasks registrants

- ❑ Clients decide PER SUBSTANCE on
  - Data and cost sharing
  - Ownership of rights and data
  - Choice of the lead registrant
  - Letter of access

=> Will be defined in a Working Group Agreement



# ROSC structure - tasks

- Secretariat:
  - Daily management
  - Prepare and control the budget
  - Coordinate preparation of the REACH dossiers
  - Build up ROSC
  - Trustee





# ROSC structure - tasks

- ❑ ARCHE and Chemservice:
  - Prepare REACH dossiers (1-10T or 10-100T)
    - ARCHE = metals / inorganics
    - Chemservice = organics / inorganics
  - Back –up for secretariat



# Summary

We can offer you cost efficient solutions!

We speak your language!

SME's are welcome!



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# Contact us for a free price offer!

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