



# REACH 2018

## How to share costs



Marko Sušnik  
Stakeholders' Day  
Helsinki, 31 January 2018

# UEAPME represents SME in Europe

---

- Umbrella organization for unions of SMEs
- European social partner
- 84 member organisations
- More than 12 million enterprises (50 million people)
- Highly horizontal
- More info: <http://www.ueapme.com/>



# WKÖ represents the Austrian economy

---

- Public body - chamber: based on the “Wirtschaftskammergesetz” (economic chamber act)
- Constitutional social partner in Austria
- All Austrian companies are members by law
- Represents their interests on a national and European level
- Executes part of the national educational system
- Manages Austrian foreign trade in over 140 countries
- More info: [www.wko.at](http://www.wko.at)



# Overview

---

- Quick basics
- Experiences, thoughts and recommendations
- Available support



# Quick basics

---

- REACH requires sharing of costs for...
  - ...animal-study-data
  - ...other studies by request of new entrands
- Data-/cost-sharing starts...
  - ...in a SIEF
  - ...with an inquiry
- Cost-sharing...
  - ...must be fair, transparent and non-discriminatory
  - ...is not a marketplace
  - ...must follow formalized minimum-standards



# What are typical costs for a substance?

- No one will answer you this straight forward...
- ... but still we have some numbers:
  - data-package for 1-10 t/a: € 30.000 to 70.000
  - data-package for 1-100 t/a: € 300.000 to 500.000
- However, don't forget the administration costs, those can sometimes almost double the costs.
  - e.g. one SIEF from 2010 had overall costs of approx. € 5 mio.
    - ~ 60% for data
    - ~ 40% for administration

# Cost-sharing is not a marketplace

---

- Every registrant pays his share - not more, but also not less!
- REACH-cost-sharing is not selling a donkey on the market:
  - Data-owners should get compensated for their costs
  - Data-owners should not set arbitrary and/or profit-oriented prices
  - Co-registrants should not haggle
  - Co-registrant should pay only for necessary data

# Cost-sharing is not a marketplace

- What if the price for my data-share is too high?
  - „Too high“ is relative
    - a very expensive dossier may be fair
    - a very cheap LoA may be unfair
    - but also the other way around

→ BUT: you can always ask for a **transparent break-down of the costs**; it is your legal right according to reg. (EU) 2016/9 (DS-reg)

→ **IMPORTANT: clearly communicate your doubts to the data-owner and give fact-based arguments**





# briefly...

---

... the DS-regulation:

- Commission Implementing Regulation (EU) 2016/9 [...] on joint submission of data and data-sharing
- Clarifies minimum-rules:
  - on transparency, fairness and non-discrimination
  - for a DS-agreement:
    - itemisation/justification of data and related costs
    - reimbursement mechanism
- Documentation needs (12y)
- Strengthens the OSOR\*-principle

(\*OSOR stands for One Substance, One Registration)



# Two main scenarios for 2018 to consider - I

- Entering an existing registration
  - Probably a letter of access (LoA) is the best option
  - Prices for a LoA should be pretty stable and transparent by now
  - You have any right **NOT** to accept an existing data-/cost-sharing-agreement; the DS-reg is very clear on that!
  - But you should have reasons for that, else you may slow down your registration-process unnecessarily
- **Do not “waive” your DS-reg-rights until you feel comfortable about the data-/cost-sharing-process for your substance!**



# Two main scenarios for 2018 to consider - II

---

- Starting a totally new registration
  - You will not have many partners; with 2 you are already lucky
  - Costs per registrant will probably be high, don't be surprised
  - Don't expect that things will just happen or will be done by others
    - Often there are no others, it's just you (and eventually the other guy from a totally different corner of the EU)
    - be proactive like there is no tomorrow, what is actually true, if you still want to make it until the deadline



# Cooperation is key

---

- Respect your co-registrant(s) and don't try to put them under pressure, probably you will have to co-operate much longer as you expect right now
- Reacting on the requests of others is obligatory and not only polite
- If you disagree, be transparent about your reasons and constructive when finding another solution
- Blocking a process will block the process for everybody, that includes you

# Co-registrant, defend your rights

---

- Pay only for that what is necessary to be compliant; make yourself well familiar with your specific obligations
- Make sure the quality of data is sufficient for your needs and considered in your financial contribution
- If you have your own data, you can use it, no need to pay twice
- If you have doubts about your financial contribution, ask questions, request a cost-breakdown
- No one can force you to waive your rights for a cost-breakdown (itemisation) and a reimbursement-scheme; do this only, if you are sure things are fair and transparent



# Some other aspects

---

- Be careful with confidential business information
  - only disclose what is necessary
  - you have mechanisms how to protect your information, get yourself informed before you act
- Respect competition law
  - some information is critical, don't exchange it
  - get yourself familiar with requirements of the competition law
  - put everything on paper
  - don't talk about business at dinner

# If things go wrong

---

- ECHA offers a dispute mechanism, use it
  - don't be scared, activating the dispute-mechanism is easy, you don't even need a lawyer...
  - ...it's more difficult to prove your case, so:
    - insist, if there is no answer
    - set (reasonable) deadlines
    - keep written notes to document your efforts
  - If you can present “your story”, ECHA can allow you to proceed with your registration



# Before things go wrong

---

## Get yourself familiar:

- with ECHA's Guidance on Data-/Cost-sharing
- the Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing
- In case you decide to look for professional support  
→ the DCG\* developed a "CHECKLIST TO HIRE A GOOD CONSULTANT"; you can find it on ECHA's webpage

(\*DCG stands for Directors' Contact Group)





# It was a pleasure talking to you



Marko Sušnik  
Austrian Federal Economic Chamber  
Department of Environment and Energy Policy  
E [marko.susnik@wko.at](mailto:marko.susnik@wko.at)  
T + 43 (0)5 90 900 4393

