

Working together with your co-registrants

11th Stakeholders' Day

25 May 2016

Daniel Sompolski



Working together brings benefits

- Shares the cost among all co-registrants of the same substance
- Minimises tests on animals
- It's fair

...and it's a legal requirement



But there are concerns...

REACH is too complex

I don't have time and resources

I will be off the market

I'm just a businessman, not chemist

I'll do it in 2018

I can't afford it

Working together with my competitors? Crazy...

Does SIEF and data sharing work?

On one hand side:

- Over **6 000** joint registrations so far, where data was successfully shared
- Under **1 %** escalated to ECHA as disputes

On the other:

- SMEs complain that data sharing principles not respected
- European Commission followed this up with an Implementing Regulation
- 2018 deadline will be different
 - Less data available – need to obtain new information
 - Role of the lead registrant – same as before?

Effective SIEF management and data sharing

- Keep it simple!
- Focus on getting things done
- Act in time
- Be fair in determining cost
- Be partners, not competitors



Sharing data and cost

- Not for profit
- The more people register, the less cost for everyone
- Must be fair, transparent and non-discriminatory



Transparency

Item	Tonnage band	Cost of study	Administration cost	Justification
Study 1	1-10 t	1 000 €	100 €	Justification 1
Study 2	1-10 t	2 000 €	80 €	Justification 2
Study 3	10-100 t	3 000 €	130 €	Justification 3
Token	N/A	-	50 €	Justification Token
SIEF	10-100 t	-	500 €	Justification SIEF

- Itemisation of data and **administrative** costs
 - Must be in relation to information requirements
 - Must be justified
 - Must be provided upon request without undue delay
- Cost-sharing model must include a reimbursement mechanism
- Co-registrants must agree on a **mechanism** for sharing future costs (e.g. spontaneous dossier updates, substance evaluation, dossier evaluation)

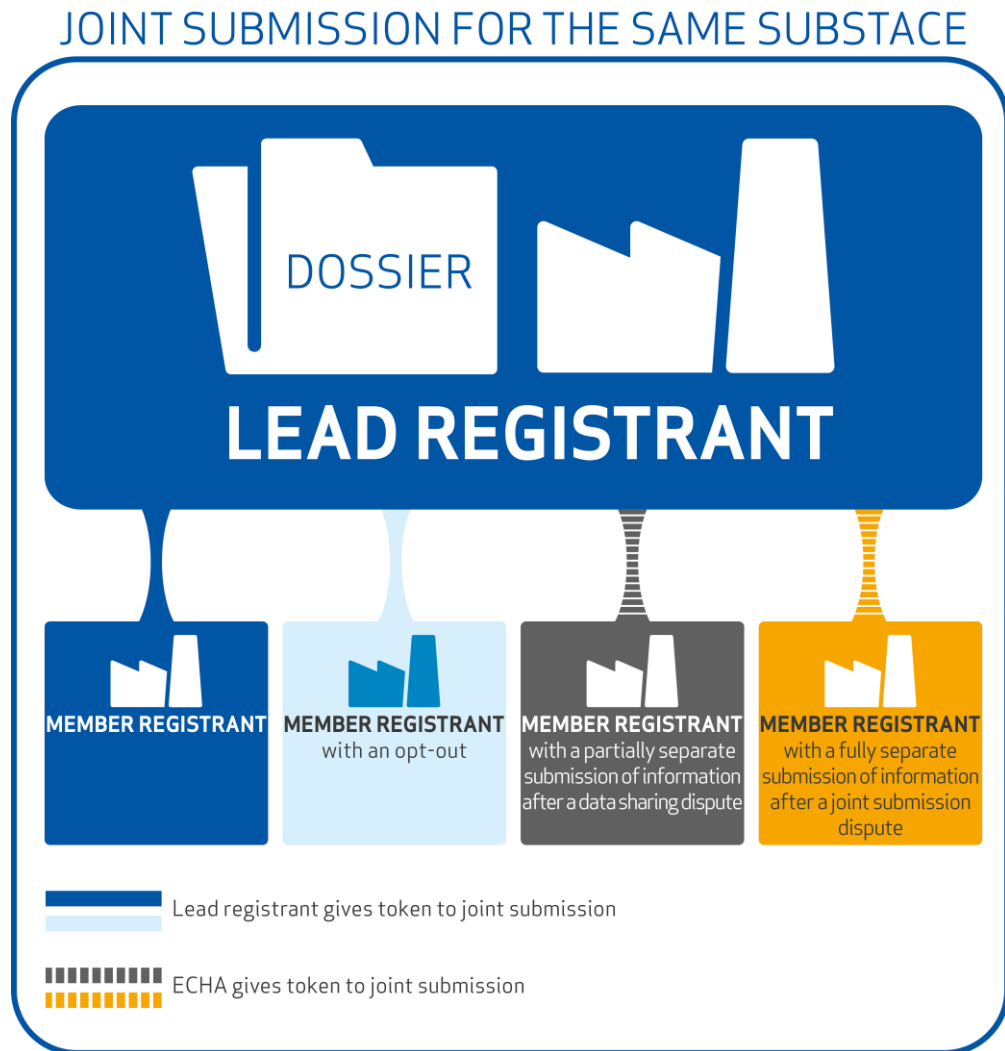
Fairness and non-discrimination

- Equal rights for all co-registrants
- Unanimous agreement needed for waiving from itemisation and reimbursement
- Model 'fair' in 2010 might not be 'fair' to 2018 registrants



Joint submission

- Typically all co-registrants agree and submit all information jointly
- Opt-outs
 - partial
 - full
- Disputes
 - on data
 - on token



Disputes

- Measure of last resort - every effort to be made first to reach voluntary agreement
- For free and no lawyer needed
- Can be on data or on token
- Reasons could be:
 - lack of transparent itemisation
 - discriminatory cost sharing mechanism (e.g. lack of reimbursement, not everyone pays its share)
 - price not dependent on information requirements
 - administration cost not related to tonnage band
 - unjustified annual increases of prices
 - risk premium applied on everything





Key messages

- Take the initiative in SIEFs that are crucial for your business – prioritise your most important substances
- Spend money and time on right substance – pay attention to substance sameness before kicking off data sharing
- Focus your discussions on getting things done
- Preparing a dossier is a shared and individual responsibility – check regularly that the work is progressing - don't just rely on the lead. Your registration is your "business card".
- Sharing data is not for profit – must be fair, transparent and non-discriminatory

Support from ECHA

- Practical advice for new SIEFs
- Joining an existing registration – negotiation tips
- Info about dispute mechanism
- Guidance on data sharing to be published in December 2016



<http://echa.europa.eu/reach-2018>

A video player interface for an ECHA webinar. The main content area has a blue background with the ECHA logo at the top left, followed by "REACH 2018 webinars" in large white text. Below this, it says "Get organised with your co-registrants - SIEF management and data sharing". The date and time "02 March 2016 11.00 - 12.00 Helsinki time" are listed. At the bottom of the main area are silhouettes of runners. On the right side, there is a video thumbnail of a man in a suit, with the text "ECHA Webinars" and "Get organised with your co-registrants" below it. The video player controls at the bottom show a play button, a progress bar at 0:05 / 1:11:37, and other standard controls.

Thank you!

daniel.sompolski@echa.europa.eu

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
[@EU_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)

