REACHLAW
COMPLIANCE. SUSTAINED.

27.10.2016 | REACHLaw Webinar

REACH COST SHARING

Implementing Regulation on Data Sharing - Implications

Welcome

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Some Practical Information for this Webinar

Let's make this webinar interactive:

1. You are able to send questions to us using the chat, please do that! We will answer your questions in Q & A, if possible.
2. Questions you have been sending in advance or during the webinar will be answered after the presentation by e-mail.
3. The presentation material will be distributed amongst the webinar participants

AND IN ANY CASE PLEASE SEND US FEEDBACK, THANK YOU!

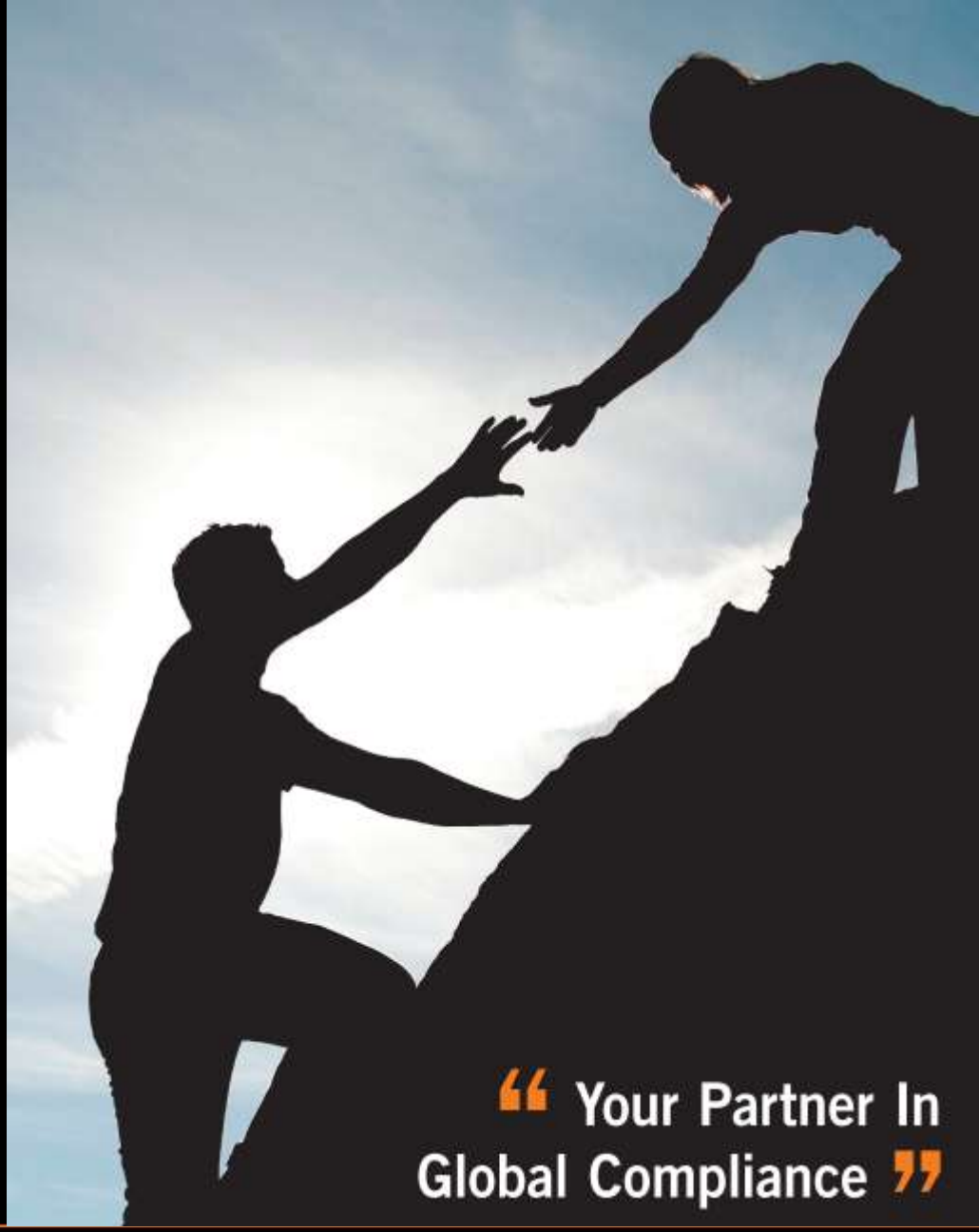
REACHLAW

What We Do

Global chemical regulatory compliance and product safety services

For our customers we provide:

1. **MARKET ACCESS** *Services*
2. **OUT-TASKING** *Services*
3. **DIGITAL SOLUTIONS**



REACHLaw in Brief

KEY FACTS ABOUT US

- ✓ Established in Helsinki
- ✓ Offices in Brussels, New Delhi and Istanbul
- ✓ 30+ toxicologists, chemists, lawyers, socio-econ. analysts, business and environmental specialists
- ✓ 20+ local partners in Europe, Asia, Latin-America and the USA
- ✓ 350+ REACH registrations by 2010 deadline, 5% of all OR
- ✓ Language support in 10+ different languages
- ✓ eSpheres investor
- ✓ More info at: www.reachlaw.fi

OUR CLIENTS

- ✓ More than 300 customers from 40+ countries, from Fortune 100 companies to SMEs.
- ✓ Major industries served: Oil, chemicals, specialty chemicals, metals, space sector and other downstream users (DU) industries, etc.
- ✓ Our customers are manufacturers, importers, traders, DU´s, industry associations and governmental organizations.

MARKET ACCESS

Strengthening your business globally.

Ready for EU REACH 2018?
REACH Authorisations affecting your Supply Chain?
How about Turkey KKDIK / SEA and GBF?
And what about Korea REACH or EU Biocides?

REACH LEAD REGISTRATION
REACH CO-REGISTRATION
ONLY REPRESENTATION
REACH AUTHORIZATION
ADVOCACY
SOCIO-ECONOMIC ANALYSIS
LEGAL SERVICES
MANAGEMENT CONSULTING
...and more

EXAMPLE SERVICES

✓ Global chemicals regulatory compliance for e.g.:

- REACH
- CLP
- Biocides
- Turkey KKDIK/SEA/GBF
- Korea REACH
- China REACH
- USA TSCA reform *(Coming)*
- Japan CSCL
- Thailand inventory *(Coming)*

✓ We prepare the required dossiers to authorities, SDSs, labels and provide related business strategy, legal and monitoring support.

OUT-TASKING

Focusing on your core.

Tired of registrations, notifications, dossier and endless SDS updates and worried about inspections? Why not outsource chemical regulatory tasks to REACHLaw's highly experienced outsourcing team? We guarantee sustained compliance!

EXAMPLE SERVICES

- ✓ Out-tasking compliance tasks to REACHLaw such as:
  - Notification & Registration
  - eSDS / SDS
  - Dossier maintenance
  - CLP compliance
  - Authority communications
  - IT systems
  - Supply Chain Compliance Checks
- ✓ We do all so that you can focus on your core business!

OUT-TASKING
PROCESS MANAGEMENT
FULL OUTSOURCING
REGULATORY MONITORING

...and more

1. THE 2010 DEADLINE AND FUNCTIONING OF DATA SHARING
2. BACKGROUND AND EXPECTATIONS AS SEEN BY ECHA
3. IMPLEMENTING REGULATION
4. NEGOTIATION ADVICE TO NEW REGISTRANTS: COURTESY ECHA
5. WHAT IF “NEGOTIATIONS” FAIL
6. ACTIONS TO EXISTING LR, CONSORTIA
7. ACTIONS TO NEW LR, CONSORTIA
8. SUMMARY

1. THE 2010 DEADLINE AND FUNCTIONING OF DATA SHARING

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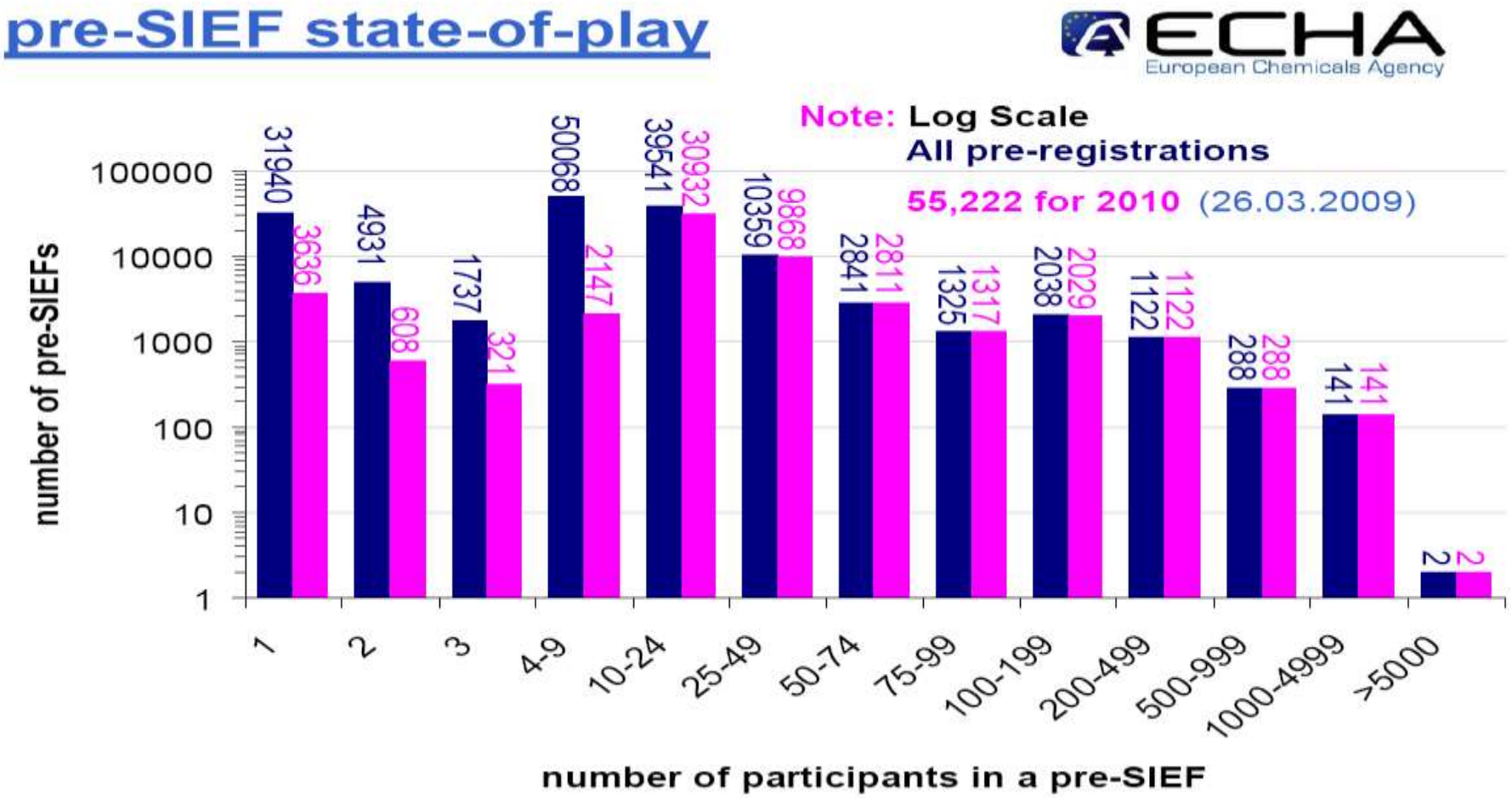
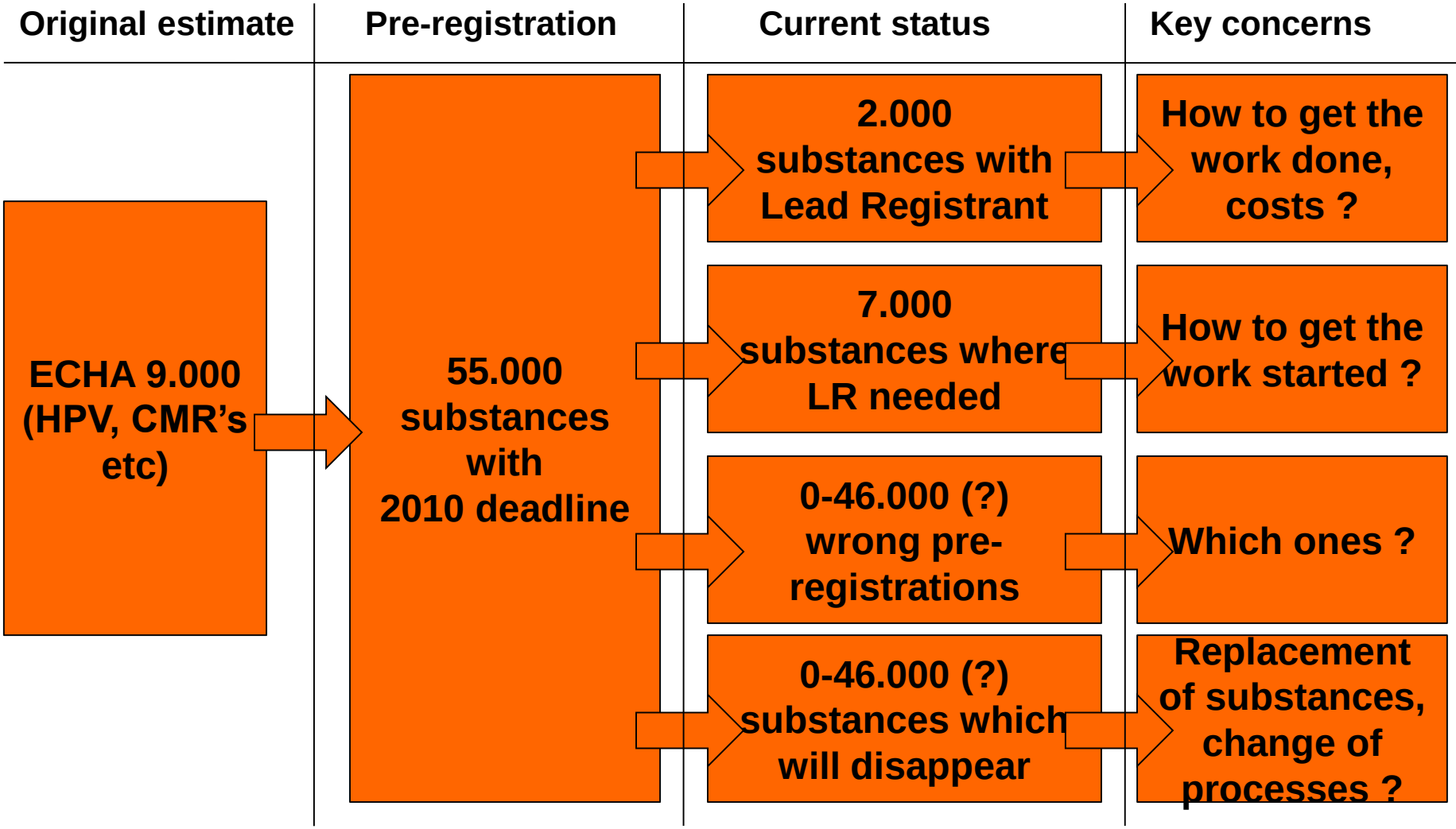
REACH – State of Play

(REACHLaw Lead Registrant Webinar March 2009)

ECHA Statistics: deadlines for registration



Some implications



Who needs to take the leading role ?

The very basic principle of REACH regulation:

- The industry has all responsibilities and major manufacturers are expected to take active role in the concrete work

ECHA

The ”clock is ticking campaign”

- Three elements
  - Trying to remove the barriers to effective SIEF working that many of you have identified
  - Raising awareness of the urgency of the need for action
  - Supporting Lead Registrants

REACH Cost Sharing: The Old vs. New
Old system and new focus

- Industry committed to REACH, and has made huge investments in the past
- Data sharing disputes rare.. No cases in Board of Appeal for a period of 12 months
- The Lead registrant / Co-registrants process with sharing of costs and rights through a Letter of Access has been robust and worked well .. Better than expected in early 2009 .. when focus was supporting LR's .. Before the deadline
- Now the focus is in Fair, Transparent and Non-discriminatory treatment of especially SME's .. Before the deadline
- (Evidence on the unfair treatment of SMEs? Price?)

2. BACKGROUND AND EXPECTATIONS AS SEEN BY ECHA

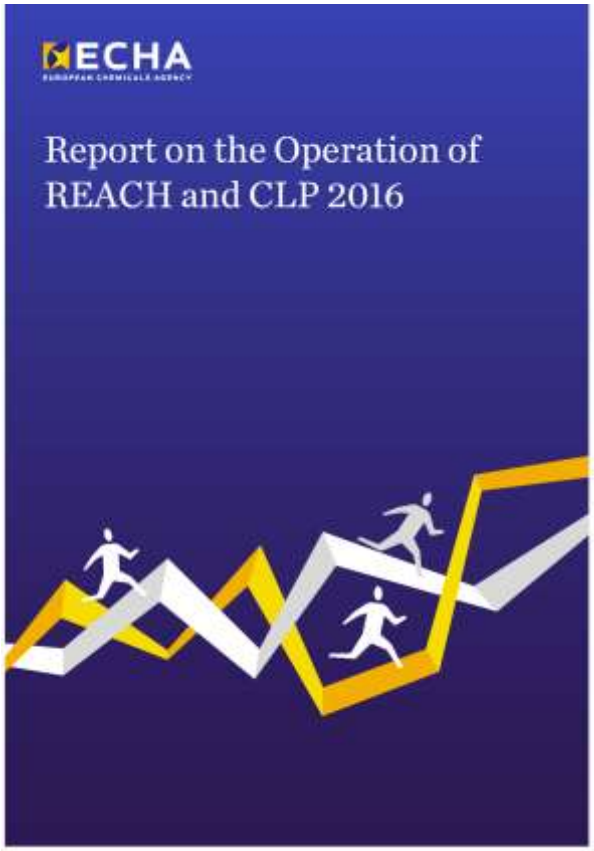
What do we expect in 2018?

	2010	2013	2018
Substances	~ 3 400	~ 3 000	up to 25 000
Dossiers	~ 20 000	~ 9 000	up to 60 000

- Situation in May 2016
  - ~ 5 700 registrations received for ~3 000 substances
  - ~ 70 % for substances produced outside the EU
    - 44 % importers, 25 % only representatives
  - 15% SME registrants
  - Top three countries:
    - Germany (31 %), UK (14 %), Netherlands (9 %)

REACH Cost Sharing: The Old vs. New

Background



Background and expectations
As seen by ECHA

SIEFs and data-sharing

Data- and cost-sharing were identified as major obstacles for SMEs in SIEFs in 2013[15]. ECHA and the European Commission reacted by providing advice and recommendations, in cooperation with stakeholders, on fair, transparent and non-discriminatory cost-sharing and data-sharing negotiations. The advice is available on ECHA's[16] and industry association websites.

This work was consolidated in a European Commission Implementing Regulation on the Joint Submission of Data and Data-Sharing of 5 January 2016[17]. The Regulation provides clearer instructions for potential and existing registrants to interact and a transparent breakdown of the costs and the differentiation between costs related to tests and SIEF administration[18]. The Regulation is therefore, expected to help newcomers to negotiate within SIEFs or with established consortia. It also mandates ECHA to ensure that registrants follow the joint submission principle of REACH.

Despite the above, ECHA still faces a number of challenges in the area of data-sharing. Firstly, the Agency does not have a complete picture of the data-sharing reality in SIEFs and therefore has difficulties assessing whether the relatively low number of data-sharing disputes is really a sign of good cooperation or just a result of under-utilisation of the process.

Background and expectations
As seen by ECHA

Secondly, the Implementing Regulation is expected to lead to an increase in the number of formal data-sharing disputes or a need for the Agency to otherwise support the new registrants because it provides more clarity to newcomers to exercise their rights in negotiations with existing registrants or consortia. As a result of the Regulation, ECHA is adapting its procedure for handling data-sharing disputes, but questions remain regarding the associated workload and timing. This may become an issue for registrants for meeting the deadline if the disputes become so numerous that they cannot be resolved in time to allow registration.

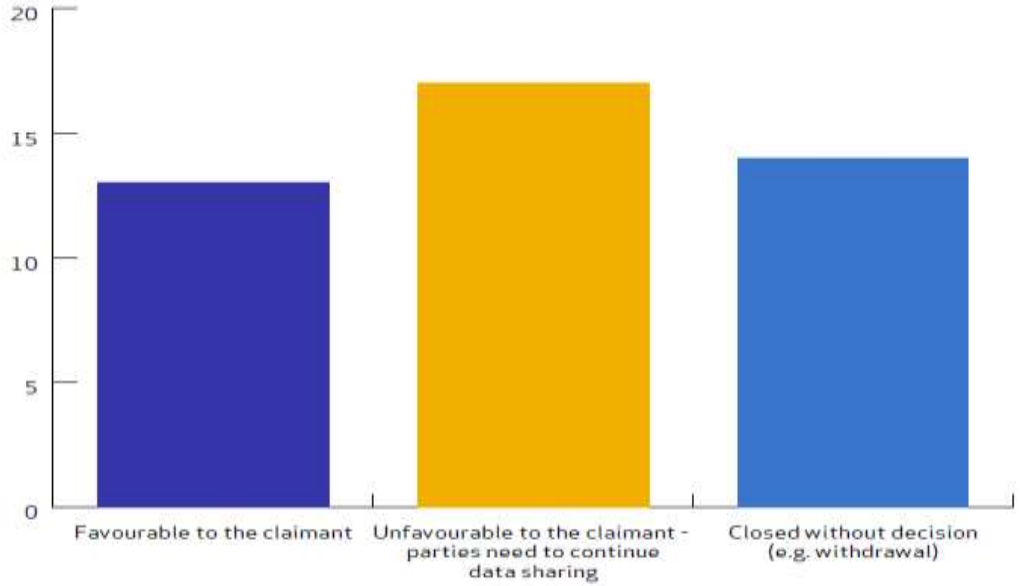
Background and expectations
As seen by ECHA

Figure 4. Number of data-sharing disputes submitted to ECHA

	2010	2011	2012	2013	2014	2015
Disputes on non-phase-in substances after inquiry	1	3	1	2	1	1
SIEF disputes (phase-in substances)	13	2	0	16	2	4
TOTAL	**14**	**5**	**1**	**18**	**3**	**5**

Background and expectations
As seen by ECHA

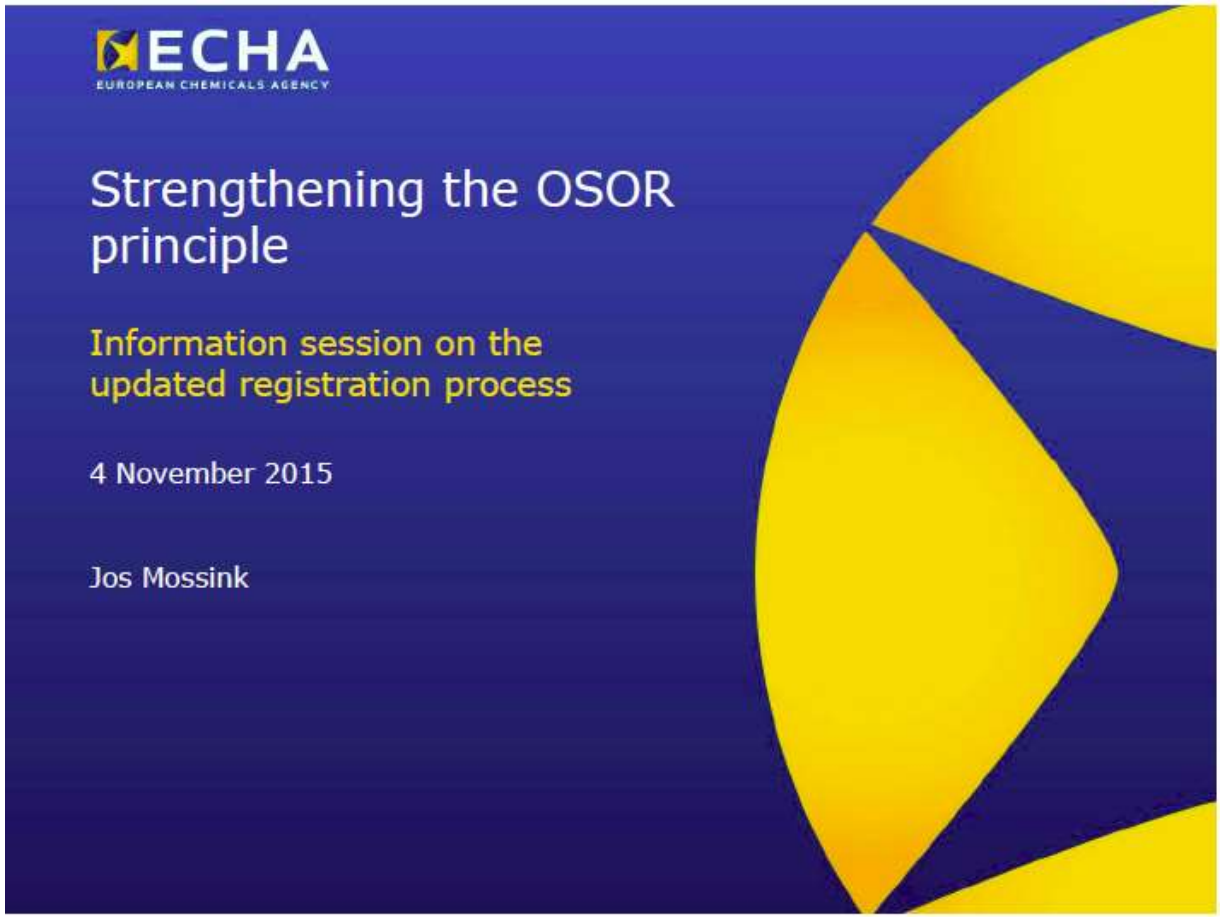
Figure 5. Outcome of the data-sharing disputes



When data-sharing disputes are submitted to ECHA, ECHA's role is to determine if the parties have made every effort to share data. When the decision is unfavourable (second column), it means that claimant has not made every effort. As the data-sharing obligation remains, parties need to continue data-sharing efforts. If the decision is favourable, every effort has been made to reach an agreement and the claimant receives permission to refer to the studies.

3. IMPLEMENTING REGULATION

Implementing regulation
Highlights



ECHA
EUROPEAN CHEMICALS AGENCY

OSOR
One Substance – One Registration

same substance

same information

ECHA
EUROPEAN CHEMICALS AGENCY

IR: what is it about (1/2)

- Transparency
  - Itemisation
  - cost-sharing model
  - documentation

- One substance, one registration
  - All registrants of same substance in one registration
  - ECHA to ensure
  - Full opt out possible

ECHA
EUROPEAN CHEMICALS AGENCY

IR: what is it about (2/2)

- Fairness and non-discrimination
  - Reimbursement mechanism
  - Equal rights to all members
- Dispute resolution
  - Access to joint registration
  - Efforts to come to an agreement

Main aim with the implementation

- Try to ensure that all registrants of the same substance (for the same registration type) are brought together.
- Limit the "easy way out" of submitting individually instead of dealing with the data sharing and the SIEF process.
- Ensure that there is a proportionate way forward for the registrants who are blocked.

4. NEGOTIATION ADVICE TO NEW REGISTRANTS: COURTESY ECHA

REACH Cost Sharing: The Old vs. New
Buying a Letter of Access vs. starting a "negotiation"

- In the previous deadlines a Co-registrant asked for a LoA price from the LR / Consortia
- The process was mostly not "individual negotiations", but of the price and process
- The Co-registrant had a clear registration intention

- In the following ECHA gives instructions for potential registrants on "LoA Negotiations" ..
  - Intentions of parties – a mixture of motives
  - If our negotiations fail I will make a claim ..
  - You have to: Justify
  - You have to: Make Every Effort

Practical advice (ECHA)

1. Ask for the price of data you need

The first step is to ask your co-registrant for the price of the data you need for the tonnage band you plan to register (considering the type of registration). You can negotiate access to individual studies or to all data that was already submitted. Normally, the price consists of costs related to tests (study costs) and costs related to administrative work (non-study costs). You will typically be able to purchase a Letter of Access (LoA), which gives you permission to refer to data you need for your registration. This could help you avoid lengthy and detailed negotiations, or make it easier for you to register by making use of documents that your co-registrants have already used and prepared. If you agree with the cost proposal you can proceed with your registration.

If you have questions or disagree with how the price was decided, you have the right to ask for explanations and justifications.

Please see all the practical advices given by ECHA via the following link:
https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations

5. WHAT IF “NEGOTIATIONS” FAIL

REACH Cost Sharing: The Old vs. New
What if “negotiations” fail

The new registrants can make a CLAIM against the data holder without cost … potentially leading into….

What if I have asked all my questions and am still convinced that the price is not fair, transparent or non-discriminatory?

Make sure you communicate clearly to your co-registrants why you consider the price to be unfair, non-transparent or discriminatory. As a last resort, if you cannot agree on data and cost sharing with your co-registrants, ECHA can assess your case. The data-sharing dispute procedure can be managed without legal support and is free-of-charge. You will only be asked to submit all records of your negotiations.

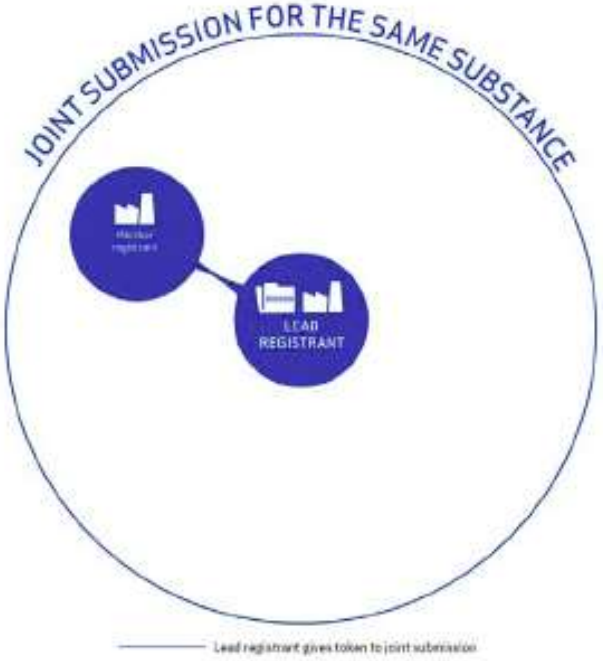
Before you submit a dispute to ECHA, you need to make sure that you are able to demonstrate that every effort has been made by you to reach an agreement, and that you have addressed all of your concerns directly with the other party. Once a dispute is filed, ECHA assesses the efforts made to reach an agreement on the sharing of data and its cost in a fair, transparent and non-discriminatory way, not the price as such and its appropriateness.

If ECHA finds that you made every effort to reach an agreement, while your co-registrants failed to do so, ECHA may grant you the permission to refer to the disputed data.

Typical joint submission

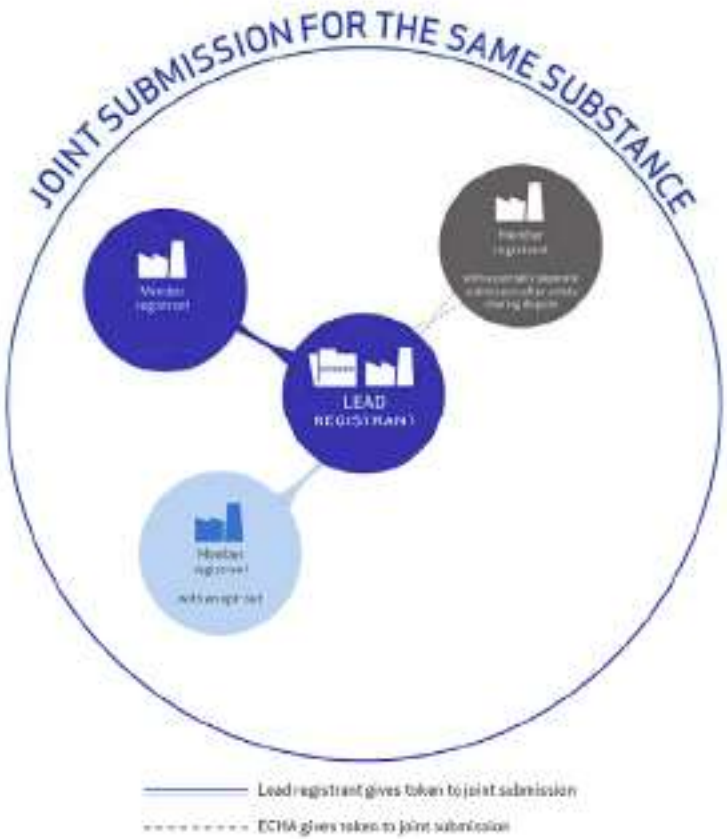
- Lead dossier
- Member dossiers
- Same information

- Lead provides token



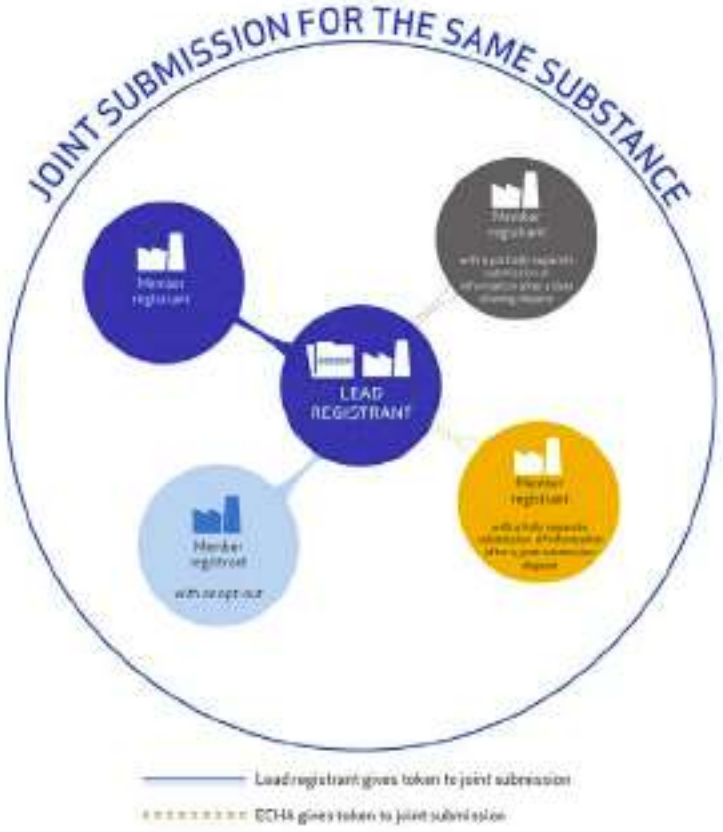
Data sharing dispute

- Partially separate submission after dispute
- Full opt out with all data is possible
- Dispute remains last resort



No data to share

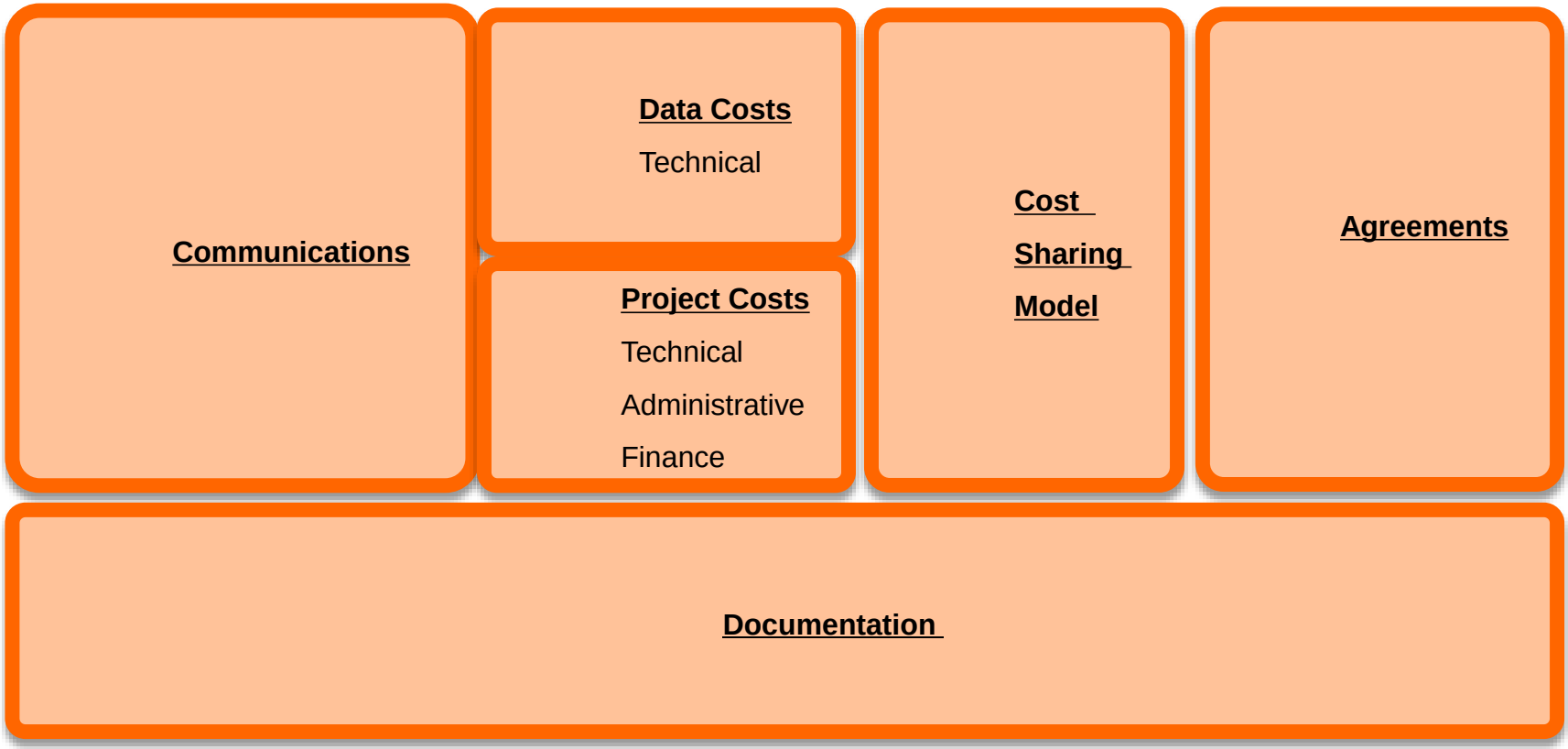
- Normally lead registrant provides token
- Echa may provide token
- Dispute is last resort



6. ACTIONS TO EXISTING LR, CONSORTIA

Actions to existing LR / Consortia

What you should do? Example - REACHLaw risk analysis



7. ACTIONS TO NEW LR, CONSORTIA

Lead registration is a significant challenge

Lead Registrant role and obligations

1. Coordinate the activities within the SIEF
2. Clarify substance identity
3. Conduct a data gap analysis and fill the gaps
4. Prepare a lead registration dossier
5. Submit the lead dossier of the joint submission.
6. Keep the joint dossier up-to-date and communicate with authorities

Lead registration is a significant challenge

Areas of expertise

Technical expert(s)	Administrative support	Legal expert	Financial expert
• IUCLID population • Hazard assessment • Exposure assessment	• SIEF communication • Information collection (data, uses, etc.) • Meetings & minutes • Record keeping	• Leadership agreements • SIEF agreements • Data sharing agreements • REACH legal advice • Competition law • Copyrights, IPR	• Cost sharing calculations • Budgeting and invoicing

Toxicologists | EHS experts | Legal | Financial

Chemists | Eco-toxicologists | Business | Administration | ...

What makes the 2018 REACH registrations unique

More substances, less information

- More inexperienced SMEs are involved -> need for support
- Less registrants per substance -> smaller SIEFS
- Less information available –> need for testing
- Mostly specialty chemicals

Higher risk than in 2010 / 2013 that certain substances remain unregistered due to lack of registrant's capability and / or resources to compile a registration file

What makes the 2018 REACH registrations unique

Information Requirements

Good news, less endpoints will need to be covered in 2018 compared to 2010 or 2013!

Tonnage bands	Annex VI	Annex VII	Annex VIII	Annex IX	Annex X
1-10 t/y	X	X			
10-100 t/y	X	X	X		
100-1000 t/y	X	X	X	X	
≥ 1000	X	X	X	X	X

FOR 2018 SUBSTANCES

+CSR

REACH Annex	Tonnage band	End points
VII	1 - 10	22
VIII	10 - 100	35
IX	100 - 1000	57
X	1000 +	65

Actions to 2018 lead registrants

Data and cost sharing – implications to LR

- Lead registrant has obligation to provide potential registrant with a cost breakdown of all relevant costs to be shared, both data-related and administrative costs
- A lot more work and extra administrative burden to data holders and Lead registrants.
- Document cost sharing model clearly
- If possible allocate all costs at end-point level
- Prepare for negotiations / explanations to justify the costs of registration
- The lead has obligation to establish a reimbursement scheme

…OR

Request for proposal from REACHLaw to cover all Lead Registration work

8. SUMMARY

REACH Cost Sharing

Summary

- For existing LR's
  - IR can be seen as a Retroactive legislation
  - The relative legal positions of the existing registrant and prospective registrant are not in balance ..
  - Issues of ownership, IP rights
  - It places a huge burden, without compensation, on existing LR's and Consortia – *Every Effort*. **Analyse past. Be prepared.**
- For new LR's the situations is better
  - **Prepare in advance.**
  - Creates an additional level of complexity for much less experienced LR's
- For the functioning of the Lead/ Co-registration
  - **Can create a systemic risk …**

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