



How to ensure transparency in cost sharing?

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Agenda

- Cost sharing obligations
- Cost sharing mechanisms
- Feedback from first registration phase
- Transparent cost sharing: recommendations
- Key messages

Cost sharing obligations

■ Requirement

- REACH: data / cost sharing obligation
- In practice: Dossier prepared and funded by the Lead Members and duty for the other co-registrants to financially compensate

■ Type of costs

- Data
- Administrative / technical work

■ Conditions

- **Transparent** i.e. you know what you pay for,
- **Fair** i.e. you pay only for what you need and,
- **Non-discriminatory** i.e. each registrant in the same situation should pay the same amount

Examples of costs

Consortium/SIEF costs

- Technical work: IUCLID5 Dossier preparation, CSR preparation, experts consultations
- All the activities done before the formation of the consortium
- Formation of the consortium
- Administrative activities: secretariat, handling of confidential information, operational costs
- SIEF management: communication, letters of access

Data costs

- All existing relevant data collected for the Dossier and owned by one or more registrants
- Newly generated relevant data jointly developed by the lead members
- Any existing relevant data owned by data holders

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Cost sharing mechanisms

- Several options in the **ECHA Guidance on Data Sharing** – section of examples

- Mechanism chosen depending on different factors
 - Size of the SIEF / Number of expected registrants per deadline
 - Availability / Quality of data
 - Substance already registered in 2010

- Any mechanism valid so long as:
 - Transparent, fair, non-discriminatory
 - **AND respectful of competition law requirements!**

Examples of cost sharing mechanisms

- ❑ Calculation of costs **before** each deadline
- ❑ Partial advance payment and **adjustment** at the moment of submission of the Dossier
- ❑ **Reimbursement** in 2013 to 2010 registrants and in 2018 to 2010/2013 registrants
- ❑ Optional **threshold** for reimbursement
- ❑ **Lump-sum** per category of registrants, based on sound estimations of number of registrants
- ❑ Share per **legal entity** or per group of legal entities (incl. affiliates)

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Feedback from first registration phase

- No harmonisation: wide range of approaches
- Lack of transparency
- Lack of understanding by co-registrants
 - Difficulty to evaluate the amount of work and the costs related
 - Complexity of cost calculation
- Complicating factors by cost sharing split at different levels
 - Substance level i.e. for substance specific work
 - Group of substances level i.e. for group related work/studies
 - Consortium level i.e. for administrative costs
- Calculation requires time

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Recommendations

- **Communicate**, explain, go into details, keep track of your expenses!
- Communication from the Lead Members to the Non-Lead Members
- Ensure transparency by sending
 - Explanation of cost sharing system
 - **Cover letter** to SIEF agreement
 - Early estimation of the costs if possible
 - Expected timing

Recommendations

- Describe very clearly the **administrative costs and the technical work** e.g.
 - Type of work: technical or administrative
 - Cost per hour of work, number of hours

- Define very clearly **the rights granted in each case** and the cost associated e.g.
 - Access rights i.e. right to use or to refer* / co-ownership
 - Rights for REACH only* / any regulatory purposes / for any purposes
 - Non-transferable rights* / transferable rights
 - Copy of (robust) study summary* / copy of full study report

* Recommended options under the CEFIC model SIEF agreement

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Key messages

In order to succeed in 2013 remember that

- ✓ Cost sharing is an obligation
- ✓ Transparency is a condition to fulfil the obligation

Therefore

- ✓ Choose your cost sharing mechanism early on
- ✓ Communicate clearly in the SIEF

Thank you !



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