



SIEF Challenges and Solutions

ECHA's Seventh Stakeholders' day

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Agenda

- A Challenge?
- SIEF Formation and Administration
- Data and Cost Sharing
- Contractual Framework
- Key Messages

A Challenge?

SIEF Challenges? or **SIEF Opportunities!**

- ✓ Up to industry to show safeness of substances
 - ❖ Burden of proof
 - ❖ It's your dossier

- ✓ SIEF formation and administration entirely belong to registrants
 - ❖ Need to find consensus
 - ❖ Flexibility

- ✓ Good news in 2013, it has all been experienced in 2010
 - ❖ No need to re-invent the wheel
 - ❖ Get acquainted with lessons learned by 2010 registrants

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SIEF Formation and Administration

Follow a pragmatic approach

- ✓ Agree on the sameness of substance
 - ❖ Verify whether the surrounding SIEF could potentially merge
 - ❖ Split if your substance is different

- ✓ Identify yourself per the SIEF code system
 - ❖ Define your substance strategy internally
 - ❖ 1. Lead Member, 2. Active, 3. Passive, 4. Dormant

- ✓ Nominate a Lead Registrant

- ✓ Be ready when approached by the Lead Registrant
 - ❖ Prepare your own substance ID
 - ❖ Communicate

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Data and Cost Sharing

Aim of SIEF: facilitate exchange of information

- ✓ One rule: be fair, transparent and non-discriminatory
 - ❖ **Transparent** i.e. you know what you pay for
 - ❖ **Fair** i.e. you pay only for what you need
 - ❖ **Non-discriminatory** i.e. each registrant in the same situation pays the same amount

- ✓ Define **precisely** the rights granted and the cost calculation model

- ✓ Make **all efforts** to reach an agreement on data and cost
 - ❖ Be responsive
 - ❖ Address your concerns to ECHA in case of failure

- ✓ Overarching umbrella: **EU Competition Law**
 - ❖ Do not exclude competitors
 - ❖ Do not exchange commercially sensitive information between competitors
 - ❖ Do refer to EU Competition Law Do and Don'ts of Cefic

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Contractual Framework

No indication in REACH on how to operate within a SIEF

Keep it simple... and standardized

- ✓ SIEF Agreement
 - ❖ Between the Lead Registrant and the SIEF members
 - ❖ Defines obligations and liabilities of the Lead Registrant
 - ❖ Provides legal framework for SIEF members, who by nature rely on the Lead Registrant

- ✓ Consortium Agreement
 - ❖ Between the Lead/Active members of the SIEF
 - ❖ Defines responsibilities, task forces, data and cost sharing
 - ❖ Creates synergies for a group of companies to prepare one or several dossiers

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Key Messages

- Remember the opportunity
- Start early
- Use the ECHA Guidance on Data Sharing
- Use model agreements of industry associations
- Communicate, communicate, communicate!

Thank You !

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