Lead Registrant Webinar
Data Sharing & Dissemination

Introduction to Data Sharing

30 April 2010
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Overview of Key principles

- Why share data
- Who is expected to share data
- 12-year rule
- Sharing of costs
- Access versus ownership
- When to share data
- Role of ECHA

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Why share data

• To prevent **unnecessary testing**
  – Mandatory sharing of vertebrate animal data
    • “In order to avoid animal testing, testing on vertebrate animals for the purpose of this Regulation shall be undertaken **only as a last resort**”
    – It is also necessary to take measures limiting duplication of other tests.”

• To **jointly submit information** - Obligation of “OSOR: one substance, one registration”
  – Intrinsic properties of the substance
  – Classification and labelling (even if different among members)
  – Testing proposal (if any)
  – Also, if they agree, can submit jointly CSR / Guidance on safe use

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Who is expected to share data

• Potential registrants
  – Manufacturers
  – Importers
  – Only Representatives, …

• Previous notifiers / registrants

• Early registrants

• Data Holders (eg. PPP/ biocides)

• Third Party (eg DUs)

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12-year Rule

• Date of submission

• For (robust) study summaries submitted in the framework of a registration

  – Can be used for the purpose of registration by another manufacturer or importer

  – Is the period of data protection, for which compensation of costs can be claimed
Cost sharing of data

• Submission at least 12 years previously
  – No compensation

• Submission less than 12 years ago
  – Compensation
    • Must request vertebrate data
    • May request non-vertebrate data
    • Determined in a fair, transparent, non-discriminatory way

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Access versus Ownership

• Data access
  – Not automatically available for use in registration

• Data ownership
  – Legitimate possession for use in registration
  – Data owner gives permission to use information

• Copyright and data protection provisions

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When to share data

• Upon request
  – SIEF member shall inquire whether a relevant study is available within the SIEF
    • Shall request that study if it involves tests on vertebrate animals
    • May request that study if it does not involve tests on vertebrate animals

  – Within one month of the request
    • The owner of the study shall provide proof of its cost
    • The owner of the study shall make every effort to ensure agreement on cost sharing (*fair, transparent and non discriminatory way*)

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Duty to share

Phase-in substances

- Pre-registration
- Data sharing in SIEF
- Registration (JS)

Non phase-in substances (mainly)

- Inquiry
- Data sharing

Notified substances; Not pre-registered phase-in

Requirements under Art. 11 & 25

Substances regarded as being registered + DH, others

Information available in the Agency

http://echa.europa.eu
Role for ECHA (1)

- SIEF formation/ management under industry responsibility
  - Outside of ECHA’s remit
  - ECHA Commitment to support LR – improve communication
    - LR database based on your input
    - Facilitation of contact between SIEF actors and LR

<table>
<thead>
<tr>
<th>Substance subject of request as displayed in the list of active Lead Registrants</th>
<th>EC number *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact details of requester</td>
<td>Name of requestor *</td>
</tr>
<tr>
<td></td>
<td>Organisation *</td>
</tr>
<tr>
<td></td>
<td>E-mail address *</td>
</tr>
<tr>
<td></td>
<td>Phone number</td>
</tr>
<tr>
<td>Role of the organisation under REACH</td>
<td>Potential registrant</td>
</tr>
<tr>
<td></td>
<td>Data holder</td>
</tr>
<tr>
<td></td>
<td>Downstream User</td>
</tr>
<tr>
<td></td>
<td>Early Registrant</td>
</tr>
<tr>
<td></td>
<td>Other (please specify):</td>
</tr>
<tr>
<td>Explanation of the request</td>
<td>...Indicate in a few lines the reason and your interest in getting into contact with the substance above-mentioned...</td>
</tr>
<tr>
<td>Date of request</td>
<td>4/27/2010</td>
</tr>
</tbody>
</table>
Role for ECHA (2)

• SIEF formation/management under industry responsibility
  – ECHA Commitment to support DUs – improve communication
• Downstream Users feedback/confirmation of registrations in 2010

Role of ECHA when disagreement in sharing data
  – Communication to be recorded
  – ECHA = arbitration role

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