Get ready for 2018
Meeting your information requirements

11th Stakeholder’s Day

25 May 2016

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Key messages

• It takes time
• Get organised
• Know your requirements 2018
• Use help from ECHA
• Look for expertise and tips

✓ No need to reinvent the wheel
It takes time

- Know your portfolio
- Make business decisions for your substance(s)
- Understand how to gather information
  - Uses
  - Identity substance
  - Properties
- Get help
Get organised

• Ask the right questions
  • Is my substance already registered?
  • Are there other registrants for my substances?
  • What level of information do I need to submit?
    • Annex VII or Annex VII+VIII?
    • Can I benefit from some reduced requirements?

• Find the right help
  • Reserve resources: time/staff
  • Understand the information you need
    • ECHA Roadmap 2018 pages/Practical Guides
  • Find how to get information/support
    • Own lab/literature
    • External provider
... so you can achieve

- Awareness
- Understand your requirements
- Prioritise your substance/
  Find own data
- Work together in SIEF
- Fill your data gap
- Prepare information of quality

2018
1-10 tonnes - requirements

Information on phys-chem, environmental and mammalian properties

• Not all are necessary in one dossier
• Testing on animals as last resort - one test
• Low risk substances
  • Possible reduced dataset
  • Fee waiver if all data submitted

http://echa.europa.eu/regulations/reach/registration/information-requirements
10-100 tonnes - requirements

Information on environmental and mammalian properties

- In addition to previous information
- Animal testing as last resort
  - Recent changes in requirements
  - Less tests on animals
  - Consider alternatives first
  - Smart testing strategies
- Ensure completeness and quality
- Relevance, adequacy and reliability

### Information required for standard registration of 10-100 tonnes a year (Annex VIII of REACH)

<table>
<thead>
<tr>
<th>Non-vertebrate animal endpoints</th>
<th>Vertebrate animal endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>In vitro</em> mutagenicity study in mammalian cells or <em>In vitro</em> micronucleus study</td>
<td><em>In vivo</em> skin irritation*</td>
</tr>
<tr>
<td><em>In vitro</em> gene mutation in mammalian cells</td>
<td><em>In vivo</em> eye irritation*</td>
</tr>
<tr>
<td>Activated sludge respiration inhibition test</td>
<td>Testing proposal for <em>in vivo</em> genotoxicity (if applicable)</td>
</tr>
<tr>
<td>Degradation</td>
<td>Acute toxicity: inhalation/dermal**</td>
</tr>
<tr>
<td>Hydrolysis</td>
<td>Short-term repeated dose toxicity (28-day)</td>
</tr>
<tr>
<td>Adsorption/desorption screening</td>
<td>Screening for reproductive/developmental toxicity</td>
</tr>
<tr>
<td></td>
<td>Short-term toxicity on fish or testing proposal for long-term toxicity on fish (if applicable)</td>
</tr>
</tbody>
</table>
Help from ECHA

- Guidance
  - Pathfinder to Guidance on information requirements and chemical safety assessment
  - Updated use description guidance, framework for exposure assessment, worker, consumer and environmental exposure assessment

- Tools to find and organise information
  - IUCLID 6 and REACH-IT
  - OECD QSAR Toolbox
  - Chesar for chemical safety assessment and reporting

- Dedicated pages on ECHA’s website
  - Testing methods to be used
  - Alternatives
Look for appropriate expertise

- Consider use of expert services
  - National helpdesks
  - Industry associations
  - Existing registrants
  - Service providers
- Expertise needed
  - Chemistry + process substance
  - (Eco)toxicology
  - Regulatory + IT
- No need to reinvent the wheel
  - Investigate and find what you jointly need in SIEF
  - Remain critical, and business-realist
Look for our tips

✓ ECHA to help - practical support
  • Targeted practical Guides and Manuals
  • Low risk substances: reduced data requirements
    • Inventory of substances not suitable
  • Sector use maps
    • Indicate typical uses and conditions of use in the sector
  • Mainstream messages + Q&As

✓ Improved access to information
Guide for SME managers

- Advice tailored to business managers
- Simple-term explanations of the information requirements for 1 to 10 tonnes/year and for 10 to 100 tonnes/year registrations
- Reference document for future business decisions
Guide on how to use alternatives to animal testing

- All-in-one advice tailored to registrants
- Make best use of the opportunities REACH offers
- Key messages on obligations and supporting business decisions
Follow the REACH 2018 Roadmap implementation:

http://echa.europa.eu/reach-2018
To take home

- Registration is challenging but manageable
- It takes time to be ready by 2018
- Animal testing is the last resort
- ECHA can support you
Thank you
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