

Dossier Submission

How to support your members

Lead Registrant Workshop

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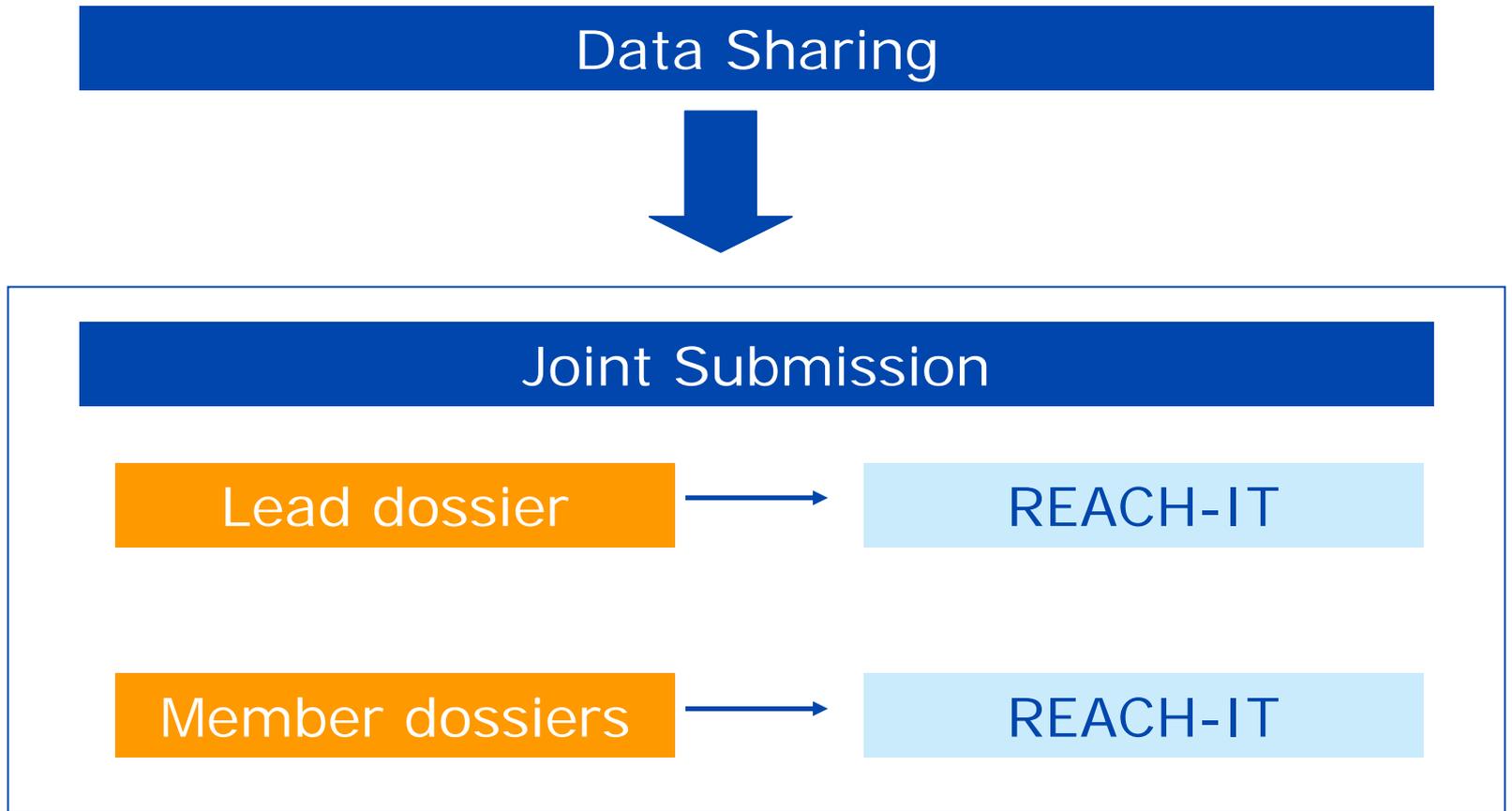


Dossier submission

How to support your members

- Overview
- Building the dossier in IUCLID
- Important steps in REACH-IT
- Key ideas

Overview



Building the dossier in IUCLID

How to best support your members



Building the dossier in IUCLID

- Substance identifiers must be exactly the same
- Preparation of draft basic dataset in IUCLID for members
- Highlight information which needs to be filled in by each member
 - Composition, analytical data
 - Tonnage, uses

Building the dossier in IUCLID

Lead



Query results | Section tree

REACH Registration above 1000 tonnes

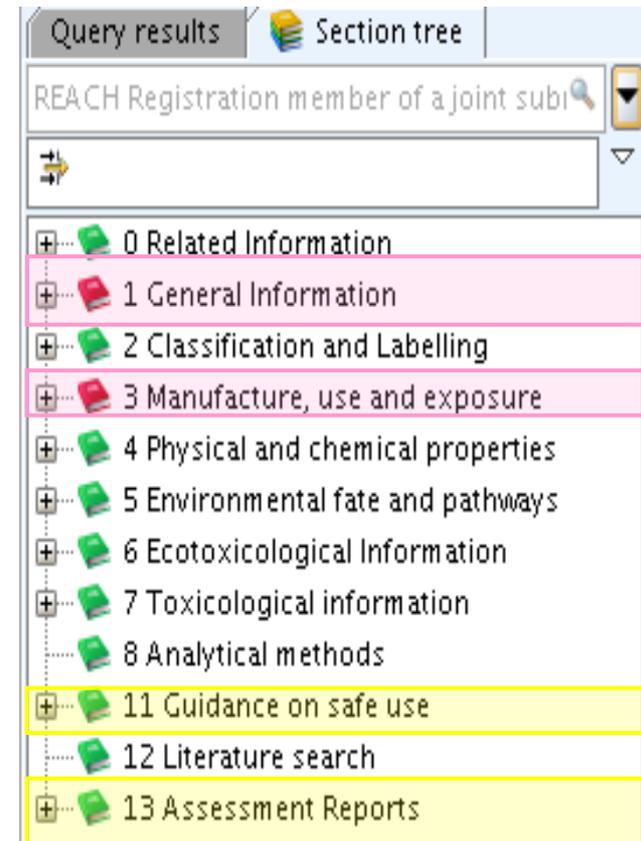
- + 0 Related Information
- + 1 General Information
- + 2 Classification and Labelling
- + 3 Manufacture, use and exposure
- + 4 Physical and chemical properties
- + 5 Environmental fate and pathways
- + 6 Ecotoxicological Information
- + 7 Toxicological information
- + 8 Analytical methods
- + 11 Guidance on safe use
- + 12 Literature search
- + 13 Assessment Reports

Private data submitted by the **LEAD and the MEMBER**

Data submitted only by the **LEAD** (if not opted-out)

Data submitted either by the **LEAD** or individually

Member



Query results | Section tree

REACH Registration member of a joint sub

- + 0 Related Information
- + 1 General Information
- + 2 Classification and Labelling
- + 3 Manufacture, use and exposure
- + 4 Physical and chemical properties
- + 5 Environmental fate and pathways
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Building the dossier in IUCLID

The screenshot displays the IUCLID software interface for building a dossier. The left-hand navigation pane shows a tree structure with '1.1 Identification' highlighted in red. The main window is titled 'Substance: Benzene / Benzene / benzene / 71-43-2 / European Chemicals Agency / Helsinki / Finland'. It contains several sections: 'Substance identification' with fields for Chemical name, Public name, Legal entity flags, Legal entity, Third party flags, and Third party; 'Role in the supply chain' with Role flags and checkboxes for Manufacturer, Importer, Only representative, and Downstream user; 'Reference substance' (circled in red) with a table of identifiers: EC number (200-753-7), EC name (benzene), CAS number (71-43-2), CAS name (benzene), and IUPAC name (benzene); and 'Type of substance' with dropdowns for Composition (mono constituent substance) and Origin (organic).

- Substance identifiers provided to members



Building the dossier in IUCLID

Substance: Benzene / Benzene / benzene / benzene / 71-43-2 / European Chemicals Agency / Helsinki / P

Substance composition

Benzene

Name: Benzene

Brief description: Mono constituent

Composition ID: L-c3431c64-95ba-4f9e-b1fc-1cf24d2ee19e

Degree of purity: 99.8 % (w/w)

Constituents: > 99.8 % (w/w)

Impurities: ca. 0.1 thiophene

Navigation: REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
- 1.1 Identification
- 1.2 Composition**
- 1.3 Identifiers
- 1.4 Analytical information
- 1.5 Joint submission
- 1.6 Sponsors
- 1.7 Suppliers
- 1.8 Recipients
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
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- But Composition and Analytical Data are company specific!

Substance: Benzene / Benzene / benzene / benzene / 71-43-2 / European Chemicals Agency / Helsinki / P

Analytical information

Analytical methods and spectral data: Description of analytical methods is provided in the attachment.

Optical activity

Results of analysis: GC

Navigation: REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
- 1.1 Identification
- 1.2 Composition
- 1.3 Identifiers
- 1.4 Analytical information**
- 1.5 Joint submission
- 1.6 Sponsors
- 1.7 Suppliers
- 1.8 Recipients
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- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods

Building the dossier in IUCLID

- Joint CSR? Decide well in advance
- Submission system allows flexibility
 - Fully joint CSR
 - Partially joint CSR
 - Part A
 - Part B



Building the dossier in IUCLID

- Finally, remind them to use these key tools:
 - TCC tool - checks completeness of dossier
 - Fee calculator - estimates fee to be paid
 - Dissemination tool - simulates information to be published

 **TCC tool**
Technical completeness check
[Run](#)

 **Fee Calculation**
Calculate the fees for a REACH dossier
[Calculate](#)

 **Dissemination tool**
Simulate what will be published
[Run](#)

Important steps in REACH-IT

How to best support your members



Important steps in REACH-IT

- Joining the joint submission in REACH-IT
 - Members need name of joint submission and security token
- Submission of member dossiers
 - After lead dossier accepted in the system
 - Before 31 May 2013!
- Recommended - Lead dossier submitted latest Q1 2013



Important steps in REACH-IT

- Keeping track of key steps in REACH-IT
 - Dossier accepted
 - Invoice opened
 - Result of completeness check
 - Registration number issued



Key ideas

How to best support your members



Key ideas

- Consider preparing a draft IUCLID substance dataset for members
- Checklist of key actions for members:
 - ✓ Highlight specific details members need to enter in IUCLID
 - ✓ If not joint CSR, remind them to start working on it well in advance
 - ✓ Remind them of the tools they should use before submitting
 - ✓ Joining joint submission in REACH-IT as soon as token is received from lead.
 - ✓ Submit dossier after the lead, but before 31 May 2013

Thank You!

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