Dossier Submission

How to support your members

Lead Registrant Workshop

2 February 2012

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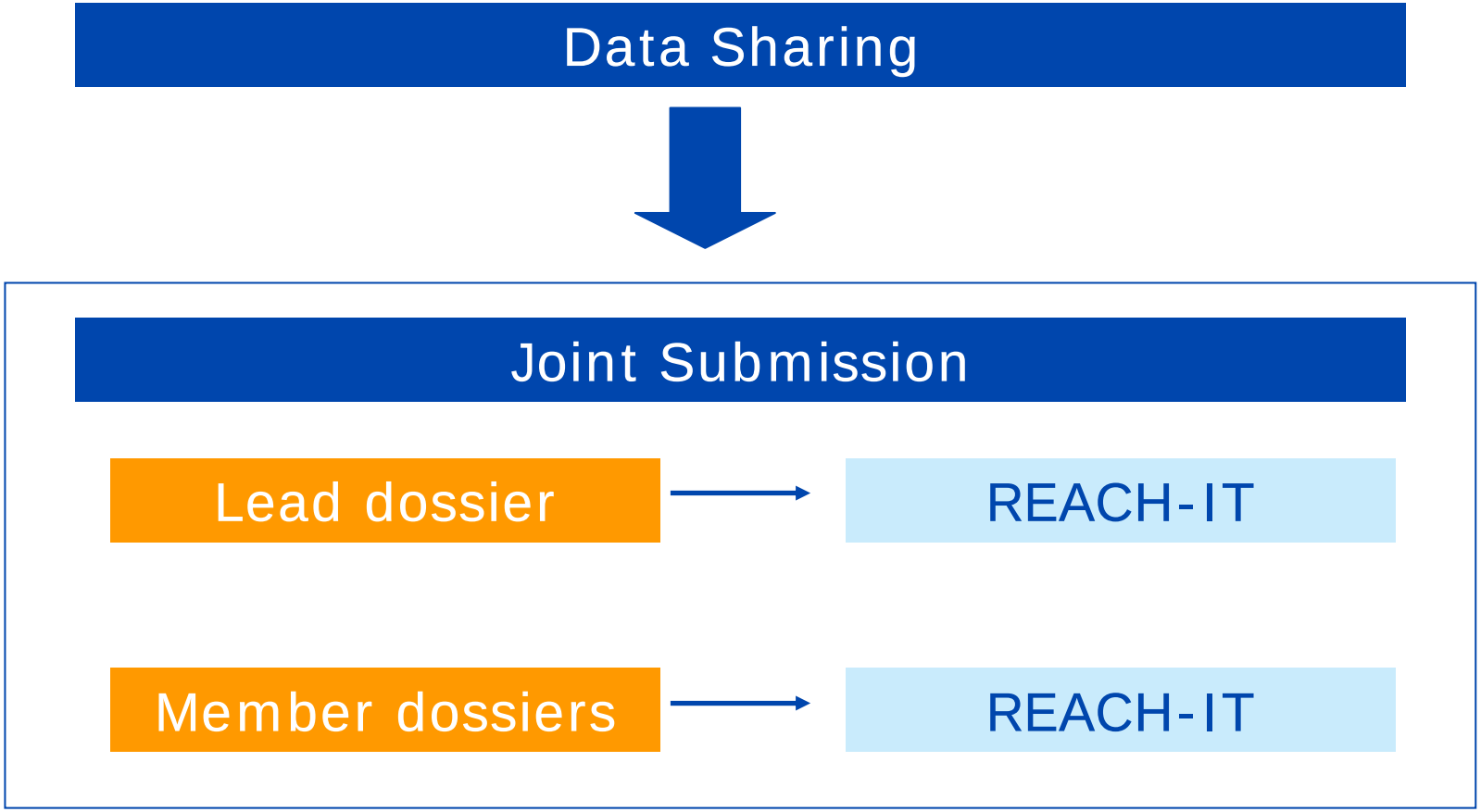
Dossier submission

How to support your members

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

Overview


Data Sharing
Joint Submission
Lead dossier
REACH-IT
Member dossiers
REACH-IT

Building the dossier in IUCLID

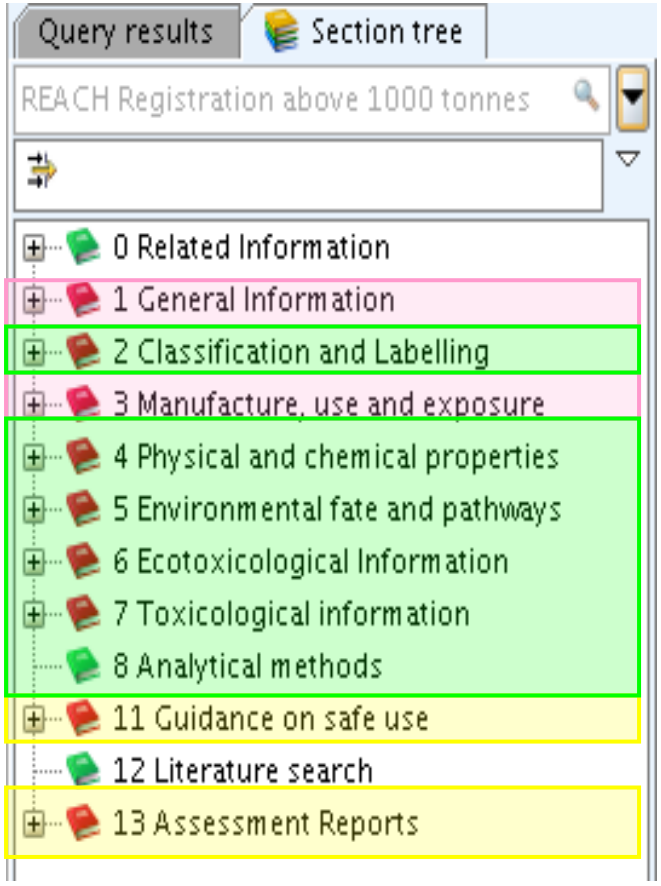
How to best support your members

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

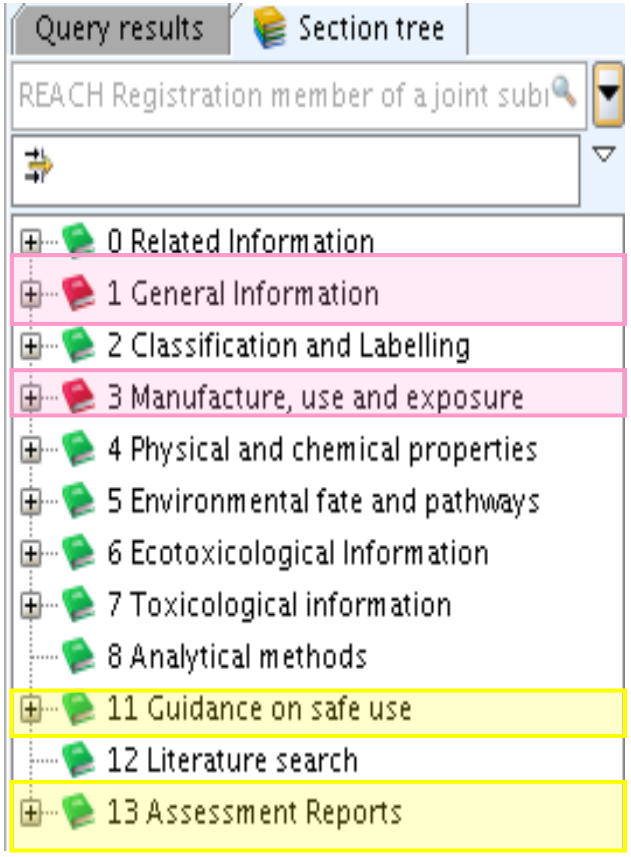


Private data submitted by the LEAD and the MEMBER

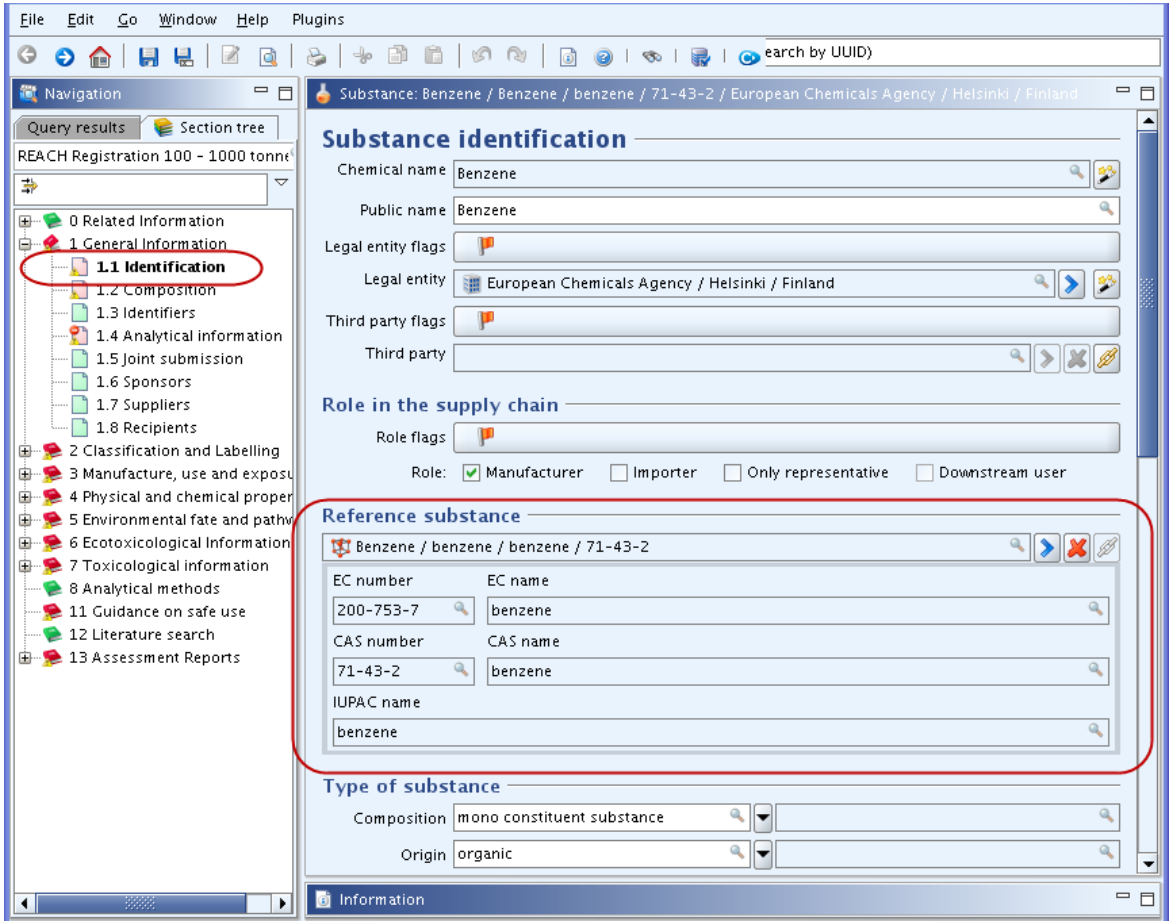
Data submitted only by the LEAD (if not opted-out)

Data submitted either by the LEAD or individually

Member

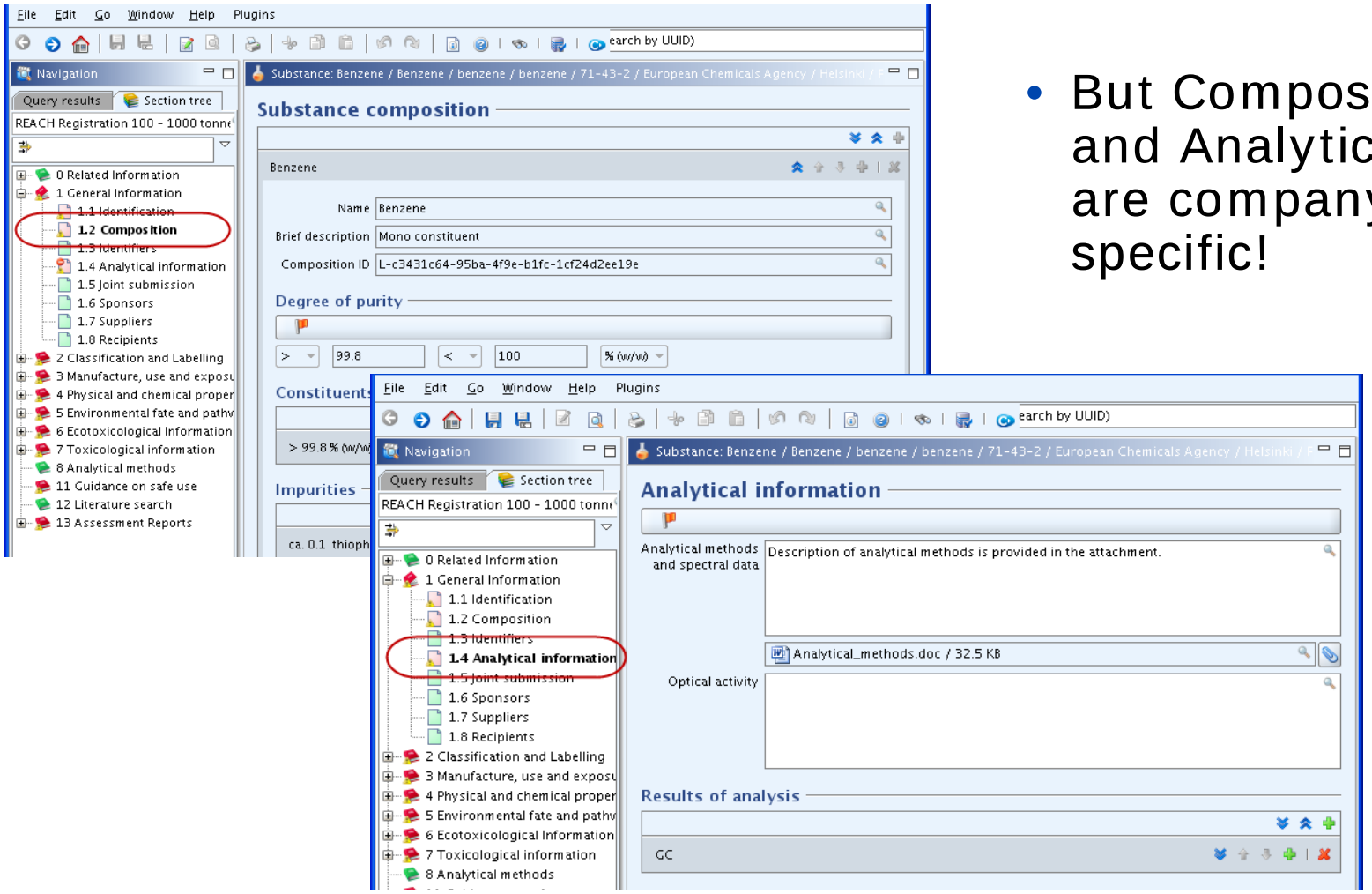


Building the dossier in IUCLID



- Substance identifiers provided to members

Building the dossier in IUCLID



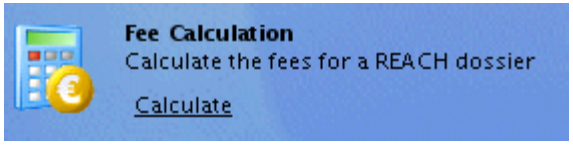
- But Composition and Analytical Data are company specific!

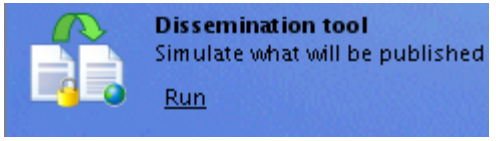
Building the dossier in IUCLID

- 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





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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