

Overview of dissemination

Dissemination & confidentiality claims

06 September 2012

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ECHA



Introduction

- What is dissemination?
- The dissemination process
- What dossiers are disseminated?
- IUCLID 5.4 / SDS information
- Examples

What is dissemination?



What is dissemination?

Dissemination = “Publication of information from REACH registration dossiers on the ECHA website”

Confidentiality = “Specific confidentiality claims on information submitted to ECHA in a REACH registration”

Balance

Transparency

Publication of
information about
(safety of) chemical
substances; in the public
interest



Protection

Legitimate commercial
interest of registrants;
competitiveness of EU
chemical industry

Legal basis

- REACH Article 77 - Tasks
 - (2)(e) – Establish & maintain database(s) with information on all registered substances, the C&L inventory and the harmonised C&L list
- REACH Article 119 – Electronic public access
 - Make information publicly available, free of charge, over the internet
- REACH Article 118 – Access to information
 - Make other information available on request

Legal basis

- REACH Article 119 – Electronic public access
 - Make information on substances publicly available, free of charge, over the internet

Article 119

Electronic public access

1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):
2. The following information on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

Legal basis

- REACH Article 119 – Electronic public access
 - Make information on substances publicly available, free of charge, over the internet

Article 119

Electronic public access

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Information in dossiers in IUCLID format



Always published



Always published



Article 119(1)

- (a) without prejudice to paragraph 2(f) and (g) of this Article, the **name in the IUPAC nomenclature** for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008;
- (b) if applicable, the **name of the substance** as given in EINECS;
- (c) the **classification and labelling** of the substance;
- (d) **physicochemical data** concerning the substance and on pathways and environmental fate;
- (e) the result of each **toxicological and ecotoxicological study**;
- (f) any **derived no-effect level (DNEL)** or **predicted no-effect concentration (PNEC)** established in accordance with Annex I;
- (g) the **guidance on safe use** provided in accordance with sections 4 and 5 of Annex VI;
- (h) **analytical methods** if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

Unless confidential



Unless confidential



Article 119(2)

- (a) if essential to classification and labelling, the **degree of purity** of the substance and the **identity of impurities and/or additives** which are known to be dangerous;
- (b) the **total tonnage band** (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;
- (c) the **study summaries** or **robust study summaries** of the information referred to in paragraph 1(d) and (e);
- (d) **information**, other than that listed in paragraph 1, contained in the **safety data sheet**;
- (e) the **trade name(s)** of the substance;
- (f) subject to Article 24 of Regulation (EC) No 1272/2008, the **name in the IUPAC nomenclature** for non-phase-in substances referred to in paragraph 1(a) of this Article for a period of six years;
- (g) subject to Article 24 of Regulation (EC) No 1272/2008, the **name in the IUPAC nomenclature** for substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:
 - (i) as an intermediate;
 - (ii) in scientific research and development;
 - (iii) in PPORD

Unless confidential



'Volunteered' information

If not claimed confidential, information not specifically excluded from dissemination but not explicitly covered by REACH Article 119 is considered to be 'volunteered' for publication by the registrant.

Never published



Never published



Not Disseminated

Information covered by Article 118

Specific details of manufacturing processes, sites

Personal data – names, email addresses

Dossier administrative data (UUIIDs, Submission numbers, creators)

Etc

The dissemination process



What dossiers are disseminated?

- REACH registration dossiers – **ALL** successful registrations will be disseminated:
 - Full, onsite intermediate, transported isolated intermediate
 - Phase-in & non-phase-in
 - Lead, member & individual submissions
- NONS notifications
- Biocides

NONS dissemination

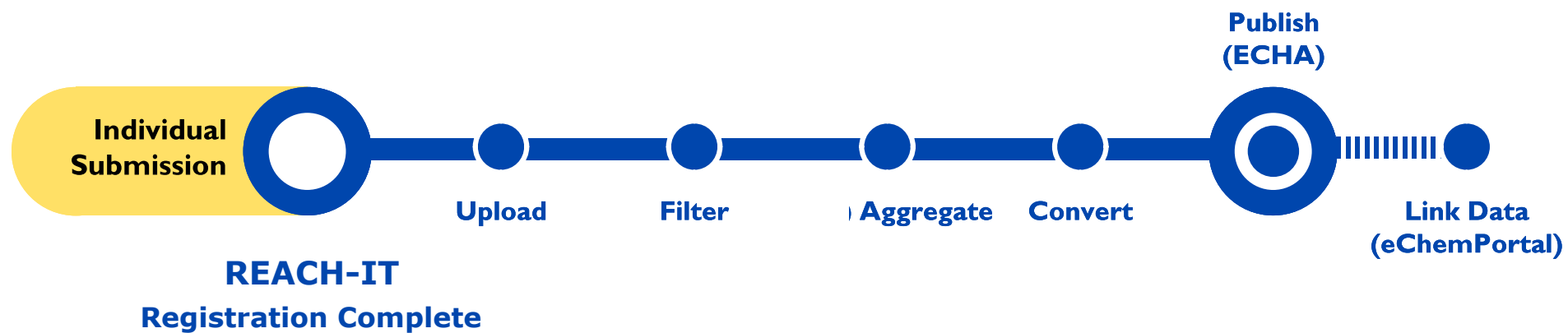
- **Three steps (CLAIMED NONS):**
- Reduced data set (from May 2012)
- + SDS information (Nov 2012)
 - Registrants have until 31 Oct 2012 to update & claim data confidential
- Full data set (Nov 2013)
 - Registrants have until 31 Aug 2013 to update, fix their dossiers, & claim data confidential

IUCLID dossier

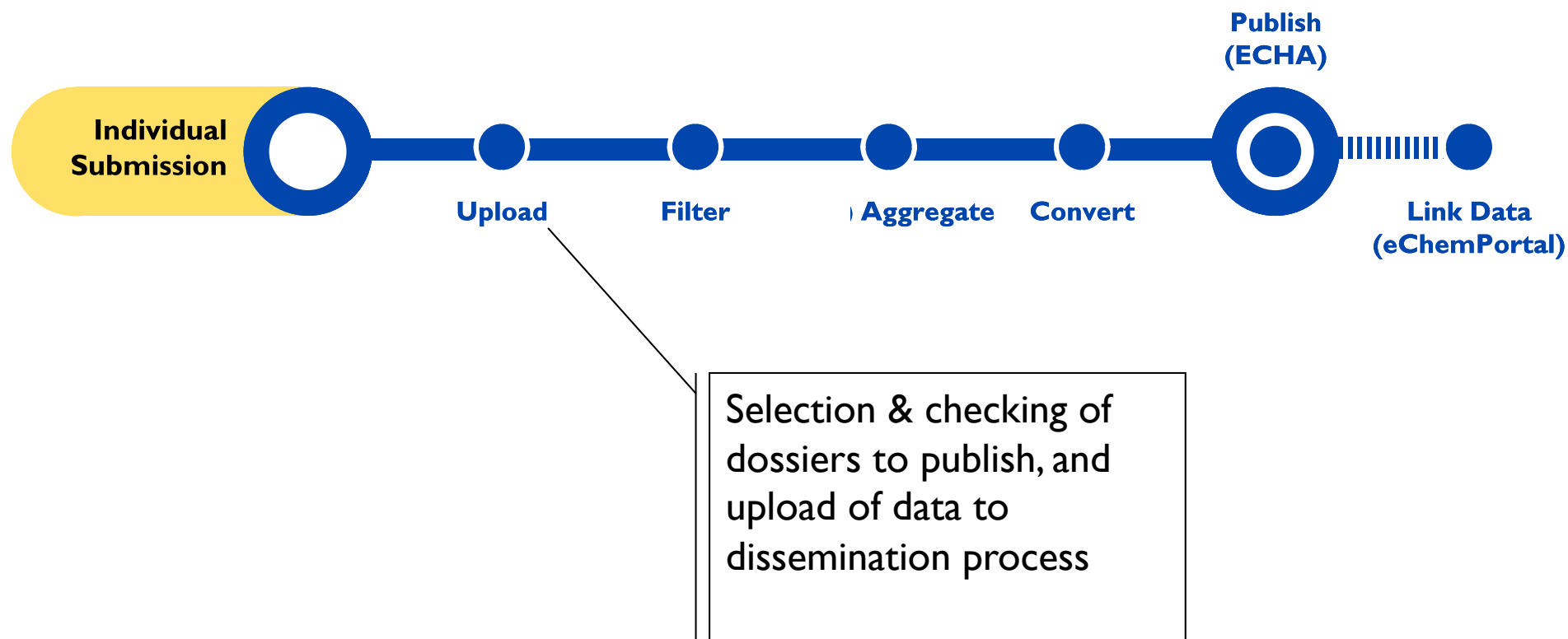


- ~10 000 individual fields for information
(IUCLID 5.3 format)
- ~18 000 fields
(IUCLID 5.4 format)
- 30 375 dossiers disseminated
(as of 31 Aug 2012)
- >300 000 000 fields processed
- IT tools are key

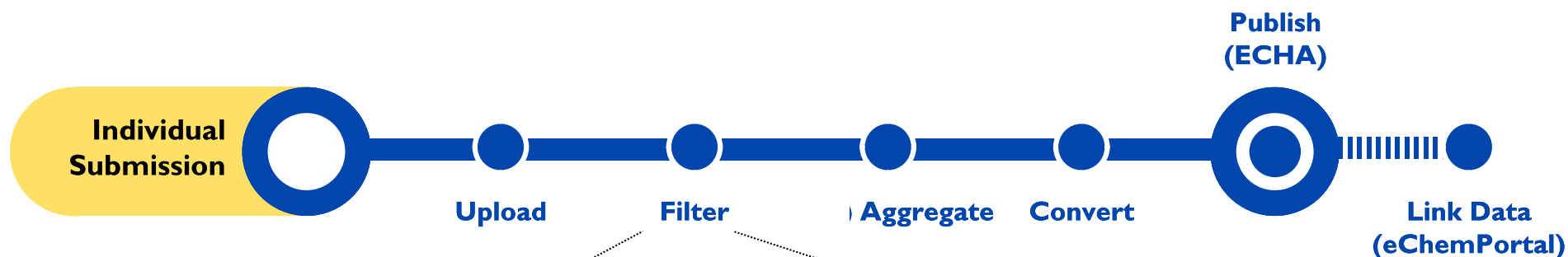
Dissemination process



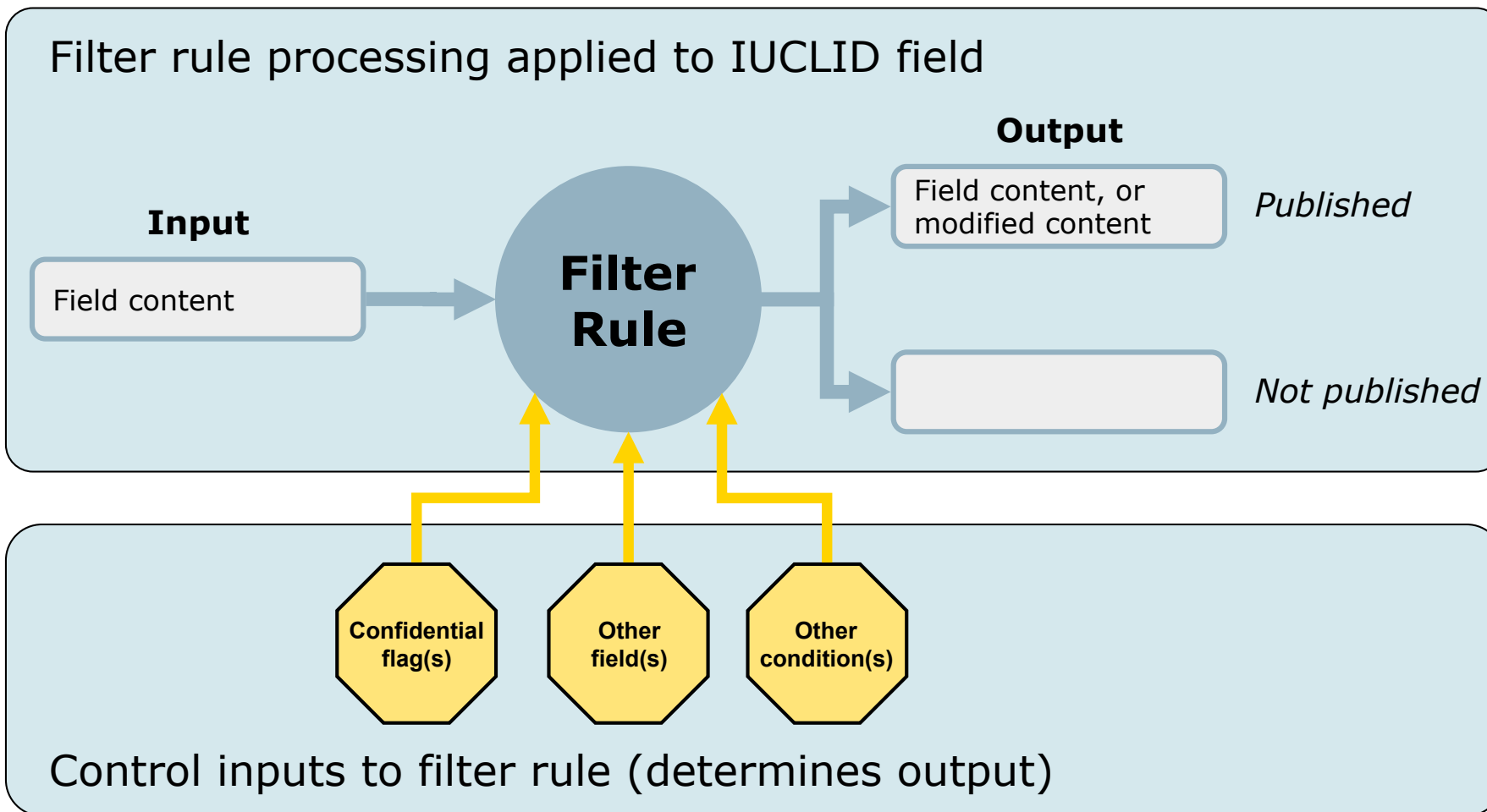
Dissemination process



Dissemination process



Filtering



Rule set

7.1.1. Basic toxicokinetics

Endpoint study record: Basic toxicokinetics.001

Detail level: Administrative Data | Data source | Materials and methods

all fields | Results and discussions | Overall remarks, attachments | Applicant's summary and conclusion

Administrative Data

Purpose flag **A**
 robust study summary **N**
 used for classification **N**
 used for MSDS **N**

Data waiving **C**

Justification for data waiving **N**

Study result type **A**
 Study period **C**

Reliability **C**

Rationale for reliability incl. deficiencies **C**

Data source

Reference

Reference type	Author	Year	Title	Bibliographic s...	Testing laborat...	Report no.	Owner company	Company study...	Report date
A	B	A	B	B	N	N	N	N	A

Data access

N

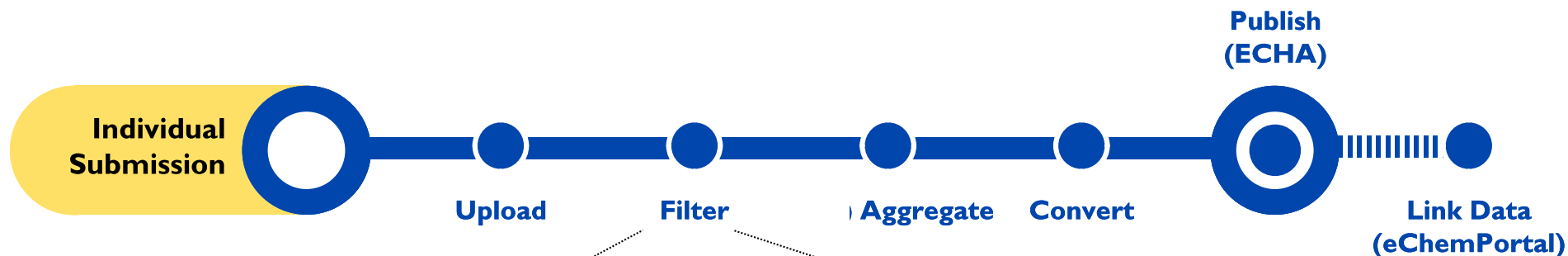
Data protection claimed

N

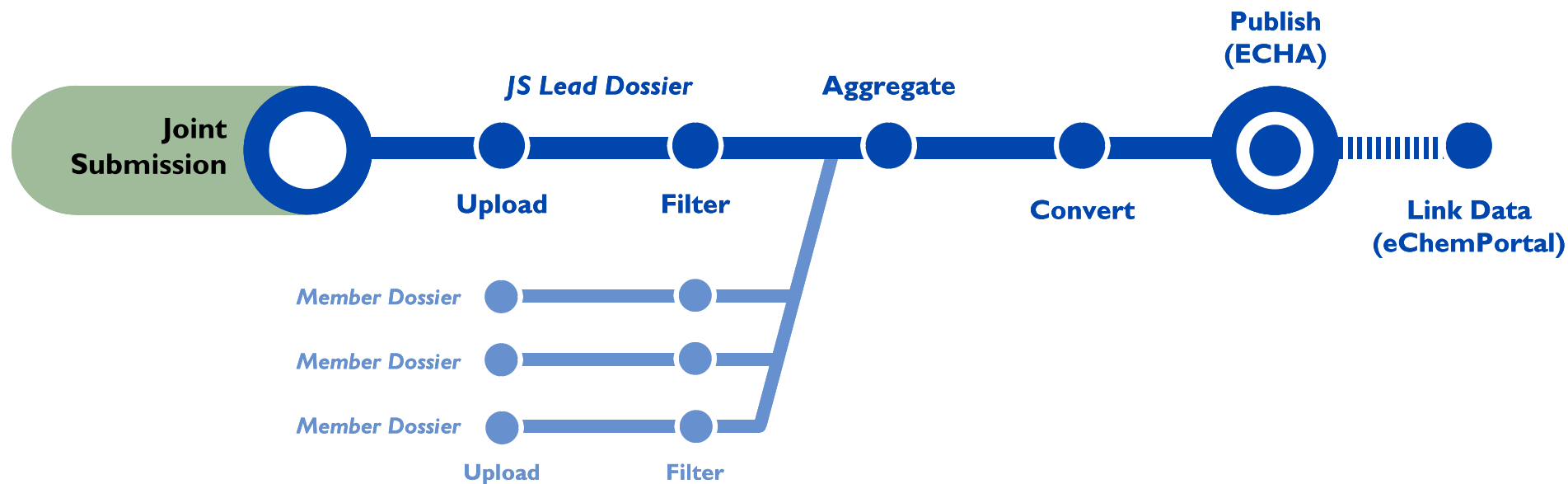
Cross-reference to same study

N

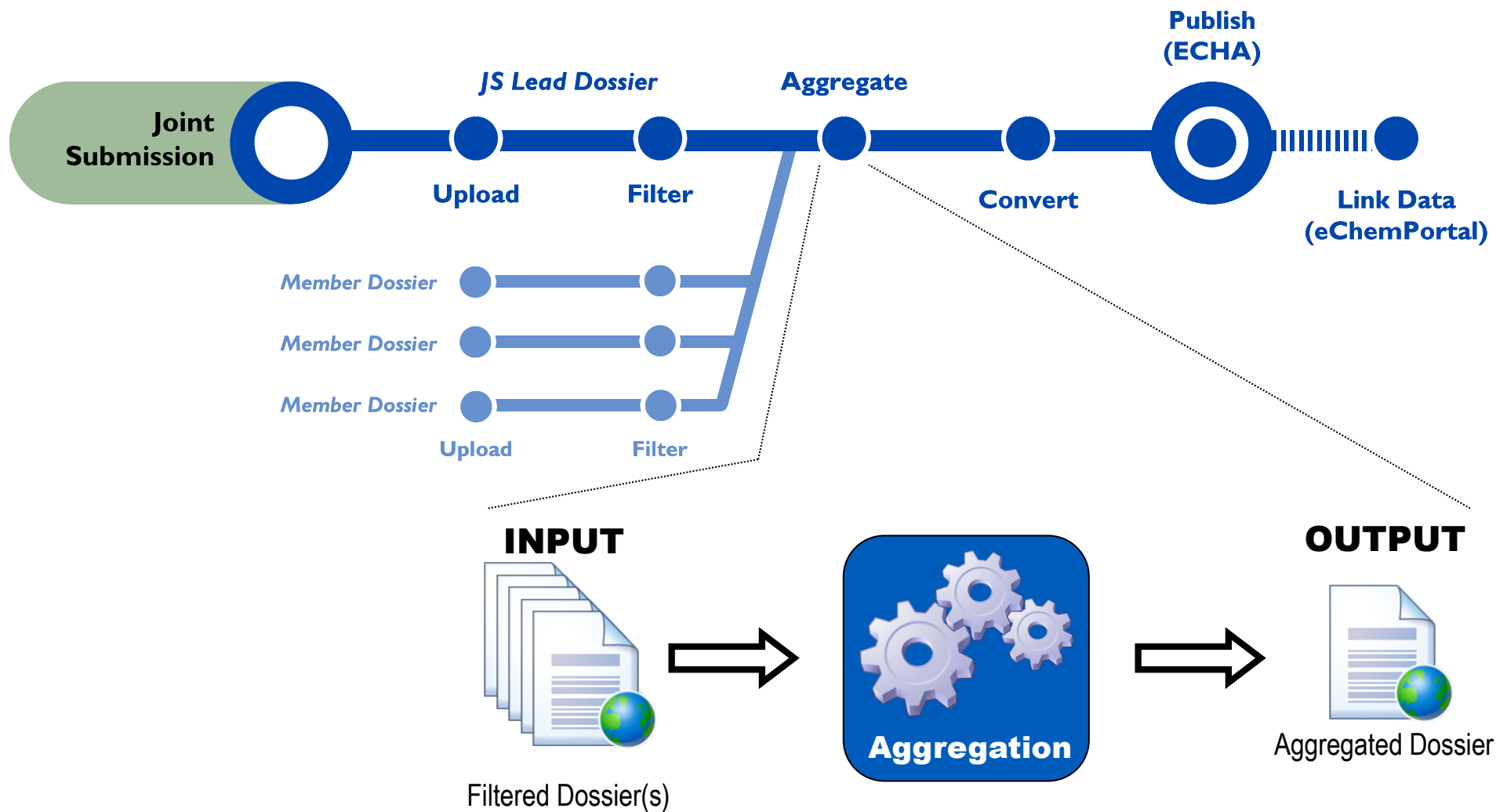
Dissemination process



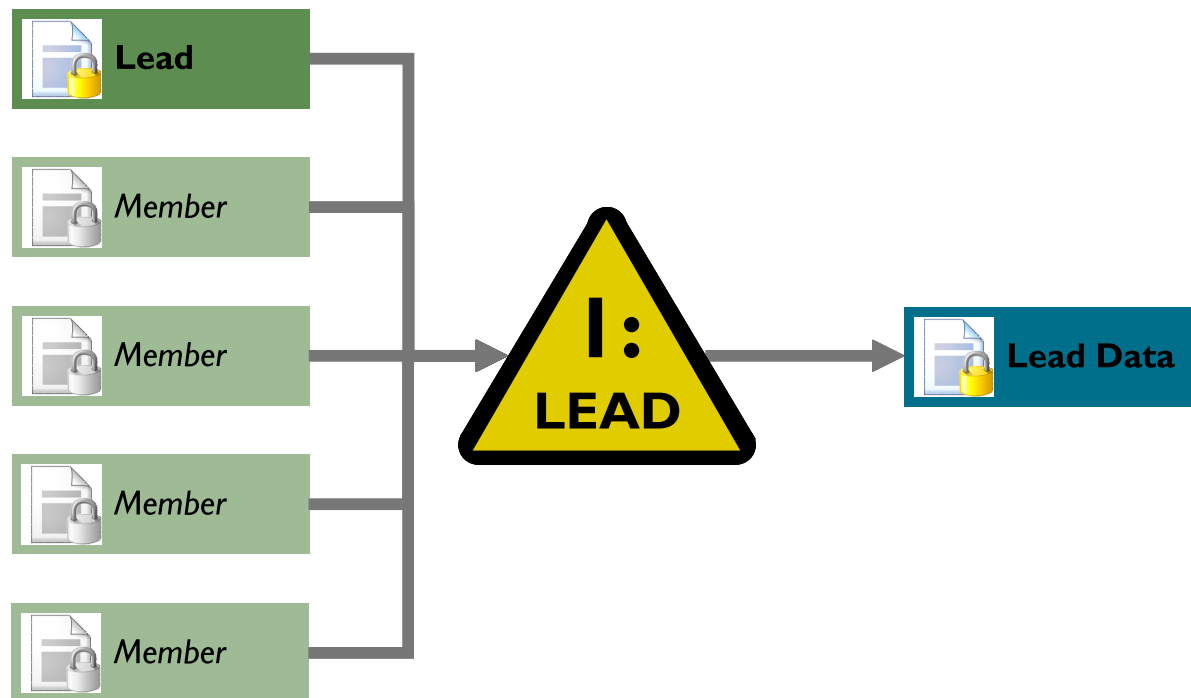
Dissemination process



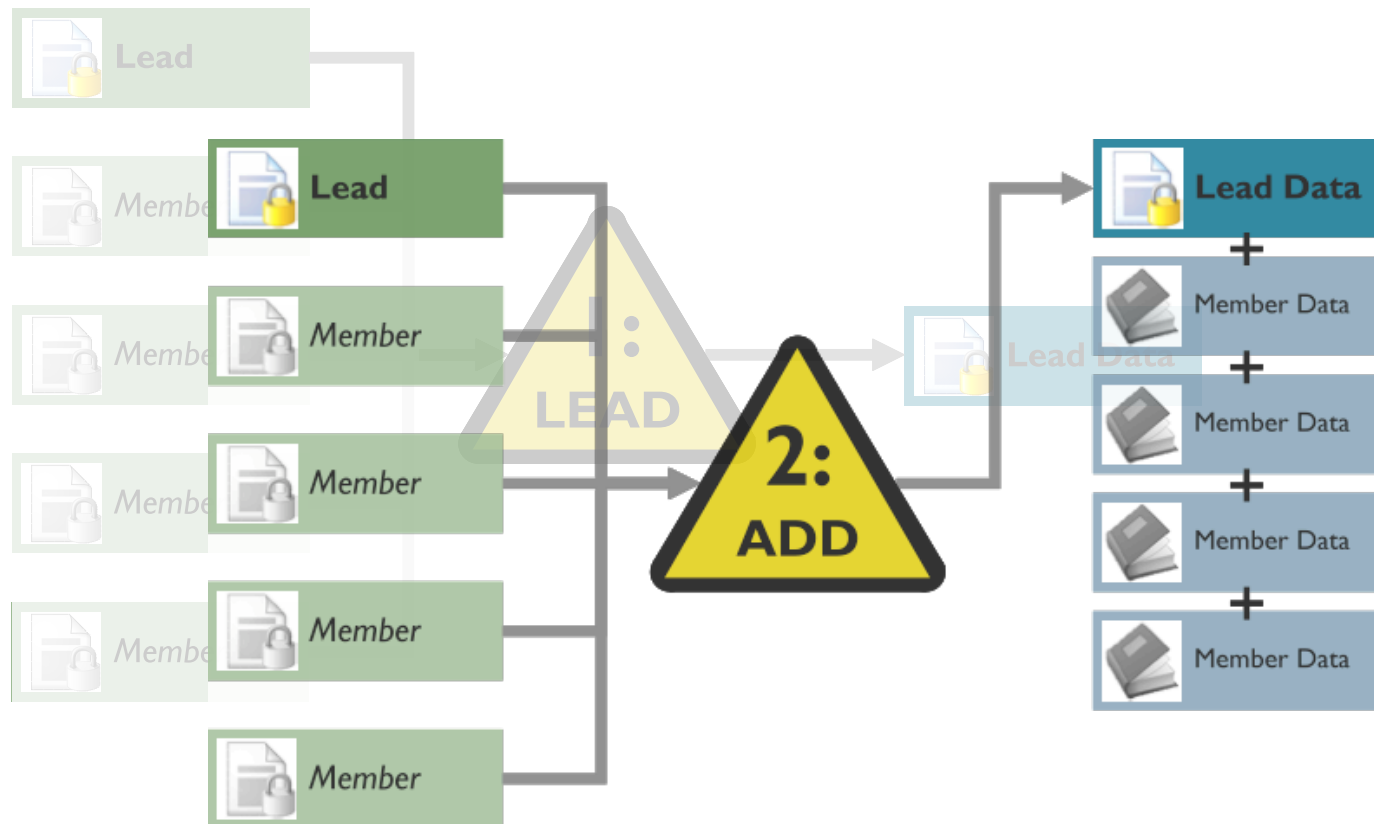
Dissemination process



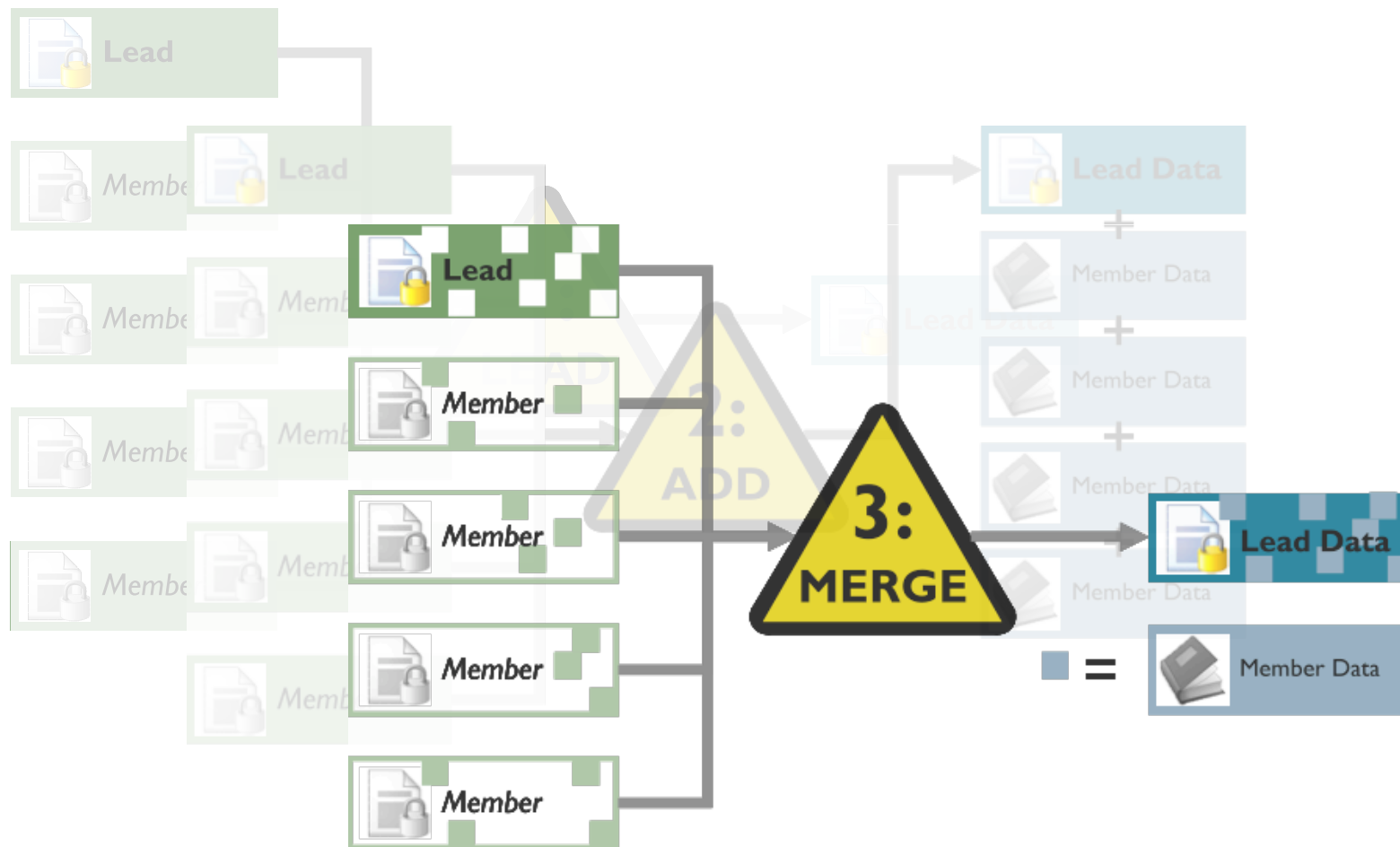
Aggregation



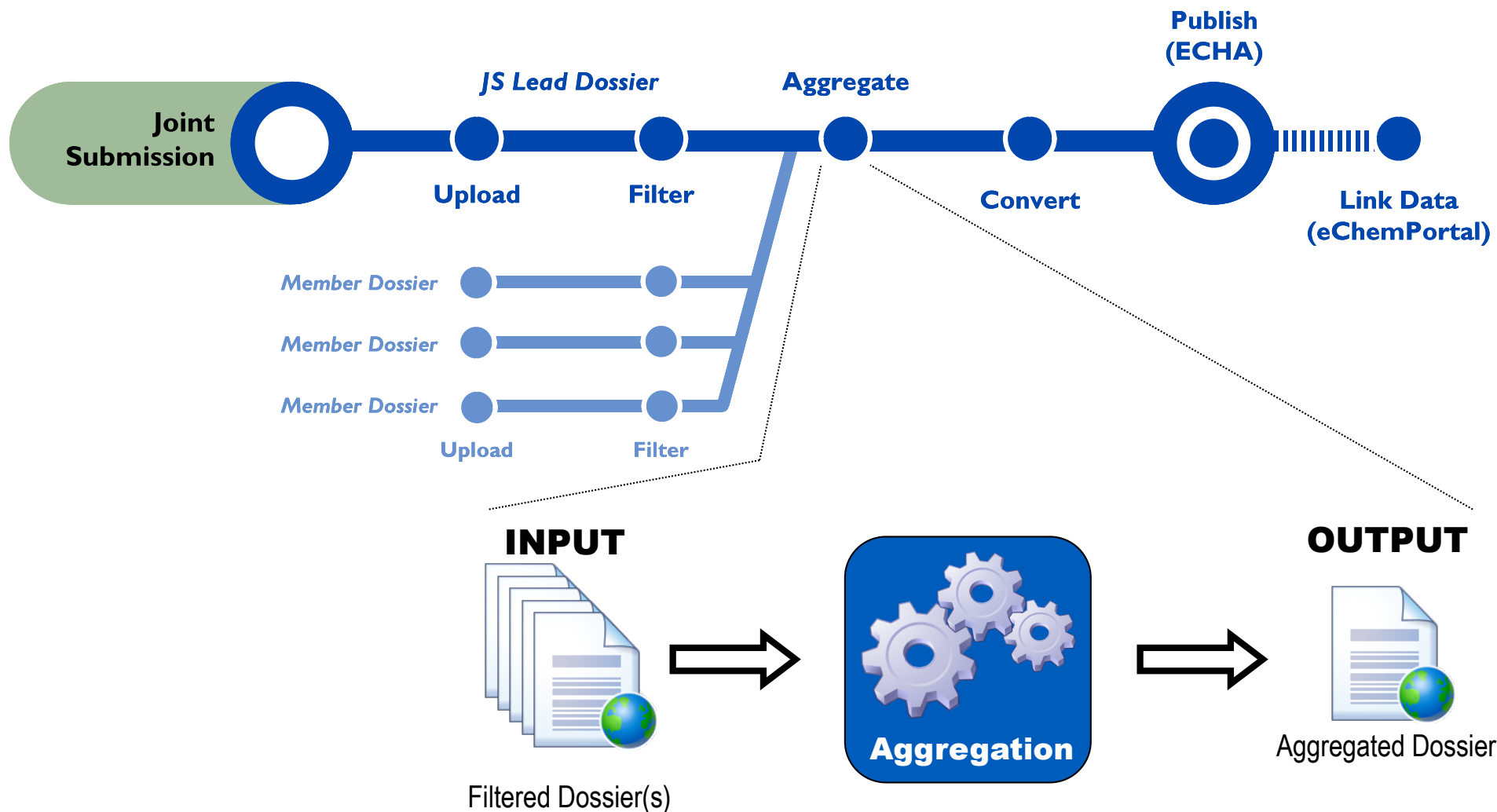
Aggregation



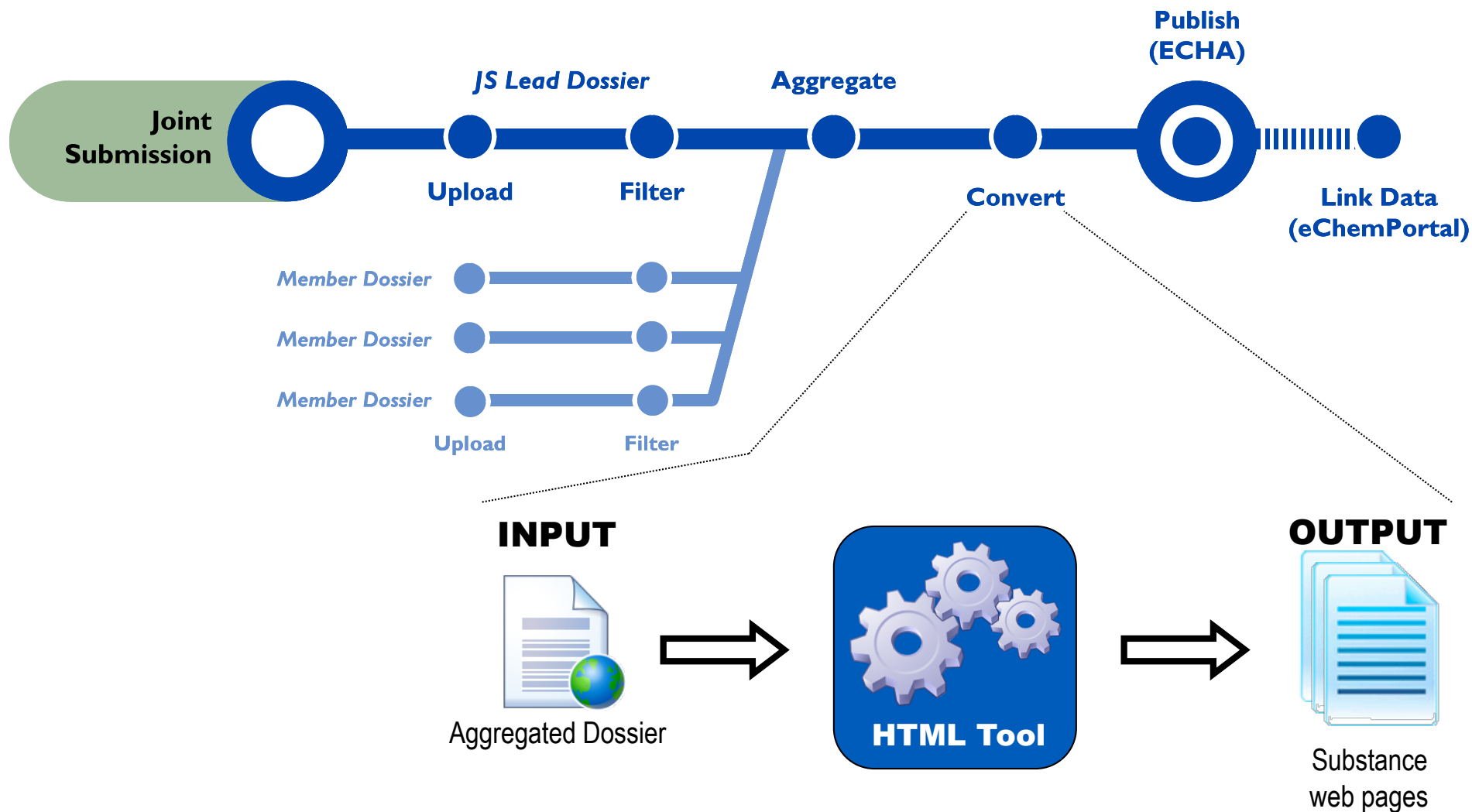
Aggregation



Dissemination process



Dissemination process



Mockup view (1)

Substance identification

Substance example

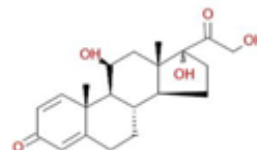
EC Number 200-123-4

EC Name substance example |

CAS Number 12-34-5

Molecular formula C₂₁H₂₈O₅

IUPAC Name 11,17,21-trihydroxypregna-1,4-diene-3,20-dione



Type of substance

Composition mono constituent substance

Origin organic

Trade names

Substance

Total Tonnage Band

100 – 1 000 tonnes per annum

Registrants / Suppliers

A company	123 Mannerheimintie, 00123 Helsinki, Finland
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland
Finchem	123 Mannerheimintie, 00123 Helsinki, Finland
Zetec Chemicals Inc	123 Mannerheimintie, 00123 Helsinki, Finland
[Confidential]	

Mockup view (2)

Registrants / Suppliers

A company	123 Mannerheimintie, 00123 Helsinki, Finland
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland
Finchem	123 Mannerheimintie, 00123 Helsinki, Finland
Zetec Chemicals Inc	123 Mannerheimintie, 00123 Helsinki, Finland
[Confidential]	

Registration Numbers

01-211457123-45-0000	01-211457123-45-0003	01-211457123-45-xxxx
01-211457123-45-0001	01-211457123-45-0004	[Confidential]
01-211457123-45-0002	01-211457123-45-0007	

Contact Persons Responsible for SDS

A company	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Finchem	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
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[Confidential]		

Chemical Safety Assessment

Performed for this substance Yes

Publish



ECHA
EUROPEAN CHEMICALS AGENCY

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Registered substances

Chemical Substance Search

Last updated 19th of July. Database contains 7 663 unique substances and contains information from 30 375 dossiers.

Enter search string - a Chemical Name, EC No, Cas No, etc. Leave blank and press 'Search' to view entire database.

I have read and I accept the disclaimer.

Lower limit(tonnes): Upper limit(tonnes):

You can narrow the search results by entering a total tonnage band (per annum)

Search results

Records per page 25 ▾

EC Number	CAS Number	Name	Total Tonnage Band	
		Di(μ-2,2',2''-nitrotris(ethanol)-diperchlorato) dinatrium	Tonnage Data Confidential	View
		5-amino-3-(4-chlorophenyl)-5-oxopentanoic acid	Intermediate Use Only	View

Introducing IUCLID 5.4

New information added to IUCLID format

Information found in SDSs

Consequences for dissemination



IUCLID 5.4

- New IUCLID format
- Large number of new fields added compared to 5.3
- Bulk of the new information is 'safety data sheet' information (SDS information)

New data disseminated

- Registrant / supplier name
- Registration number
- Contact for SDS
- Persistent Bioaccumulative Toxic (PBT) assessment
- Whether or not a chemical safety assessment (CSA) was performed
- Information on uses (already disseminated)

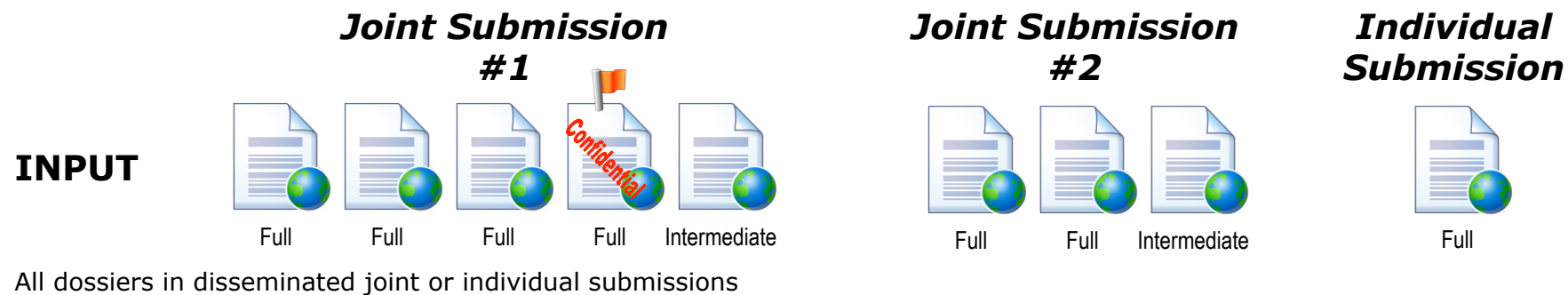
Examples of data aggregation

Total tonnage band

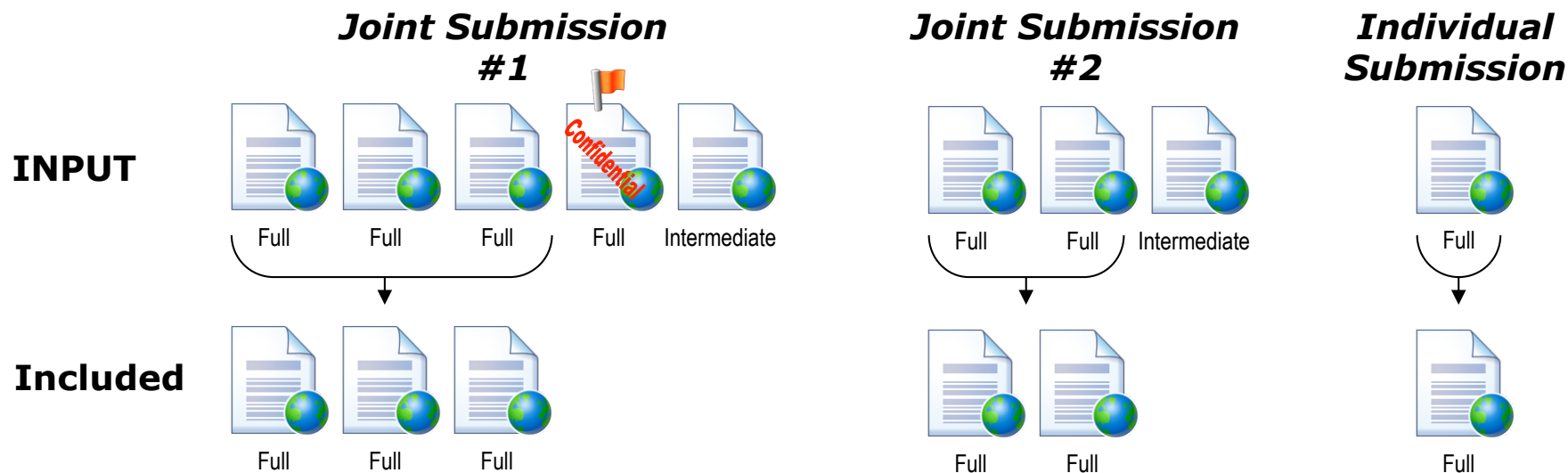
Registrants / suppliers



Total tonnage band

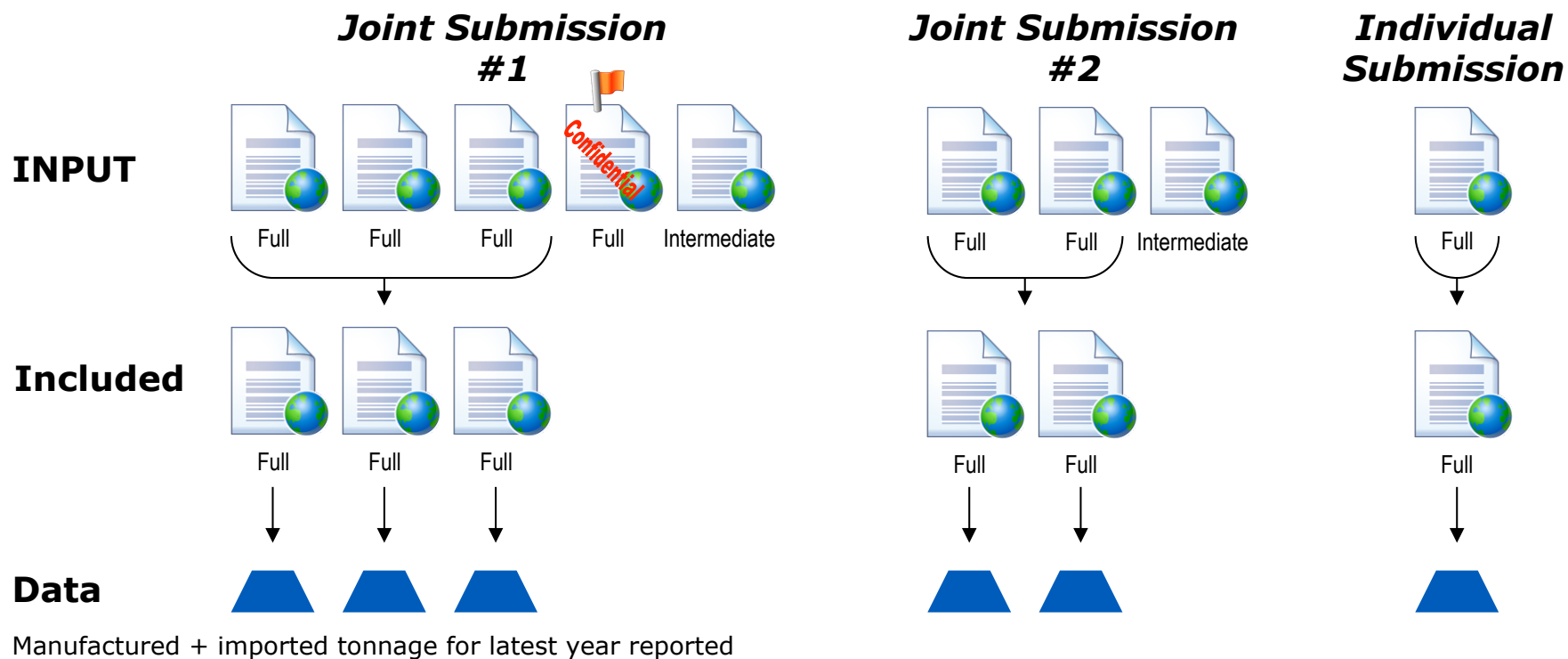


Total tonnage band

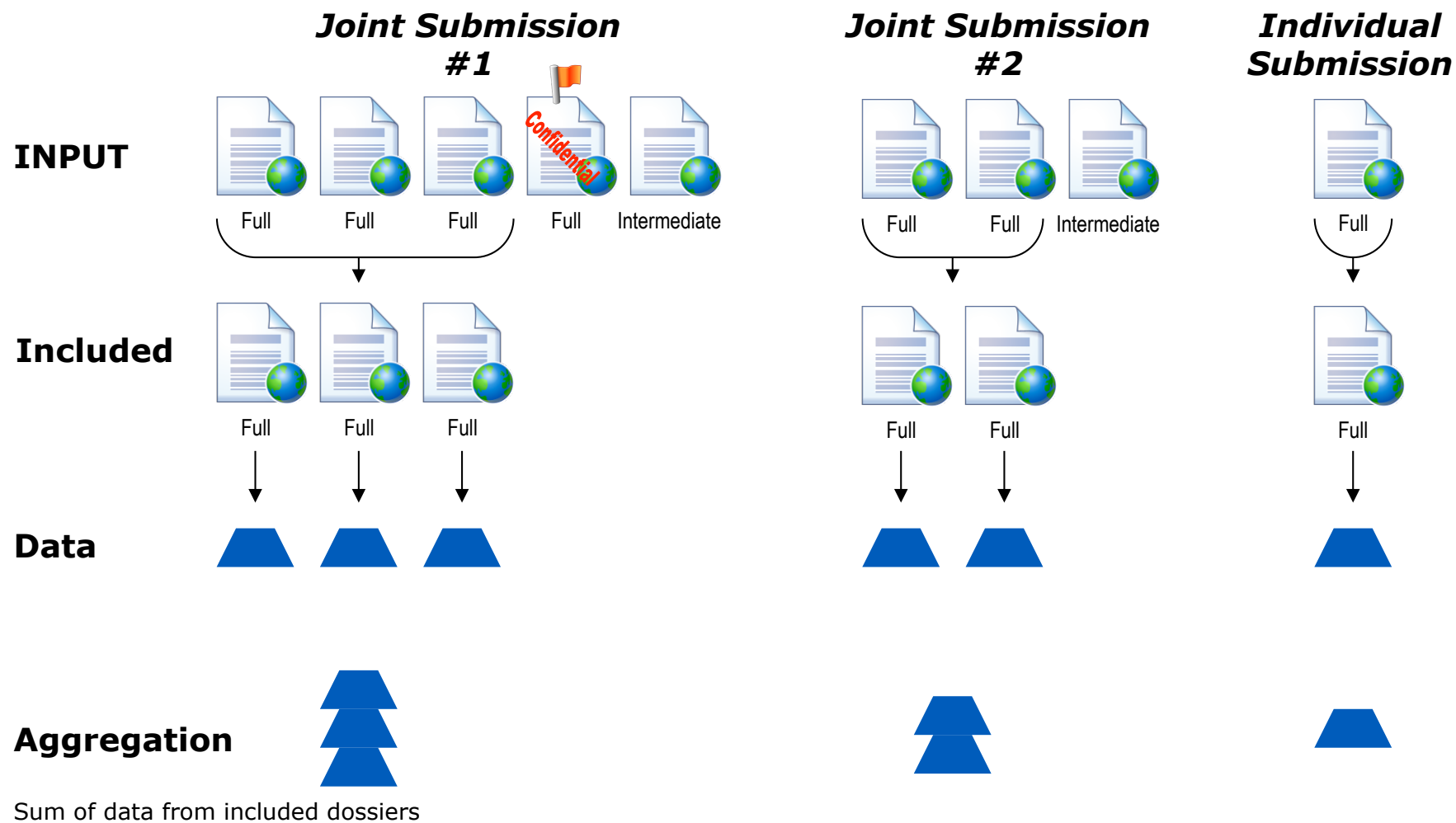


Only full registration dossiers where the tonnage band has not been claimed confidential are considered for the total tonnage band calculation

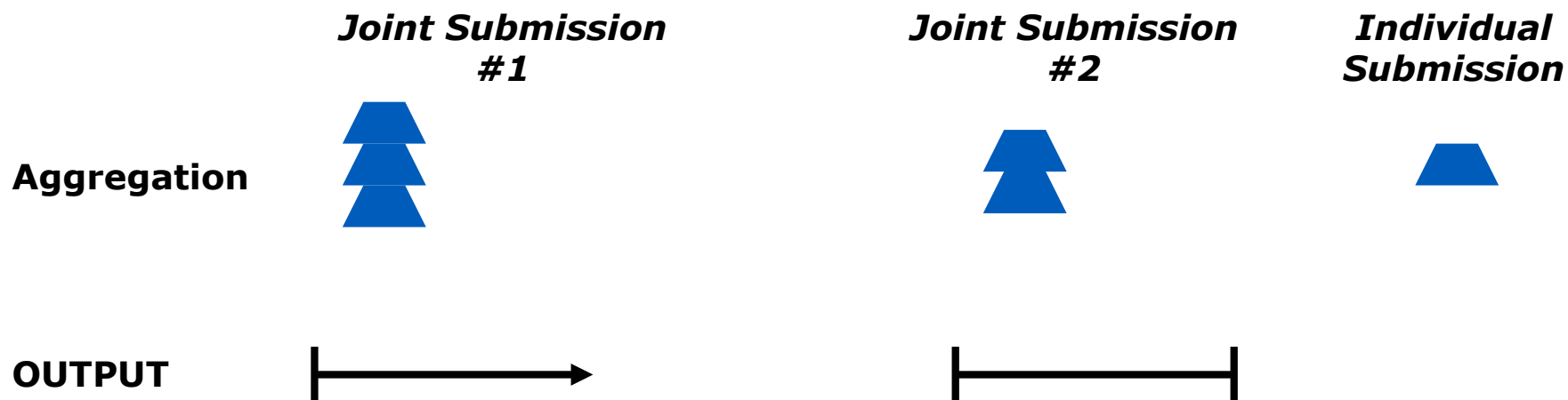
Total tonnage band



Total tonnage band



Total tonnage band



Summed value converted to a band

Open tonnage band

Where 1+ dossiers are claimed confidential. This indicates that there is additional tonnage data not accounted for in the calculation, which might bring the total tonnage up to the next band.

- 1+ tonnes**
- 10+ tonnes**
- 100+ tonnes**
- 1 000+ tonnes**
- 10 000+ tonnes**
- 100 000+ tonnes**
- 1 000 000+ tonnes etc**

Closed tonnage band

Where tonnage data from all dossiers is accounted for in the calculation.

- 1 – 10 tonnes**
- 10 – 100 tonnes**
- 100 – 1 000 tonnes**
- 1 000 – 10 000 tonnes**
- 10 000 – 100 000 tonnes**
- 100 000 – 1 000 000 tonnes**
- 1 000 000 – 10 000 000 tonnes etc**

Examples of data aggregation

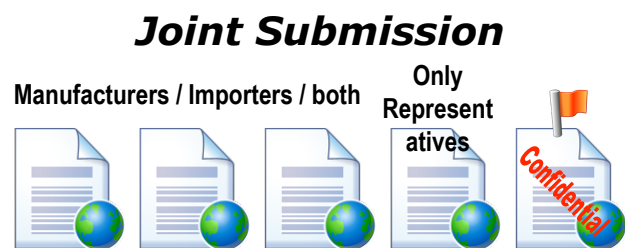
Total tonnage band

Registrants / suppliers



Registrants / suppliers

INPUT



Individual Submission #1

Manufacturer / Importer / both

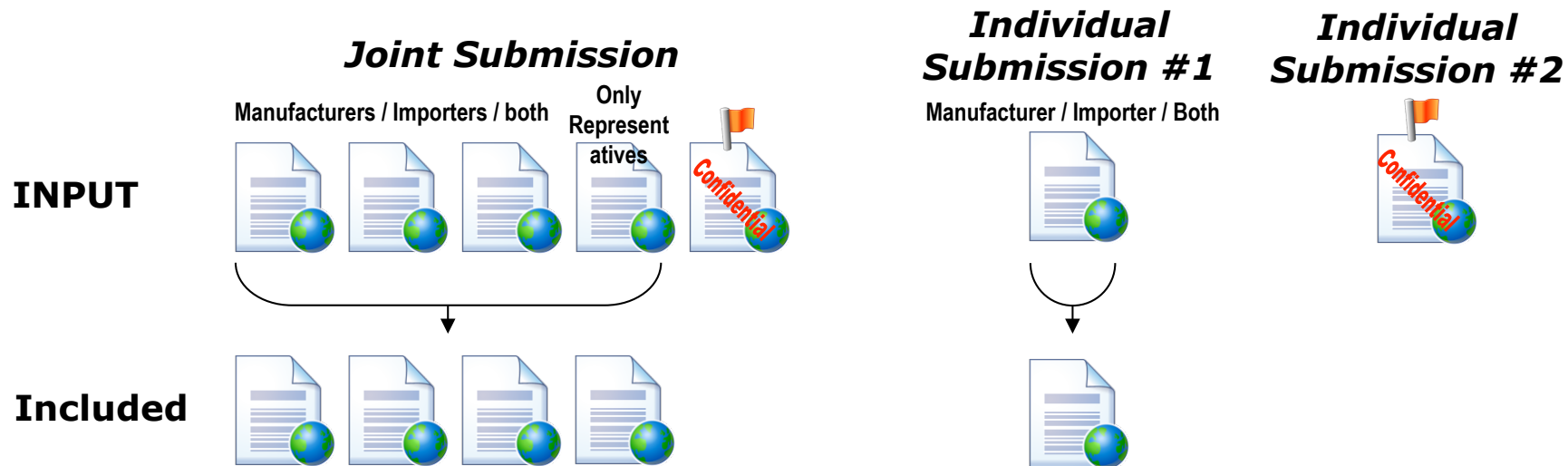


Individual Submission #2



All dossiers in disseminated joint or individual submissions

Registrants / suppliers



Dossiers where the registering Legal Entity (LE) has not been claimed confidential in IUCLID section 1.1:

Substance identification

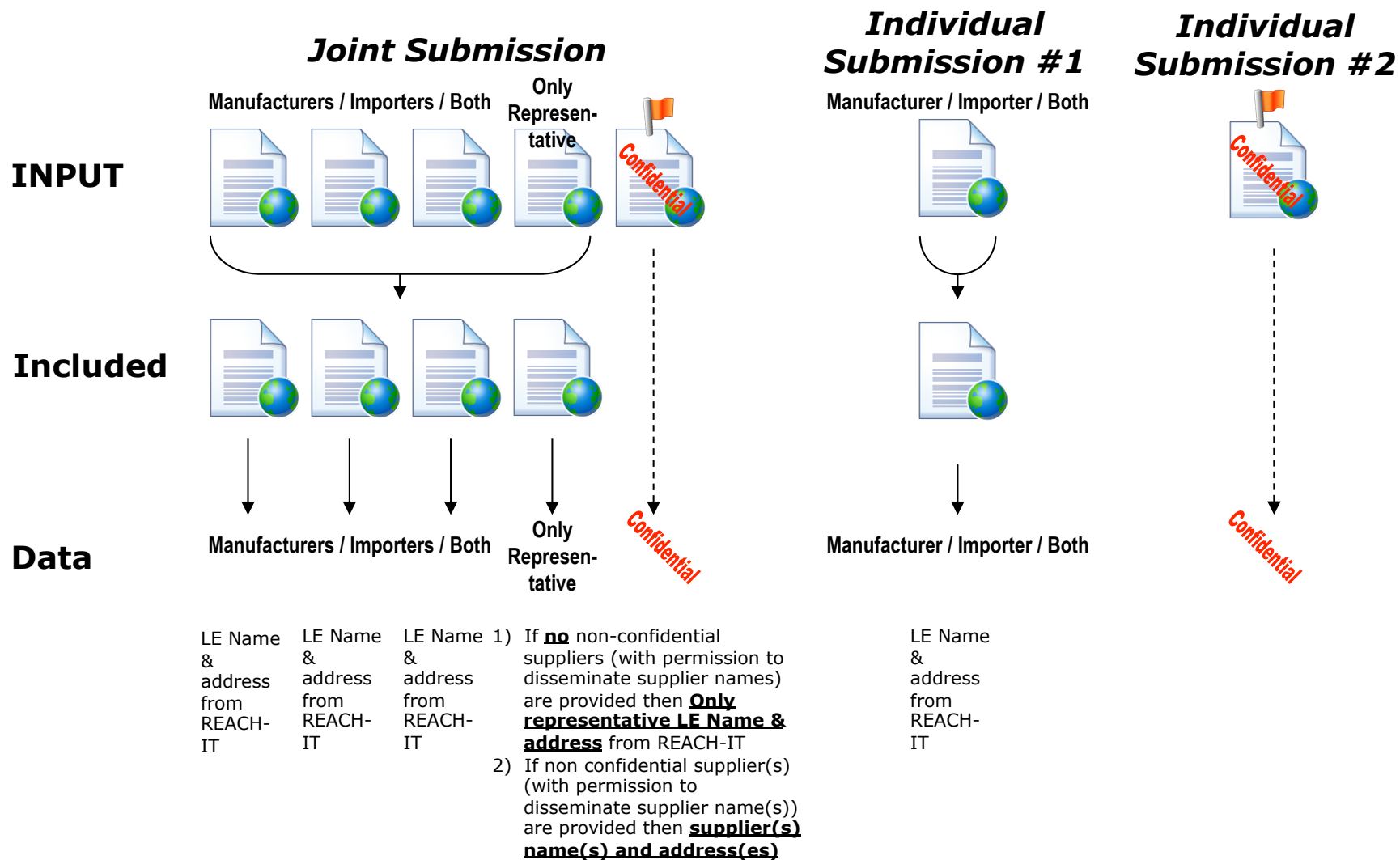
Chemical name

Public name

Legal entity flags [CBI, I want to keep my company name confidential.]

Legal entity

Registrants / suppliers



Registrants / suppliers

Data	Joint Submission			Individual Submission #1	Individual Submission #2
	Manufacturers / Importers / both			Manufacturer / Importer / both	
			Only Representatives		
	LE Name from REACH-IT	LE Name from REACH-IT	LE Name from REACH-IT	LE Name from REACH-IT	
			1) If no non-confidential suppliers (with permission to disseminate supplier names) are provided then Only representative LE Name from REACH-IT 2) If non confidential supplier(s) (with permission to disseminate supplier name(s)) are provided then Supplier (s) name(s) and address (es)		
Aggregation OUTPUT	A Enterprises B Incorporated C & Sons Importing Ltd D Fine Chemicals GmbH E & Associates SpA [Confidential]			A Chemicorp plc	[Confidential]

Registrant / supplier names are merged, sorted alphabetically and disseminated. NB: There is no distinguishing between registrant and supplier companies. NB: If one or more LEs are claimed confidential this will be indicated in the disseminated OUTPUT.

Registrants / suppliers

Substance identification

Substance example

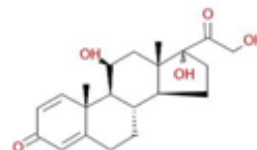
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Composition mono constituent substance

Origin organic

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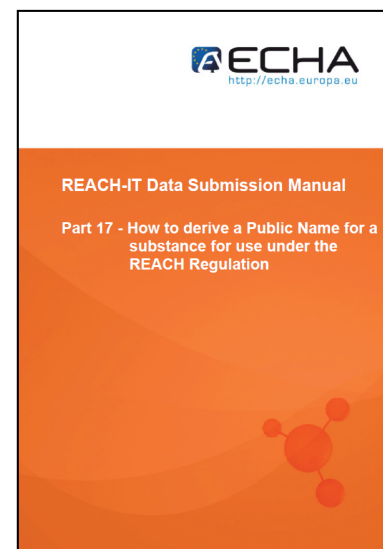
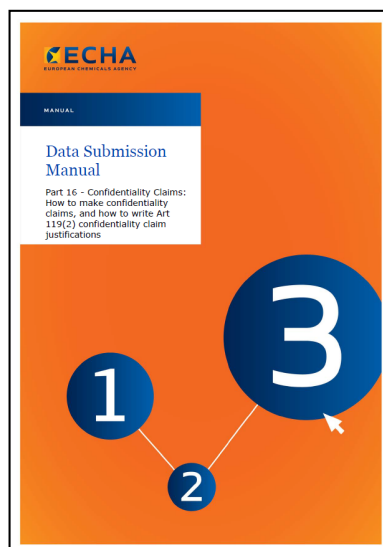
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[Confidential]	

Conclusion

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- The dissemination process
- What dossiers are disseminated?
- IUCLID 5.4 / SDS information
- Examples

Dossier Submission Manuals



Thank you

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