

Visit from the Brazilian Ministry of Environment and Institute of Environment and Renewable Natural Resources

ECHA, Helsinki

Janne Maaranen

15 April 2013

Registration and dissemination

Registration

- Why – What – Who – When?
- Preparing and submitting dossiers
 - IUCLID and REACH-IT
- Processing of dossiers at ECHA
- Preparations for 2013

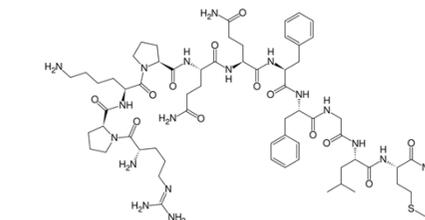
Dissemination and confidentiality

Registration – Why?

- **Core of REACH:** REACH is the regulatory framework for chemicals management under which manufacturers and importers of chemicals are required to submit hazard, use, exposure and risk data for identified uses of substances manufactured or imported in quantities of more than one metric tonne per year in EU
- The above information must be sent by the registrants to ECHA for processing and evaluation.
- Specific hazardous chemicals are then regulated or restricted, communicated to downstream users and enforced by the member states
- The target is to increase knowledge about substances in EU, to promote their safe use and restrict the use of non-safe chemicals

What must be registered?

- Registration only concern **Substances**.
 - ...and not **Preparations** and **articles**



- Only substances over 1 ton/year



What must be registered?

Phase-in substances:

- Listed in European Inventory of Existing Commercial Chemical Substances (**EINECS**) (excluding polymers)
- Manufactured in the Community... at least once in the 15 years preceding REACH, but not placed on the market.
- Meet the criteria of 'No Longer Polymer' after the 1993 amendment of EU legislation

Non phase-in substances:

- Everything else – including all 'brand new' substances

The **European Inventory of Existing Commercial Substances (EINECS)** originally listed all substances that were reported to be on the market in Europe between 1 January 1, 1971 and September 18, 1981. The substances placed on the market for the first time after this target date are "new". There are 100,196 different substances in the EINECS.

Exempted from Registration

- R&D
- PPORD (but subject to notification).
 - Temporal exemption of 5 years.
- Medicines, food, and feeding stuffs covered by relevant EC legislation.
- Well-known substances *e.g.* water, fatty acids, cellulose (Substances in Annex IV).
- Substances for which registration would be inappropriate, *e.g.* naturally occurring substances (Substances in Annex V).
- Recovered (recycled, re-used) Substances under certain conditions:
 - original substance has been registered;
 - substance resulting from recovery process is the same one; and
 - SDS (where relevant) or information required under Article 32 is available.
- Re-imported Substances (under similar conditions as for recovered substances).

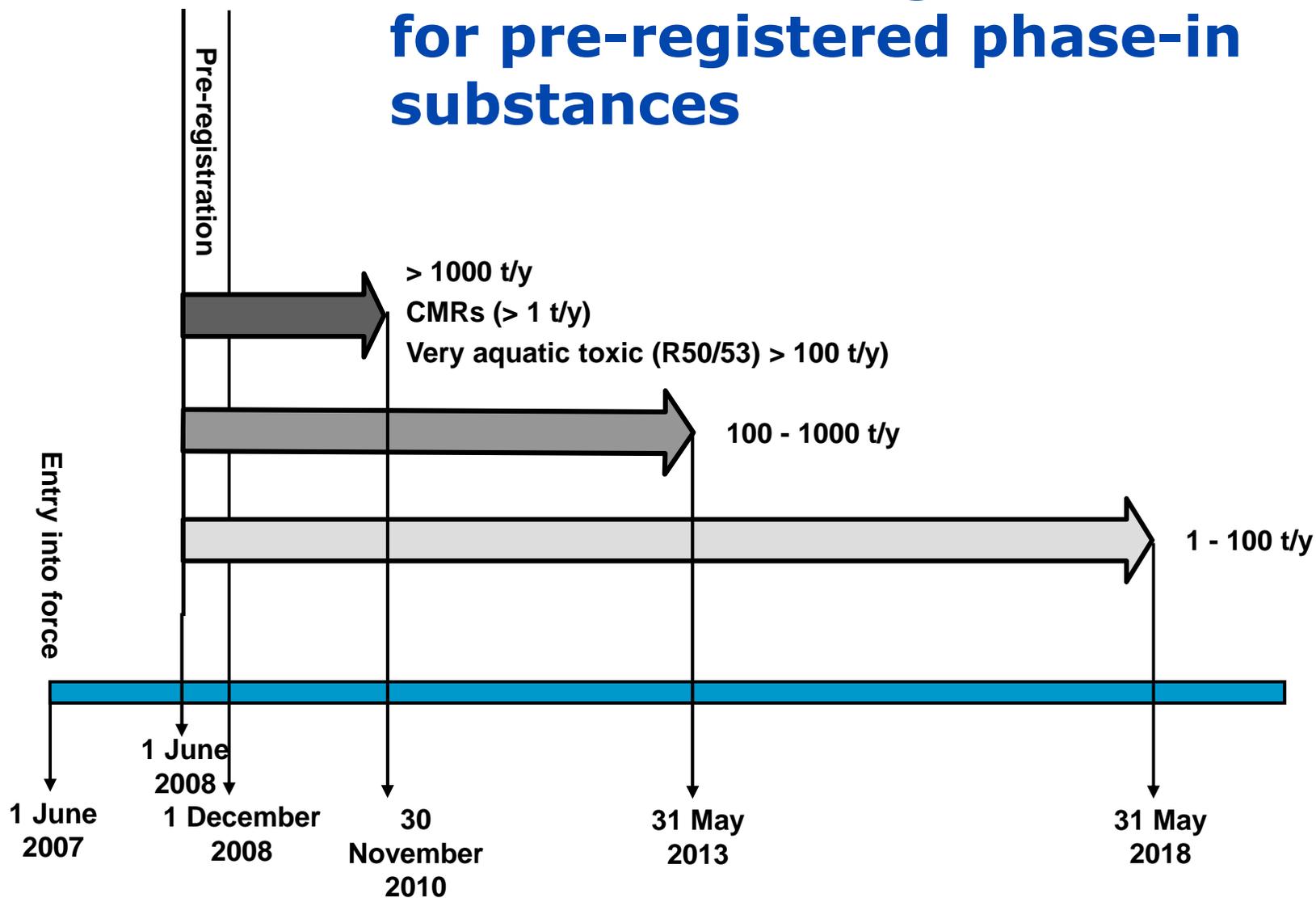
Regarded as registered

- Substances notified under previous legislation (Directive 67/548/EEC)
- Plant Protection Product active substance (PPP uses)
- Biocidal active substances (biocidal uses)

Who has to register?

- Manufacturers and importers.
- Producers of articles (in the conditions of Article 7).
- Manufactures of substances outside the EU may appoint an “only representative” to fulfil their REACH obligations.
 - “Only representative” relieves importers of their duties.
 - Importers are then considered downstream users.

Timelines for Registration for pre-registered phase-in substances

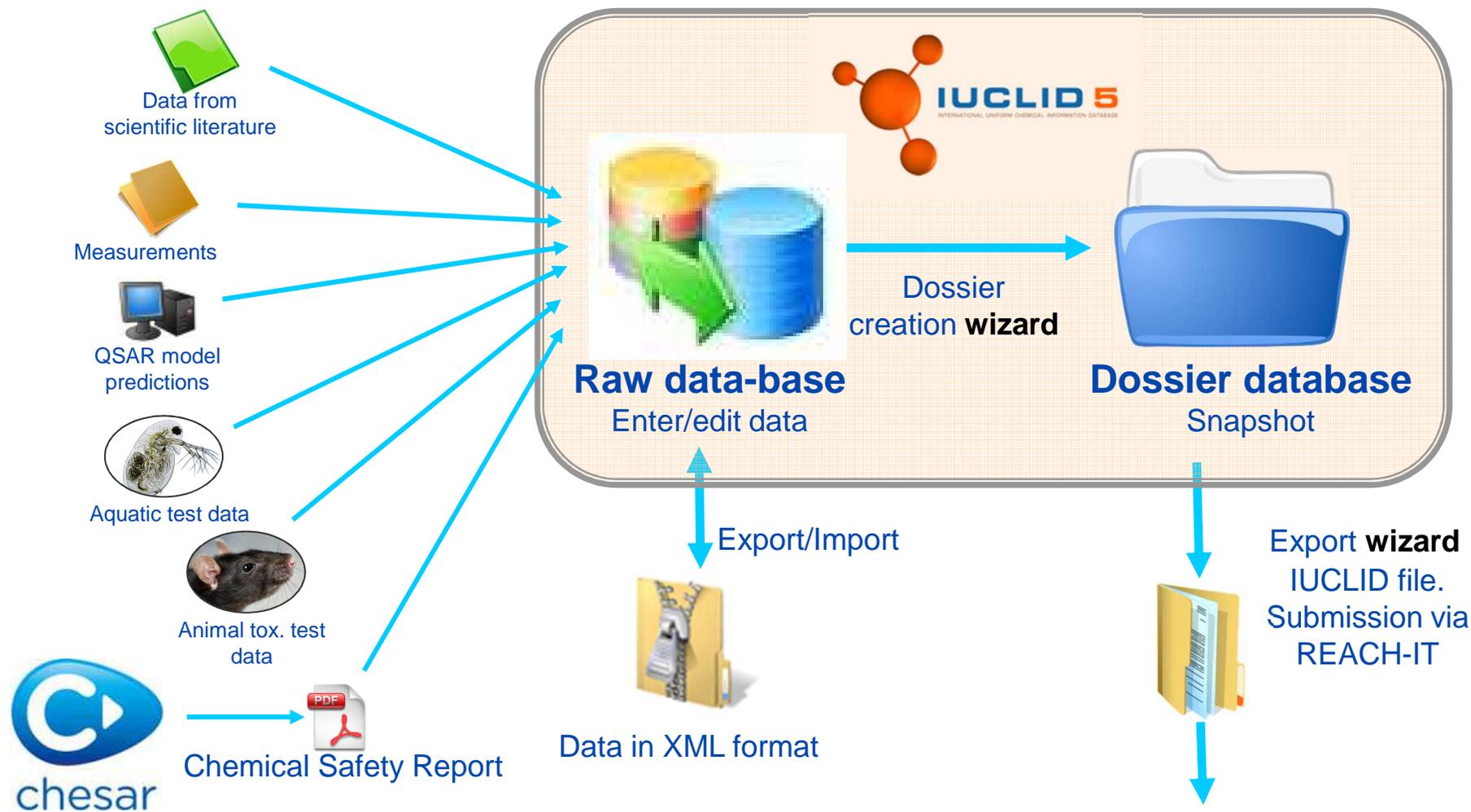


Preparing the registration dossier



- Dossier in IUCLID 5 format for substances at 1 t.p.a. submitted using REACH-IT
- Standard **information linked to tonnage**
- **Testing Proposals for higher-tier studies** (i.e. at 100 & 1,000 t.p.a.)
- **Chemical Safety Report** for substances at 10 t.p.a.
- Transitional arrangements, i.e. **'phase in' substances registered in 3 stages**

Preparing and submitting dossiers



IT tools are essential



Processing of registration dossiers



Dissemination and Confidentiality



Introduction

Dissemination =

“Publication of information on registered substances on the ECHA website”

Confidentiality =

“Specific confidentiality requests on information submitted to ECHA in a REACH Registration”

Confidentiality

- Registrants can indicate confidentiality requests on (almost) any items in a IUCLID dossier
- Only information covered by Article 119(2) will generate a fee, require justification for confidentiality, and require assessment by ECHA

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.

Published unless claimed 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

Other categories

- Not published
 - Article 118(2)
 - Personal data – names, addresses, etc
 - Specific details of manufacturing process, sites, etc
- ‘Volunteered’ information – published unless claimed confidential
 - Information not specifically covered by Article 118 or 119
 - e.g. IUPAC name for non-hazardous substances is also disseminated if not claimed confidential

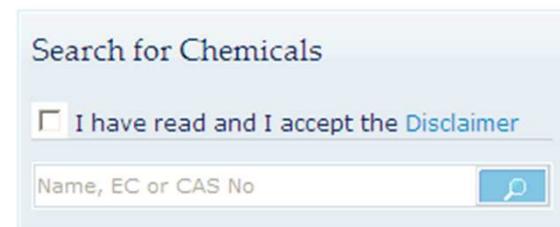
ECHA Dissemination Portal

- ECHA homepage > Information on Chemicals > Registered Substances



The screenshot shows the top navigation bar of the ECHA website. It features the ECHA logo on the left, a search bar with a magnifying glass icon, and a language dropdown menu set to 'English'. Below the search bar is a horizontal menu with six items: 'About Us', 'Regulations', 'Addressing Chemicals of Concern', 'Information on Chemicals', 'Chemicals in our Life', and 'Support'. At the bottom of the navigation bar, there are social media icons for Facebook, Twitter, Email, and Print, along with a notification icon showing '110'.

- Search for substances allows searching for a substance across several ECHA lists (registered substances, C&L inventory, public consultations, substances in articles, Candidate list, ...)



The form is titled 'Search for Chemicals'. It includes a checkbox labeled 'I have read and I accept the [Disclaimer](#)'. Below this is a text input field with the placeholder text 'Name, EC or CAS No' and a magnifying glass search icon.

Registered substances

Chemical Substances Search

Last updated 28 Nov 2012. Database contains 7 649 unique substances and contains information from 30 216 dossiers.

NB: The Tonnage band column contains aggregated total tonnage band values per joint / individual submission. These values are calculated from the non-confidential tonnage data of ALL registrants in a joint submission.

Registered Substances

EC / List number	<input type="text"/>	Registration Number	<input type="text"/>
CAS Number	<input type="text"/>	Registrant	<input type="text"/>
Name	<input type="text"/>	Total tonnage band (min)	<input type="text"/>
Total tonnage band (min)	<input type="text"/>	Total tonnage band (max)	<input type="text"/>
Country in which registered	<input type="text"/>	Registration type	<input type="text"/>
PBT Assessment outcome	<input type="text"/>	Submission type	<input type="text"/>

I have read and I accept the legal notice

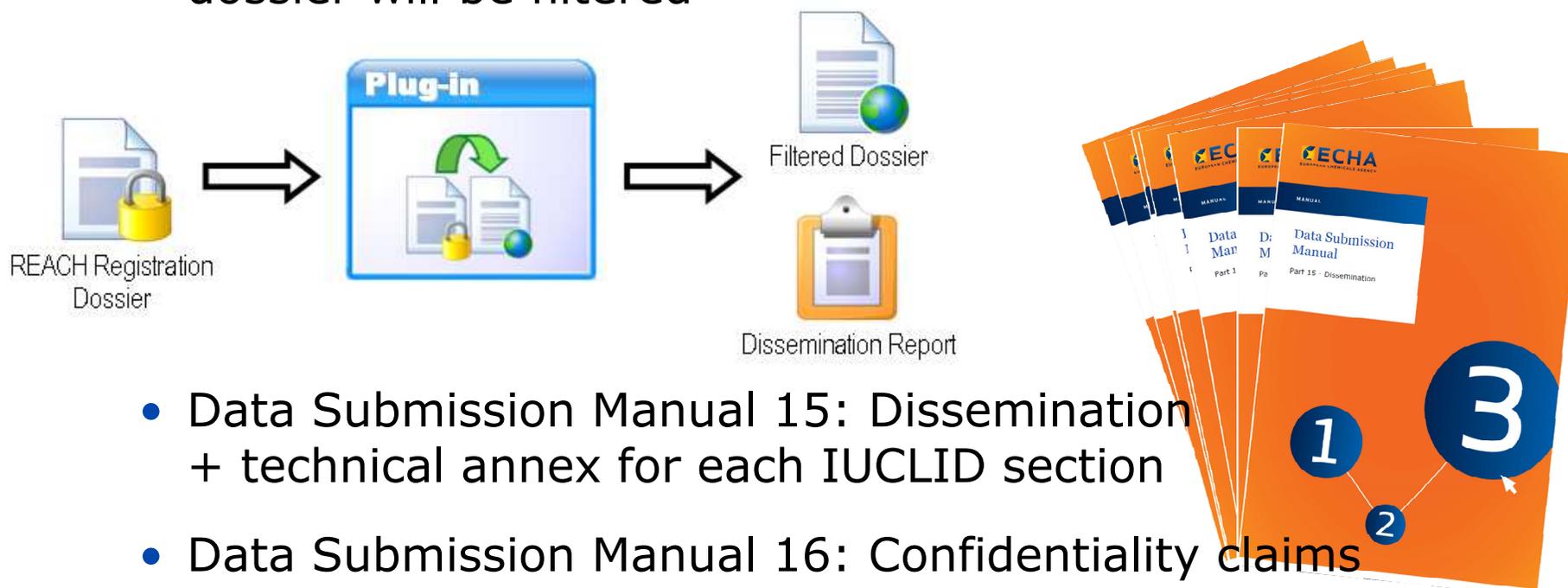
Showing 1 - 20 of 8,758 results.

Items per Page 20 Page 1 of 438

EC / List No.	CAS No.	Name	Registration type	Submission type	Tonnage band	View
200-001-8	50-00-0	formaldehyde	Intermediate	Individual Submission	Intermediate Use Only	

Tools for registrants

- IUCLID 5 dissemination plug-in: simulates how your dossier will be filtered



- Data Submission Manual 15: Dissemination + technical annex for each IUCLID section
- Data Submission Manual 16: Confidentiality claims
- Data Submission Manual 17: Deriving a public name

Thank You

janne.maaranen@echa.europa.eu