

# IUCLID 5 Project overview

*REACH-IT / IUCLID Stakeholder Webinar  
21 June 2010*

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*ECHA – Scientific IT tools Unit (C1)*

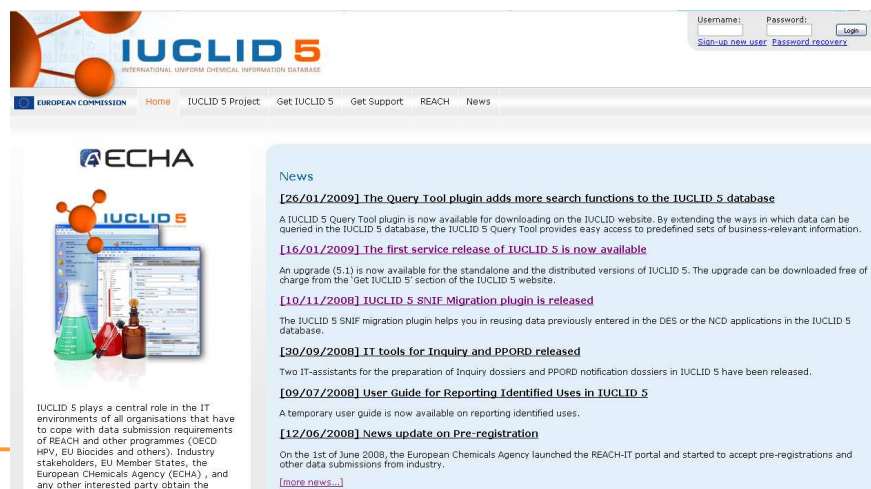
# Content

- Some figures on IUCLID 5
- From IUCLID 5 publication until now (brief recap)
- IUCLID 5.2
- Next steps

# Figures: Jun 2007 – June 2010

Update 16/06/2009

- User Accounts on the IUCLID Download Site:
  - **30,159** active
  - plus 6,093 not active (never clicked the activation link)
- IUCLID 5.0/5.1 downloads
  - Standalone: **96,510** (of which **58,914** Windows setup kit)
  - Distributed: **13,452**
- IUCLID 5.2 downloads
  - Standalone: **15,526** (of which **13,270** Windows installer)
  - Distributed: **2,829**
- LEOs: **27,894**
  - Germany 4,383
  - United Kingdom 2,928
  - France 2,245
- [iuclid.echa.europa.eu](http://iuclid.echa.europa.eu) or [iuclid.eu](http://iuclid.eu)

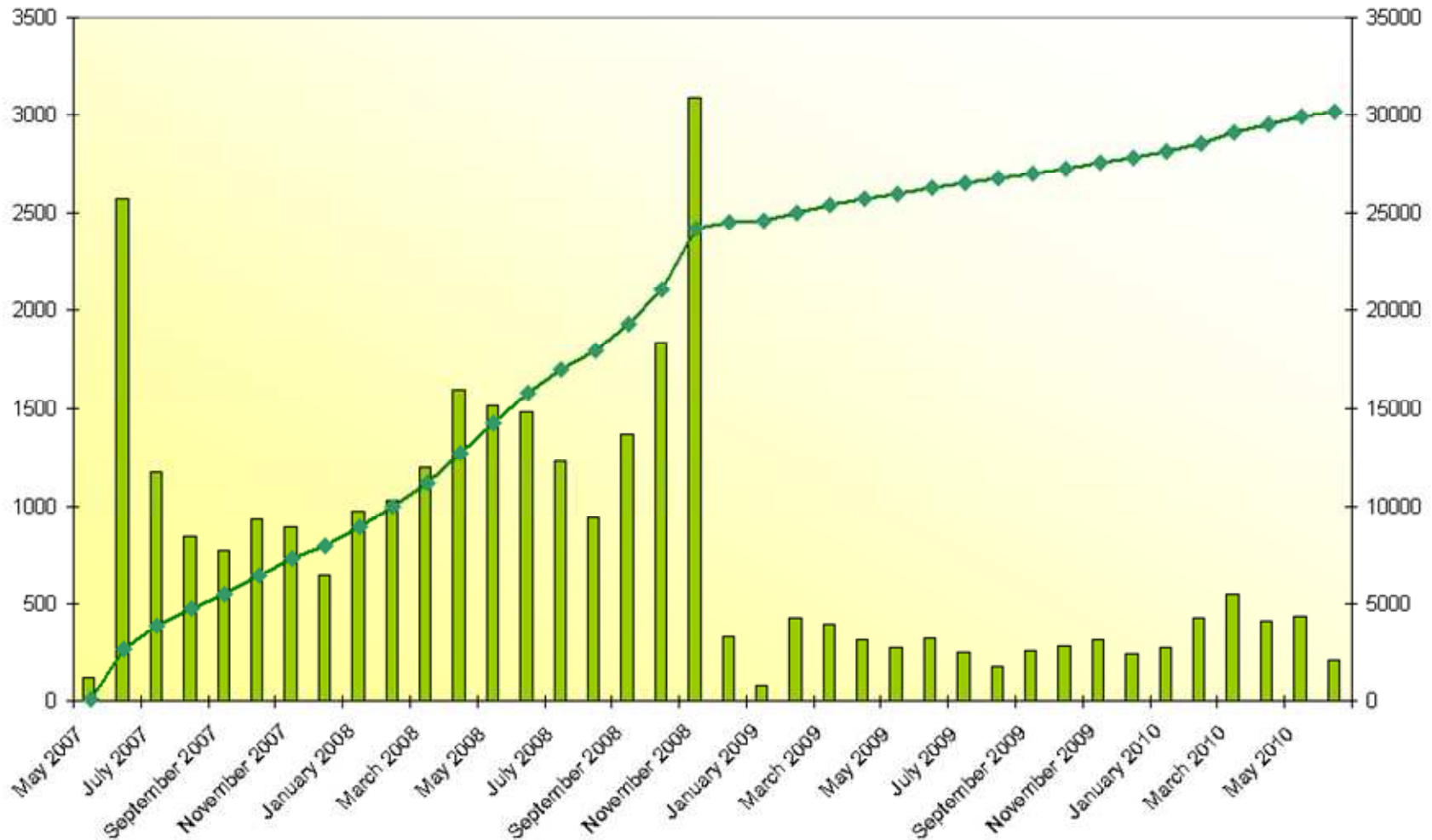


The screenshot shows the IUCLID 5 website interface. At the top, there is a navigation bar with links for Home, IUCLID 5 Project, Get IUCLID 5, Get Support, REACH, and News. Below the navigation bar, the ECHA logo is displayed. The main content area features a 'News' section with several announcements, including updates on the Query Tool plugin, the first service release of IUCLID 5, and the migration plugin. A sidebar on the left contains a description of IUCLID 5's role in IT environments.

<http://echa.europa.eu>

**CLP**

# Number of users registered on the website



# From IUCLID 5.0 to IUCLID 5.2

- 12/06/2007: IUCLID 5
- 17/12/2007: IUCLID 4 to IUCLID 5 migration tool
- 26/03/2008: Pre-registration plugin
- 10/11/2008: SNIF migration plugin
- 16/01/2009: IUCLID 5.1
- 26/01/2009: Query Tool plugin
- 04/02/2009: Translations of the Use Manual
- 26/03/2009: CSR plugin
- 08/05/2009: Web Services
- 05/06/2009: IUCLID 5.1.1
- 26/06/2009: Bulk Export and Exchange Lit. Ref. plugins
- 17/12/2009: TCC tool plugin
- 04/02/2010: backup plugin



**Migrate data**  
Migrate data from IUCLID 4 to IUCLID 5 format



**Query tool**  
Advanced search for endpoint studies, endpoint summaries, substances or mixtures  
[Find](#), [Administration](#)  
<http://www.iuclid.eu>



**Exchange literature references**  
Transfer literature references to/from spreadsheet

**TCC tool**  
Technical completeness check

**Backup**  
Backup all data.  
[Run](#)

## IUCLID 5.2 release

- Requirements discussed in September 2008 at OECD level
- Specifications prepared until June 2009
- First delivery for testing October 2009
- External testing phase in Nov-Dec 2009
- Synchronisation with REACH-IT 2.0
- Publication on 15.02.2010 ~ 1 month before the release of REACH-IT 2.0

# IUCLID 5.2 - OECD Harmonised Templates\*



- Correction / enhancement of harmonised templates for endpoint study records: more than one hundred changes have been approved by the OECD Harmonised Templates Group and will be implemented in IUCLID 5.2
- Addition of 'new' templates
  - OECD Template #87: Analytical methods
  - OECD Template #85-2: Metabolism in livestock
  - OECD Template #85-3a: Metabolism in crops
  - OECD Template #85-3b: Metabolism in rotational crops
  - OECD Template #85-4: Residues in livestock
  - OECD Template #85-5: Residues in rotational crops

\*[http://www.oecd.org/document/13/0,3343,en\\_2649\\_34365\\_36206733\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/13/0,3343,en_2649_34365_36206733_1_1_1_1,00.html)

ORGANISATION  
FOR ECONOMIC  
CO-OPERATION  
AND DEVELOPMENT

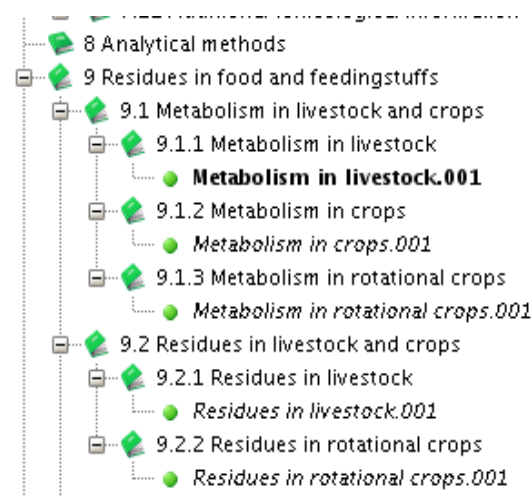


Environment Directorate

Home: [Chemical Safety](#) > [OECD Harmonised Temp](#)

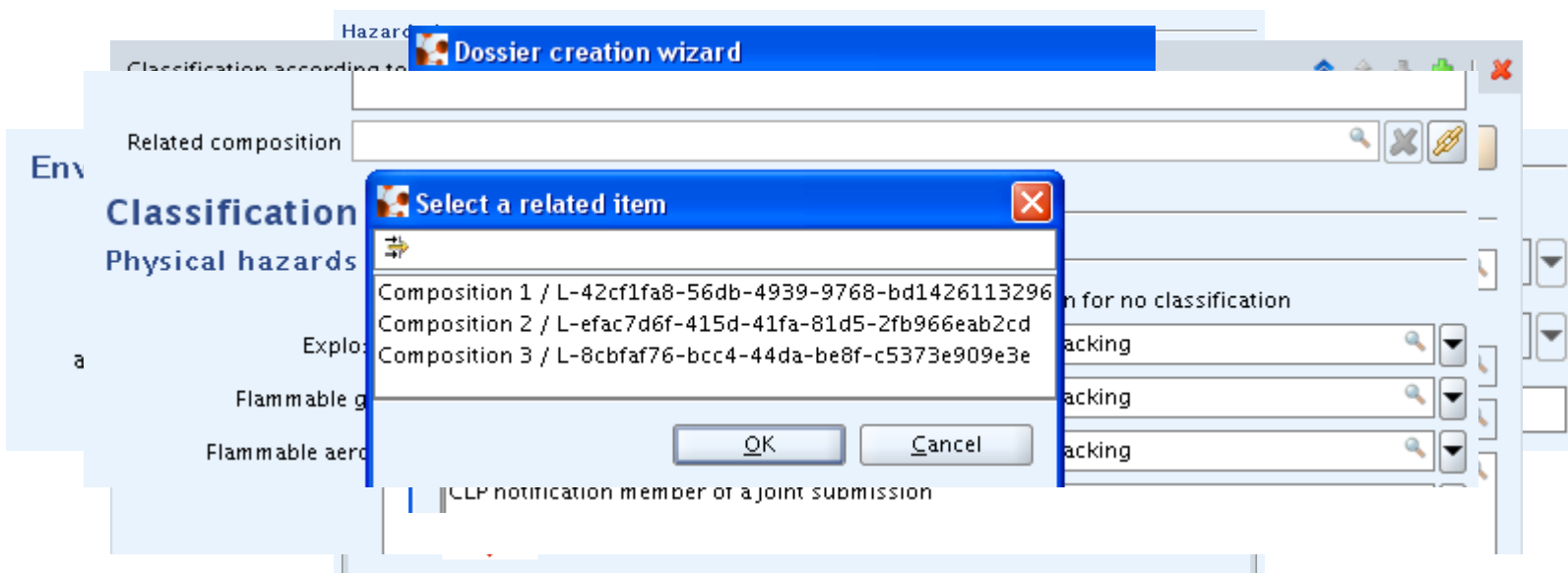
> [About](#) > [Statistics](#) > [Publications & Documents](#) > [In](#)

## OECD Harmonised Templates



# IUCLID 5.2 - C&L

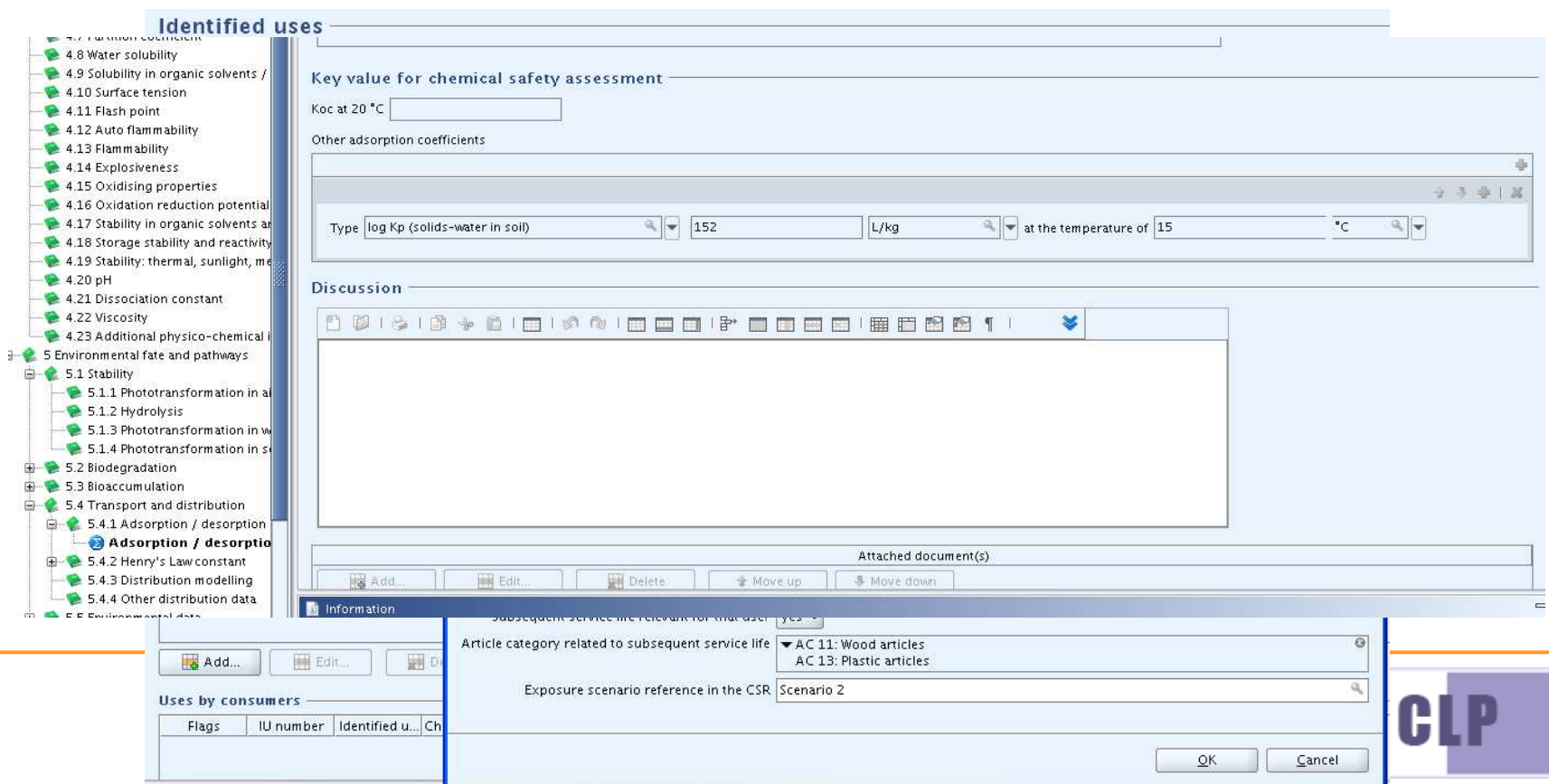
- CLP notification templates
- Adaptation of the GHS (CLP) section
  - Hazard pictogram
  - M-factor
  - EU hazard statements
  - State / form of the substance...
- Link between Composition (section 1.2) and Classification (sections 2.1/2.2)





# IUCLID 5.2 - Chemical Assessment

- Modifications for chemicals assessment tools like CHESAR
  - Section 3.2: estimated quantities
  - Section 3.5: identified uses
  - Section 3.6: uses advised against
  - Enhancement of endpoint summaries



**Identified uses**

Key value for chemical safety assessment

Koc at 20 °C

Other adsorption coefficients

Type	Value	Unit	at the temperature of	Unit
log Kp (solids-water in soil)	152	L/kg	15	°C

Discussion

Attached document(s)

Information

Subsequent service life relevant for that use: yes

Article category related to subsequent service life: AC 11: Wood articles, AC 13: Plastic articles

Exposure scenario reference in the CSR: Scenario 2

Uses by consumers

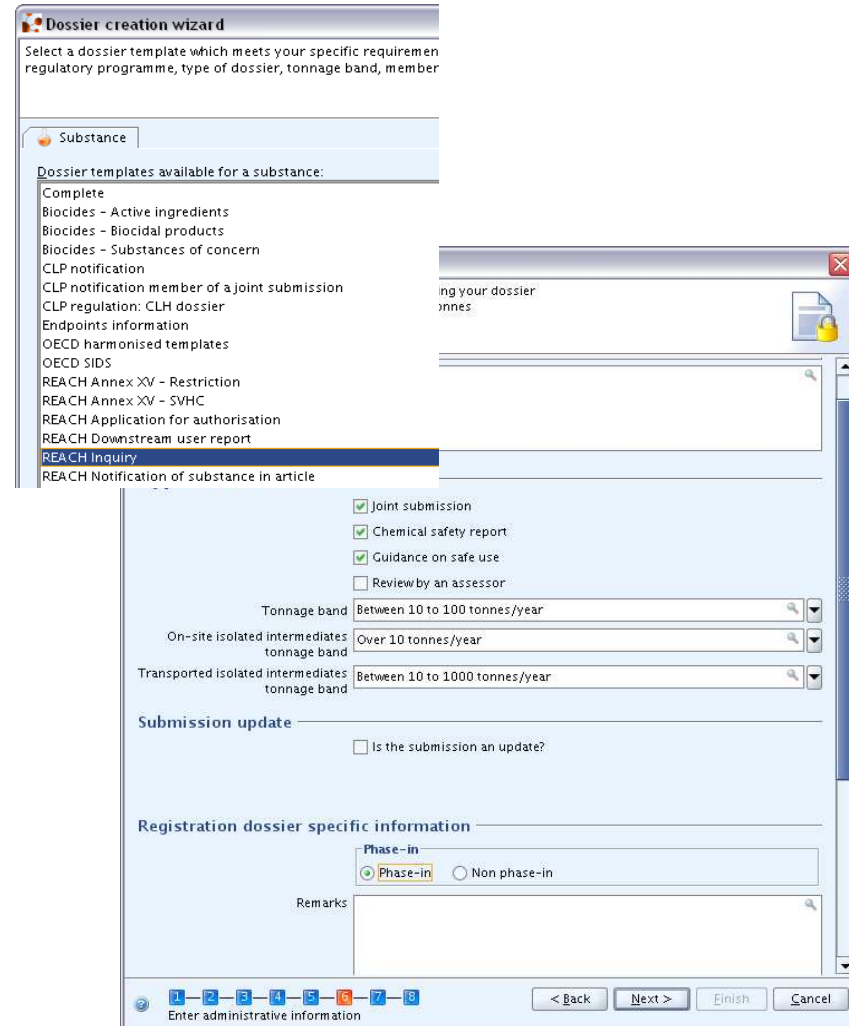
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OK Cancel

**CLP**

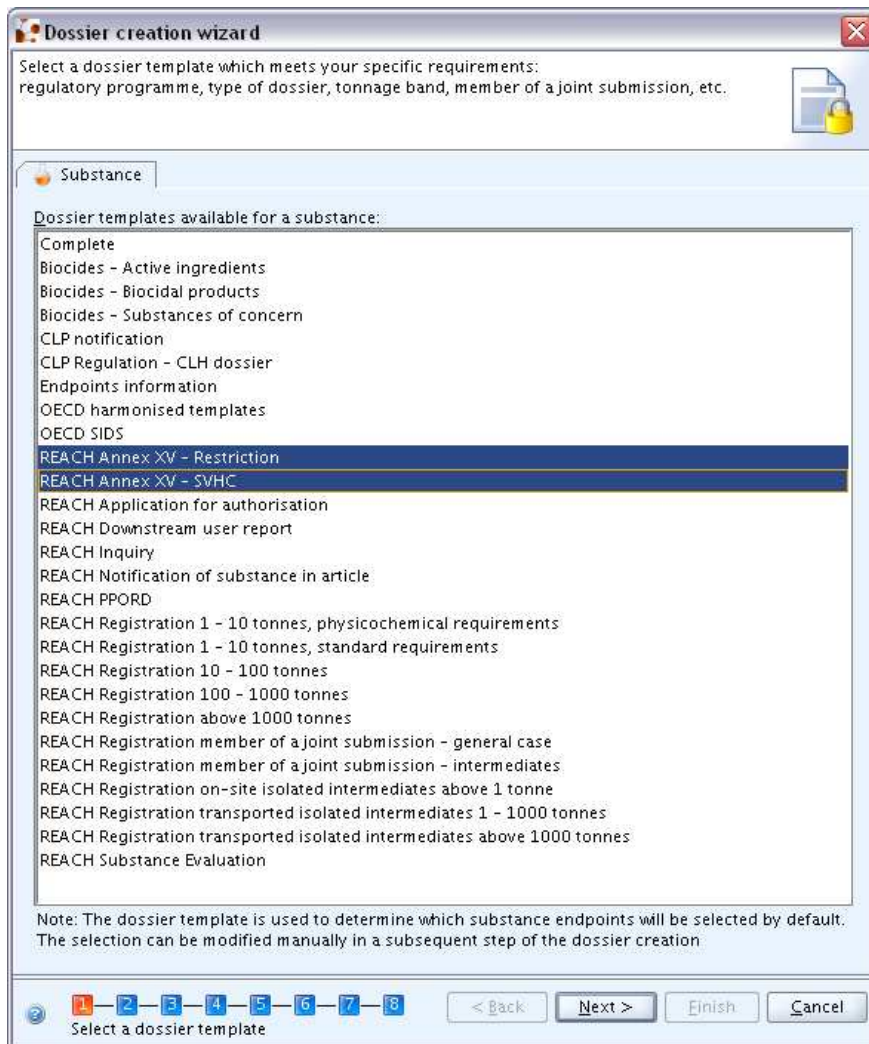
# IUCLID 5.2 – REACH dossiers submission

- Dossier templates
  - Inquiry
  - CLP notifications
- Dossier header
  - REACH-IT submission data transferred to IUCLID:
    - registration tonnage bands
    - phase-in status
  - Joint submission
    - Opt-out per information type
    - Optional information submitted by the lead on behalf of the members
- Inquiry: new section request for information



The screenshot shows the 'Dossier creation wizard' window. The title bar reads 'Dossier creation wizard'. Below the title bar, there is a subtitle: 'Select a dossier template which meets your specific requirements regulatory programme, type of dossier, tonnage band, member'. The main area is divided into two panes. The left pane, titled 'Substance', lists 'Dossier templates available for a substance:' with the following items: Complete, Biocides - Active ingredients, Biocides - Biocidal products, Biocides - Substances of concern, CLP notification, CLP notification member of a joint submission, CLP regulation: CLH dossier, Endpoints information, OECD harmonised templates, OECD SIDS, REACH Annex XV - Restriction, REACH Annex XV - SVHC, REACH Application for authorisation, REACH Downstream user report, **REACH Inquiry** (highlighted), and REACH Notification of substance in article. The right pane shows a list of templates with a search icon and a lock icon. Below the panes, there are several sections: 'Submission update' with a checkbox 'Is the submission an update?'; 'Registration dossier specific information' with radio buttons for 'Phase-in' (selected) and 'Non phase-in'; and a 'Remarks' text area. At the bottom, there is a progress bar with steps 1-8, and navigation buttons: '< Back', 'Next >', 'Finish', and 'Cancel'. The text 'Enter administrative information' is visible at the bottom left of the window.

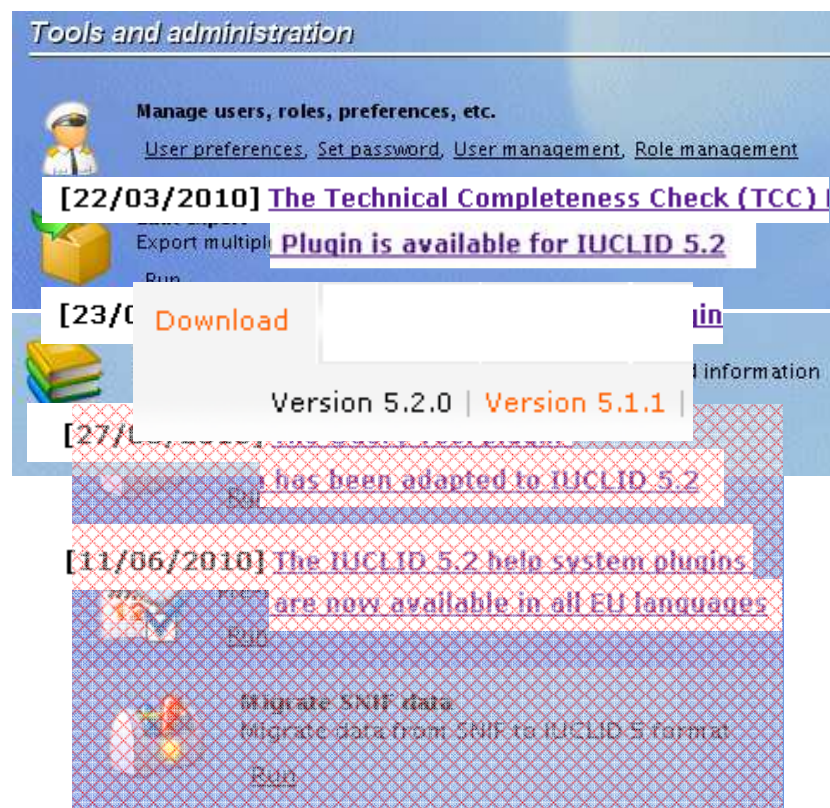
# Dossier types processed by ECHA



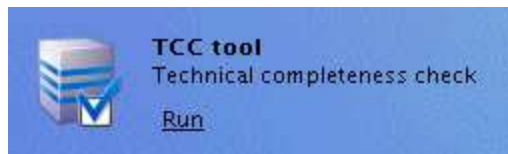
- Data Submission Manual 5: How to complete a technical dossier for **registrations** and **PPORD** notifications
- Data Submission Manual 2: How to prepare and submit an **inquiry** dossier
- Data Submission Manual part 12: How to prepare and submit a **C&L notification** using IUCLID
- Guidance on the preparation of dossiers for **harmonised classification and labelling**

# IUCLID 5.2 - Plugins compatibility

- IUCLID plugins:
  - Category 1: plugins which will be compatible with IUCLID 5.2
    - Bulk export plugin
    - Literature Exchange plugin
  - Category 2: plugins that will be updated with IUCLID 5.2
    - Technical Completeness Check plugin
    - Chemical Safety Report Tool
    - Query Tool
  - Category 3: plugins no longer supported in IUCLID 5.2
    - SNIF migration tool
    - IUCLID 4 migration tool
    - Pre-registration plugin



# TCC plugin



- Purpose
  - Perform an automatic Technical Completeness Check of a substance dataset or dossier
- First release 17.12.2009
- Regular updates
- IUCLID 5.2 compatible version available on 22.03.2010
- All Business Rules that can be checked outside REACH-IT are included
- Update foreseen to include Business Rules checking for
  - CLP notifications
  - Inquiry notifications
- Update notification included in the plugin

The screenshot displays the 'Technical completeness check' window. It features a title bar, a descriptive text area, and a table of results. The table has columns for Section number, Section name, Endpoint name, Failure description, and Type. Below the table, there are version fields for TCC engine, Business rules, and Completeness rules. At the bottom, there are navigation buttons: < Back, Next >, Finish, and Cancel. A status bar at the very bottom indicates 'Current program is up to date.' and 'Define check options'.

Section number	Section name	Endpoint name	Failure description	Type
Section 11			study" in the "Purpose flag" picklist. Supporting studies should be provided but will not be checked for completeness.	TCC failure
Section 13			Section 13: A CSR or a justification for not providing a CSR must be submitted. In order to submit a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and attach the CSR in the field 'Document'. In order to submit a justification for not providing a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and provide the justification for not providing the CSR either in the field 'Remarks' or in the field 'Discussion'.	TCC failure
Section 1.1			Failure in Business Rule BR090	BR failure
Section 1.1	Identification		The substance is specified as a mono-constituent in section 1.1. The first composition block of section 1.2 is expected to contain a single reference substance that has the same UUID than the reference substance of section 1.1. Note: The UUID of the reference substances is indicated in the 'Information' pane of IUCLID 5.	BR failure

TCC engine version: 5.05.1    Business rules version: 2.0.5    Completeness rules version: 2.0.4.0

< Back    Next >    Finish    Cancel

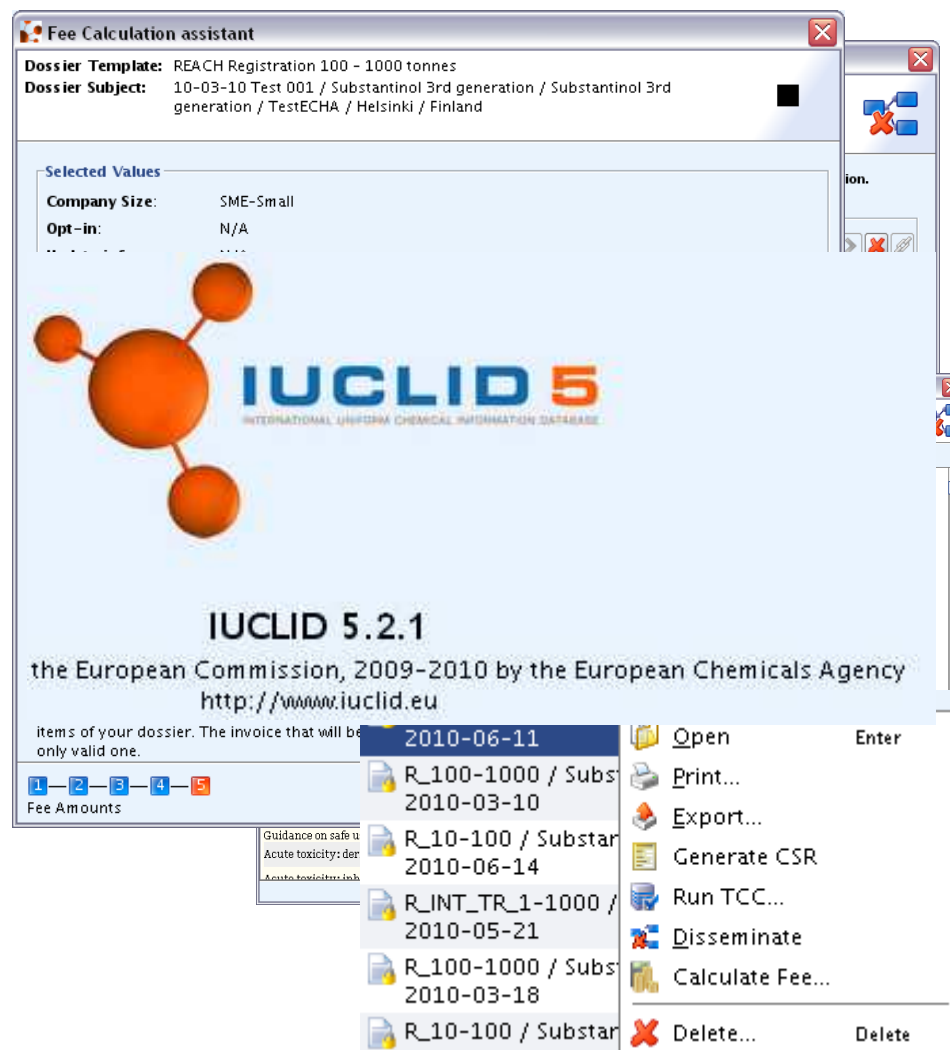
Current program is up to date.


Define check options    < Back    Next >    Finish    Cancel



# Next steps

- Dissemination plugin - 07.2010
- Fee calculator plugin - 08.2010
  
- IUCLID 5.2.1
  - Proxy configuration fixed
  - Ordering of repeatable blocks and attachments
  - Small dossier header changes
  - **No compatibility issue / Upgrade not mandatory**
  
- IUCLID 5.3
  - Q1/2010: definition of the scope of IUCLID 5.3 with the OECD IUCLID Expert User Group Panel (only functional changes)
  - Q2/2010: definition of the scope and technical specifications
    - 7 new OECD Harmonised templates
    - Update of picklists
    - ...
  - Q3/2010: development
  - **Publication date to be decided**





## **IUCLID 5**

### **Project overview**

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***Thank you for your attention***