

Specific IUCLID 5.5 aspects

IUCLID 5.5 Basics

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- Introduction – what is new in IUCLID version 5.5
- IUCLID 5 and the Biocidal Products Regulation
 - Dataset management
 - Dossier creation
- Future IUCLID developments
- Support

Introduction – What is new in IUCLID version 5.5



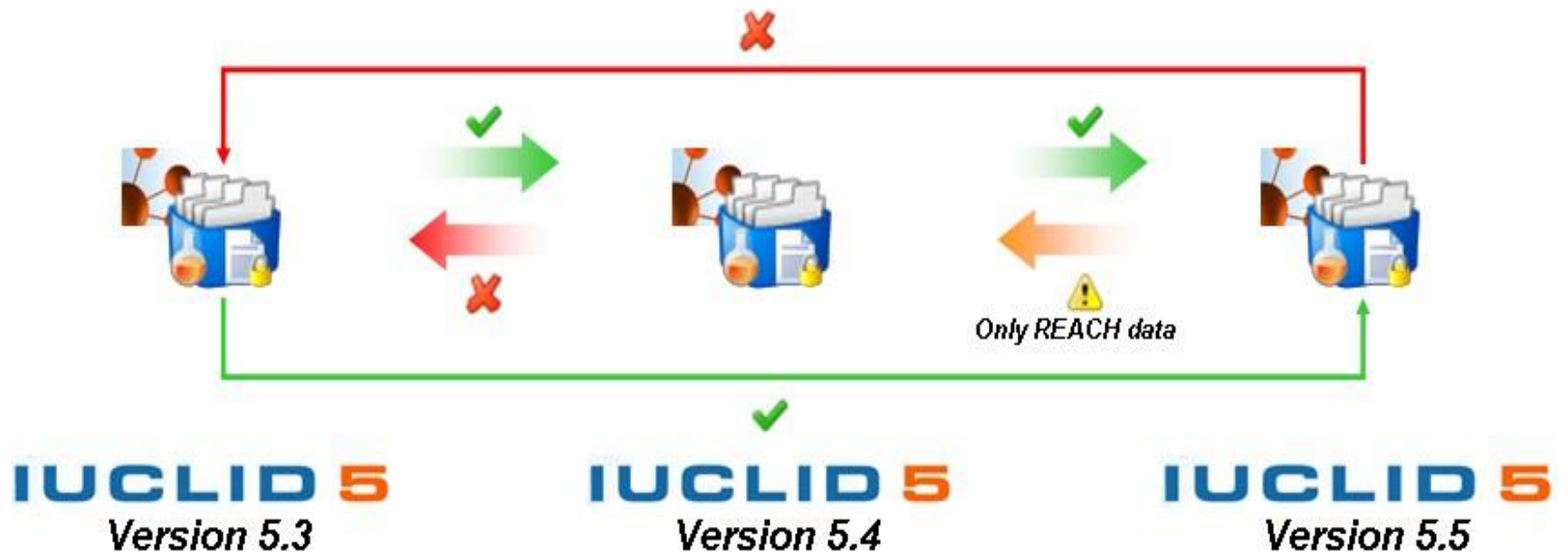
IUCLID 5.5 What's new?

- IUCLID 5.5 released 2 April 2013
- Compatibility between IUCLID versions 5.4/5.5 – for REACH data
- Documents comparison, at the field level
- Open IUCLID document via hyperlink
- 13 new OECD Harmonised Templates (OHTs) for Nanomaterials

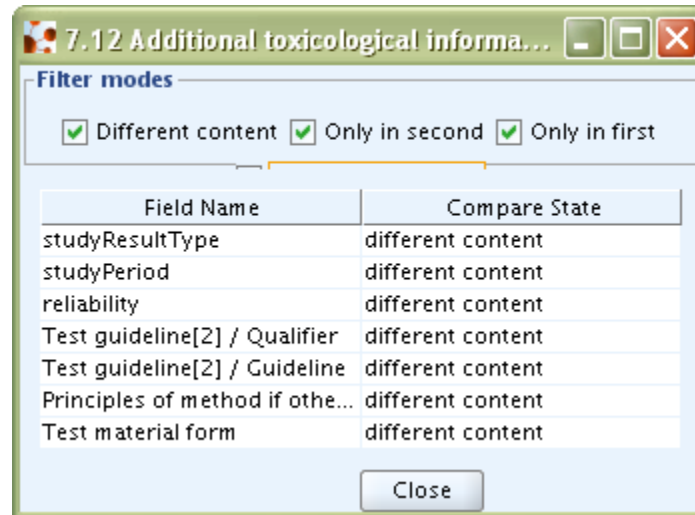
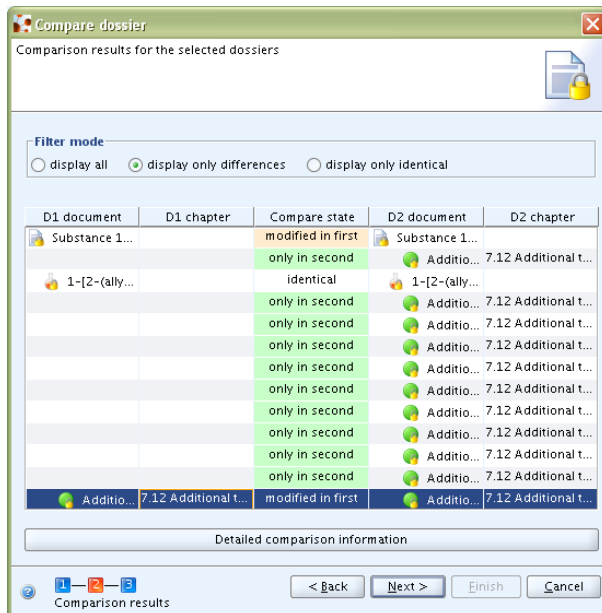
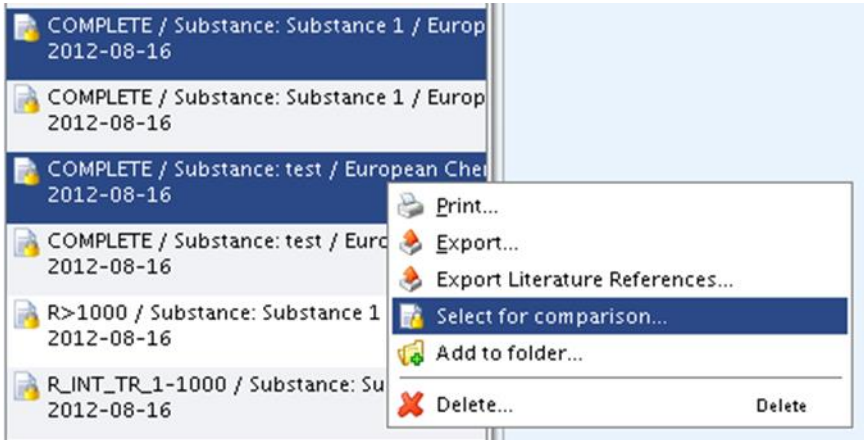
IUCLID 5.5 What's new?

- Integration of OHT for 'Emissions from preservative-treated wood' - (IUCLID Section 3.9.1)
- Light dossier export
- Role management improvements
- Literature inventory improvements
- Additional search features
- Biocides functions

Compatibility between IUCLID versions 5.4/5.5



Dossier comparison



Comparison report

Compare dossier ✕

Create a Comparison Report for the selected dossiers

Output path 📁

Filename

Include all sections
 Include only different sections
 Include only identical sections
 Include field details
 Open viewer for comparison output once finished

1-2-3
Comparison report

IUCLID Dossier Comparison report

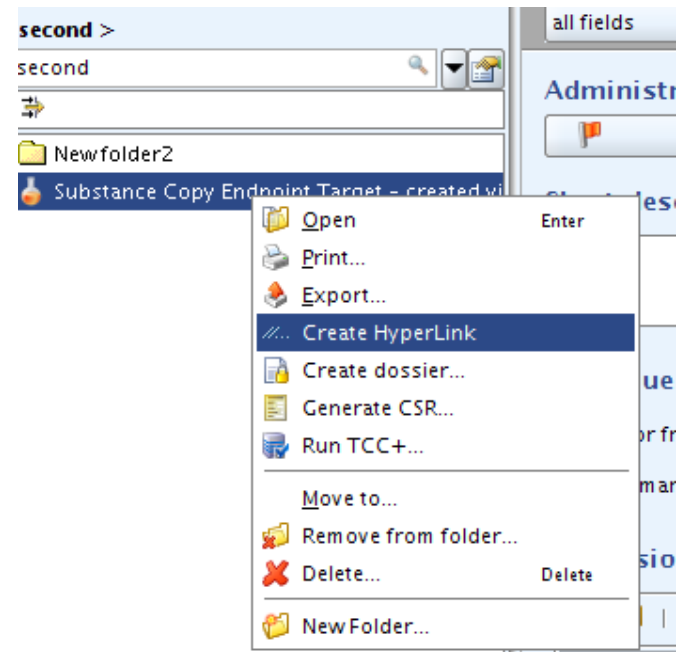
Compared Dossiers	
Dossier 1	COMPLETE / Mixture: MM_Mixture_4-1.02 / Tartu / Tartu / Estonia 2011-07-21 / MM_Mixture_4-1.02 - MM_Mixture_4-1.02 / Tartu / Tartu / Estonia (COMPLETE)
Dossier 2	COMPLETE / Mixture: MM_Mixture_4-1.02 / Tartu / Tartu / Estonia 2011-07-21 / MM_Mixture_4-1.03 - MM_Mixture_4-1.02 / Tartu / Tartu / Estonia (COMPLETE)

High Level report (comparison on sections)

D1 document	D1 chapter	Compare state	D2 document
Dossier Mixture MM_Mixture_4-1.02 / Tartu / Tartu / Estonia		modified in second	Dossier Mixture MM_Mixture_4-1.02 / Tartu / Tartu / Estonia
		only in second	Reference substance Additive 1 / Additive 1 / Additive 1 / 50-12-4
		only in second	Reference substance Additive 2 / Additive 2 / Additive 2 / 50-13-5
		only in second	Reference substance Impurity 2 / Impurity 2 / Impurity 2 / 50-10-2
		only in second	Reference substance Impurity 3 / Impurity 3 / Impurity 3 / 50-09-9

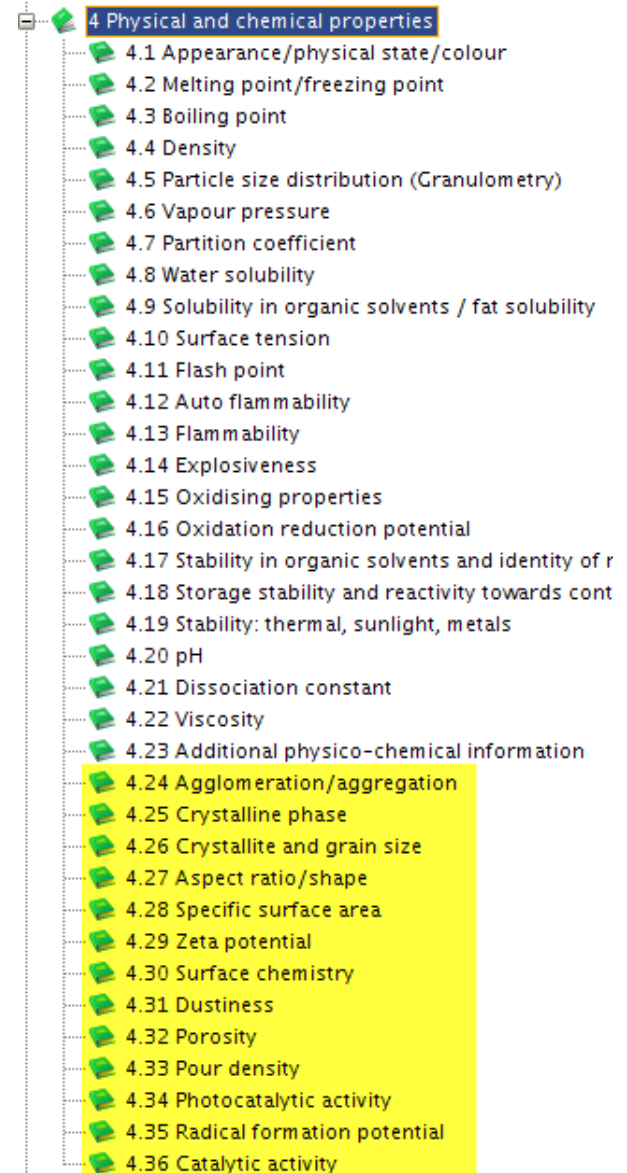
Opening IUCLID documents from hyperlinks

- Hyperlinks can be generated for IUCLID documents in a distributed version
<http://iuclid.eu/extern?UUID=IUC5-8dfe1093-96b3-49a7-8fae-c403e42ef7b9>
- If the user has access to the relevant IUCLID instance, the document will be opened directly



New for Nanomaterials

- 13 new OECD Harmonised Templates (OHTs) for Nanomaterials



4 Physical and chemical properties	
4.1	Appearance/physical state/colour
4.2	Melting point/freezing point
4.3	Boiling point
4.4	Density
4.5	Particle size distribution (Granulometry)
4.6	Vapour pressure
4.7	Partition coefficient
4.8	Water solubility
4.9	Solubility in organic solvents / fat solubility
4.10	Surface tension
4.11	Flash point
4.12	Auto flammability
4.13	Flammability
4.14	Explosiveness
4.15	Oxidising properties
4.16	Oxidation reduction potential
4.17	Stability in organic solvents and identity of r
4.18	Storage stability and reactivity towards cont
4.19	Stability: thermal, sunlight, metals
4.20	pH
4.21	Dissociation constant
4.22	Viscosity
4.23	Additional physico-chemical information
4.24	Agglomeration/aggregation
4.25	Crystalline phase
4.26	Crystallite and grain size
4.27	Aspect ratio/shape
4.28	Specific surface area
4.29	Zeta potential
4.30	Surface chemistry
4.31	Dustiness
4.32	Porosity
4.33	Pour density
4.34	Photocatalytic activity
4.35	Radical formation potential
4.36	Catalytic activity

IUCLID 5.5 and the Biocidal Products Regulation (BPR)



IUCLID 5 and the Biocidal Products Regulation (BPR)

- The technical dossiers for biocides should be submitted using IUCLID
- Dossiers created with IUCLID 5.5 fits the criteria and requirements outlined in the regulation (BPR)

Article 79

Formats and software for submission of information to the Agency

The Agency shall specify formats and software packages and make them available free of charge on its website for submissions to the Agency. The competent authorities and applicants shall use these formats and packages in their submissions pursuant to this Regulation.

The technical dossier referred to in Article 6(1) and Article 20 shall be submitted using the IUCLID software package.

IUCLID 5 for the Biocidal Products Regulation (BPR)

- Biocidal Products Regulation (BPR) enters into operation on 1 September 2013
- From 1 September 2013 onwards companies can start submitting their biocides dossiers
- The dossiers that can be generated from IUCLID 5.5 for the purpose of complying with the Biocidal Products Regulation are the following:
 - Biocidal product authorisation
 - Active substance application

IUCLID 5 for the Biocidal Products Regulation (BPR)

New data templates to store BPR-specific information

1. Biocidal product composition
2. Technical characteristics of the biocidal product
3. Physical and chemical compatibility with other products
4. Intended uses and exposure
5. Likely tonnage to be placed on the market
6. Directions for use
7. Toxicological profile for human and animals (ESS)
8. Measures to protect humans, animals and the environment
9. Packaging
10. Summary and evaluation

IUCLID 5.5 – key features for biocides

- IUCLID view for active substance and biocidal product in line with numbering of the BPR information requirements annexes
- New dossier types implemented

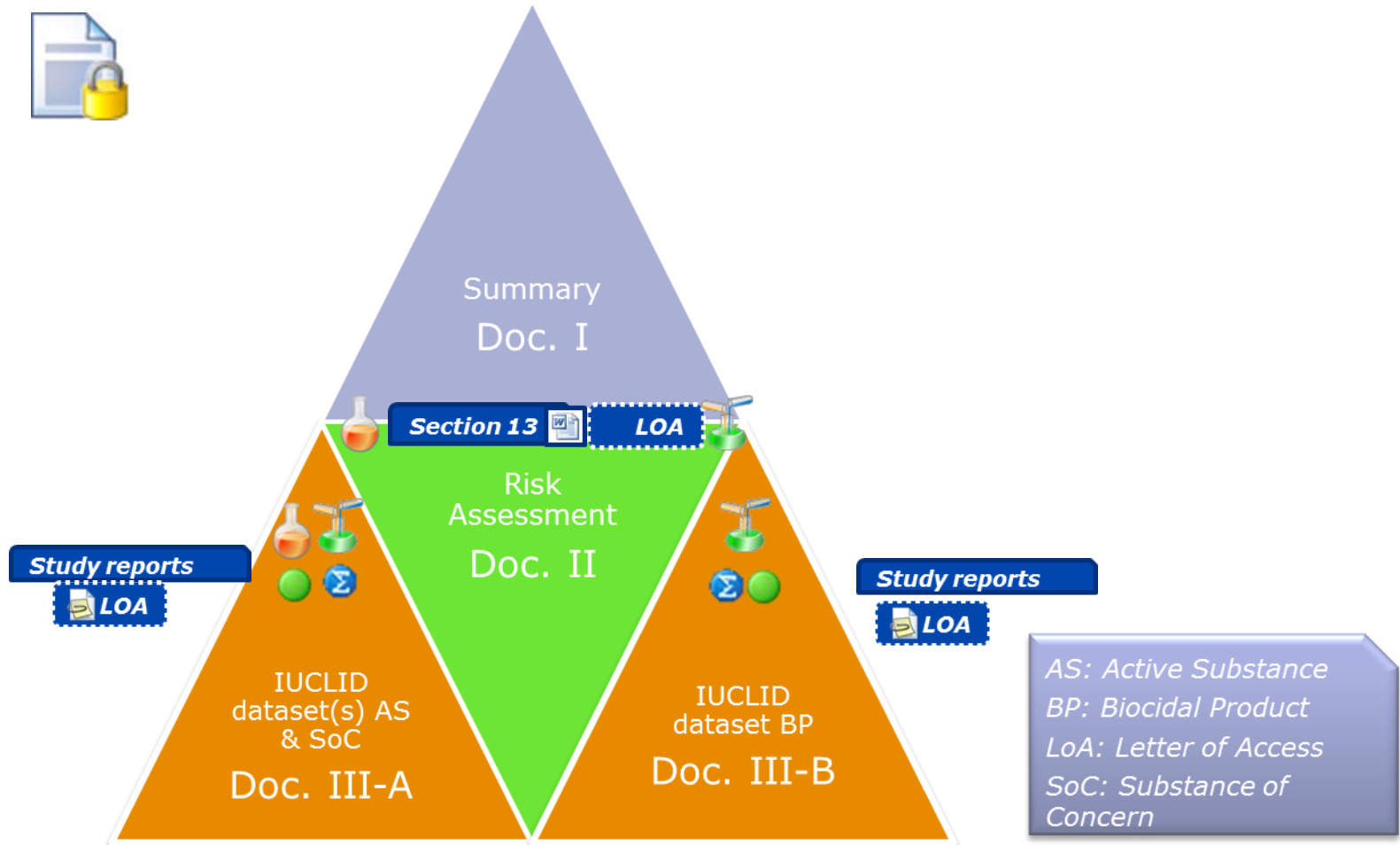
Biocidal Products Regulation

- BPR Active substance application
- BPR Biocidal product authorisation

The screenshot displays the IUCLID 5.5 interface for a BPR Active substance application. The window title is "BPR Active substance application". The main area shows a hierarchical tree view of the dossier structure:

- 0 Related Information
- 1 Applicant
- 2 Identity of the active substance
- 3 Physical and chemical properties of the active substance
 - Physical and chemical properties of the active substance
 - 3.1 Appearance
 - Appearance
 - Appearance.001
 - 3.2 Melting/freezing point
 - 3.3 Acidity, alkalinity
 - 3.4 Boiling point
 - 3.5 Relative Density
 - 3.6 Absorption spectra data (UV/VIS, IR, NMR) and a mass sp
 - 3.7 Vapour pressure and Henry's law constant
 - 3.8 Surface tension
 - 3.9 Water solubility
 - 3.10 Partition coefficient (n-octanol/water) and its pH deper
 - 3.11 Thermal stability, identity of breakdown products
 - 3.12 Reactivity towards container material
 - 3.13 Dissociation constant
 - 3.14 Granulometry
 - 3.15 Viscosity
 - 3.16 Solubility in organic solvents, including effect of tempe
 - 3.17 Stability in organic solvents used in biocidal products a
- 4 Physical hazards and respective characteristics

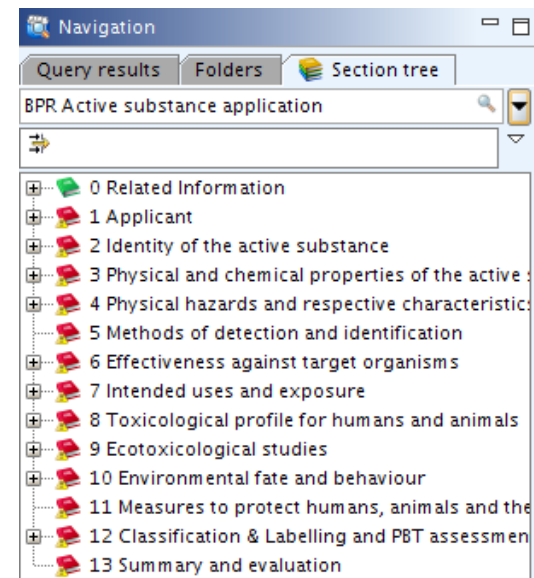
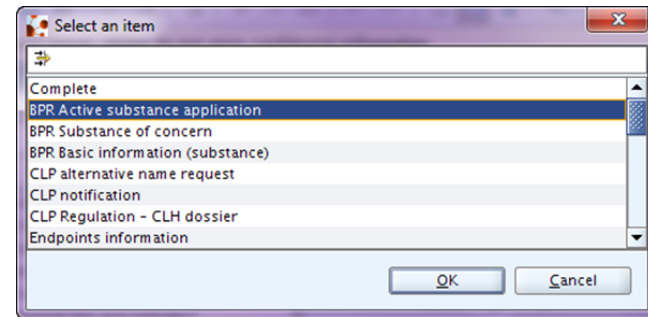
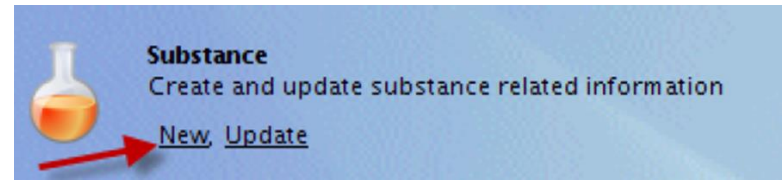
IUCLID (BPR) dossier structure



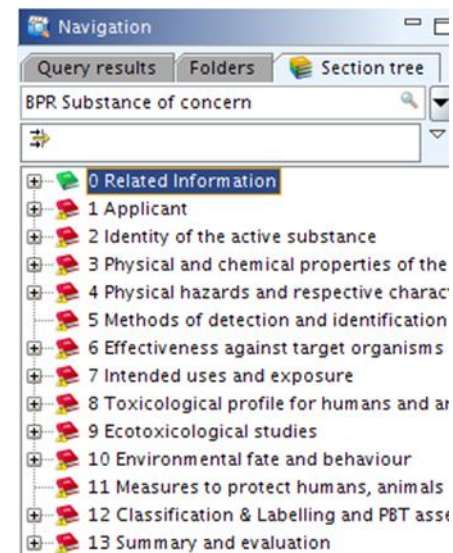
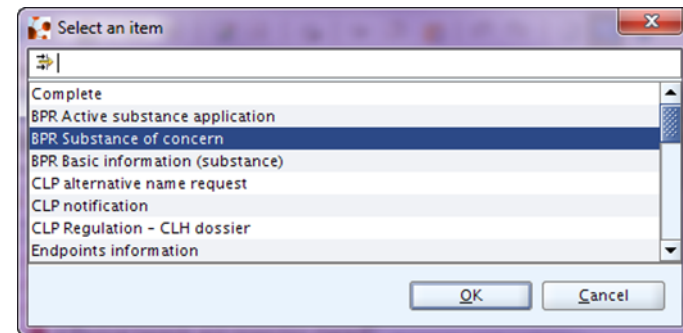
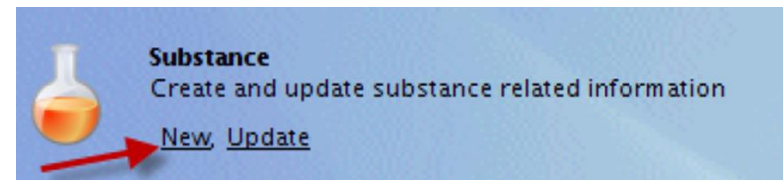
Dataset management for Biocides



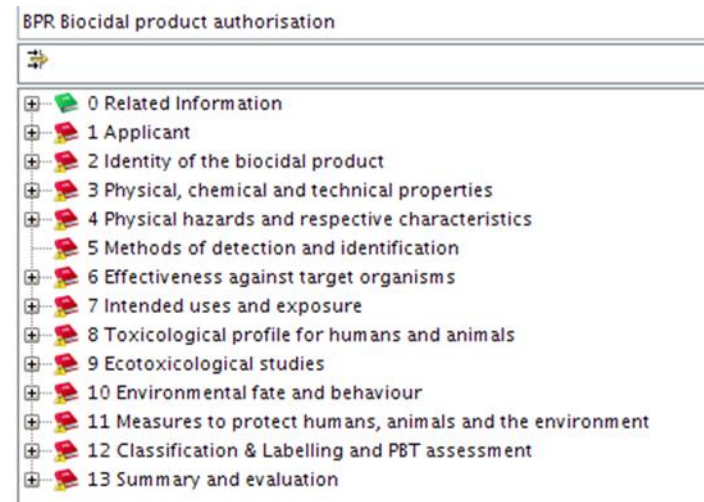
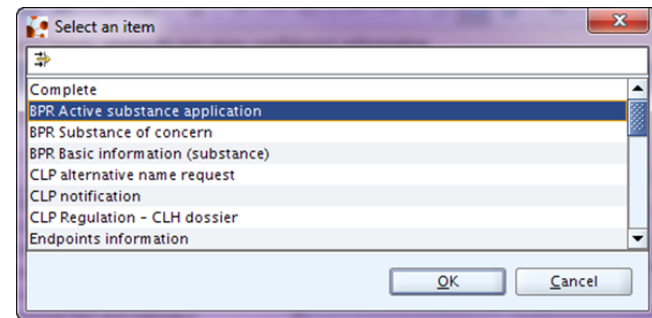
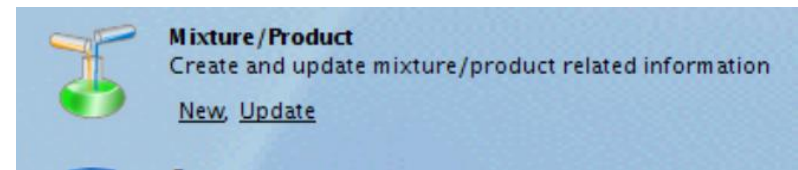
- Create a substance dataset
- Select the '**Active Substance**' filtered view
- Enter information requirements for '**Active Substance**' (Annex II BPR)



- Create a substance dataset
- Select the '**Substance of Concern**' filtered view
- Enter information requirements - similar for '**Active Substance**' (Annex II BPR)



- Create a mixture/product dataset
- Select the '**Biocidal product**' filtered view
- Enter information requirements for '**Biocidal product**' (Annex III BPR)



Biocidal Product dataset creation

Specific information requirements for Biocidal Products:

- (Section 2.3) Product Composition
- (Section 7.1) Product Types and Uses
- (Section 7.6) Instructions for Use
- (Section 12.4) Packaging

Dossier creation for BPR



Create Biocidal Product Authorisation Dossier

Creation of a biocidal product dataset *Done* ✓

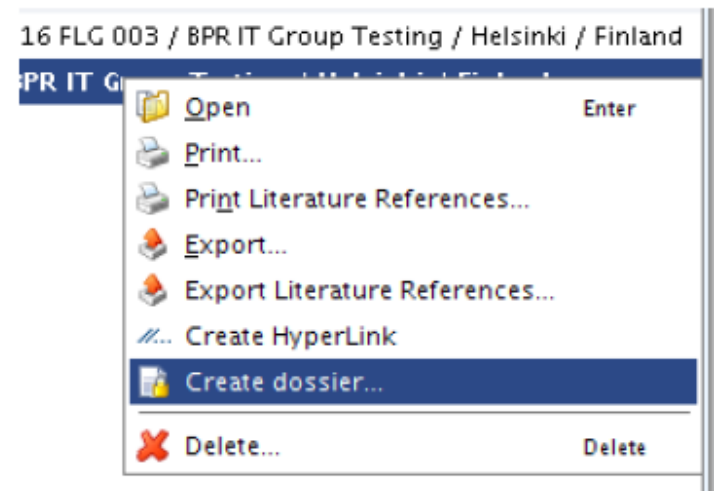
Identification of the constituents in the composition section *Done* ✓

Creation of the dossier from the biocidal product dataset:

Right click on the product dataset,  select

'Create dossier'; select the template '**BPR Biocidal product**

authorisation'; Continue the wizard until the end by selecting all information.



Finish >> View dossier >> Export i5z file

Create Active Substance Application Dossier

Creation of a active substance dataset **Done ✓**

Creation of a substance of concern dataset
(if relevant) **Done ✓**

Creation of a generic biocidal product dataset:
including identification of the constituents of the
generic product used for active substance application
in the composition section of the product **Done ✓**

Create Active Substance Application Dossier

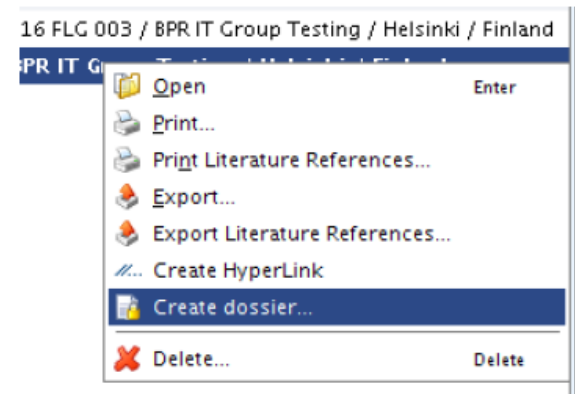
Creation of the dossier from the biocidal product dataset:

- 1) Right click on the product dataset,
- 2) Select '**Create dossier**'
- 3) Select the template



'**BPR Active substance application**'.

- 4) Continue the wizard until the end by selecting all information



Finish >> View dossier >> Export i5z file

Support



Support and manuals

- IUCLID 5 User Manual and help system
 - Updated and made available with IUCLID 5.5.0
- BPR dossier creation quick guide (already available in the IUCLID web site) and video tutorial soon available
- Dossier submission manual - available by the 'Biocides Stakeholder Day'
- Authority User Manual – *(before September 2013)*
- FAQs
- ECHA Helpdesk via our contact form

Future IUCLID developments



Future IUCLID developments

This summer:

- IUCLID 5.5.1
 - Report generator will not only be able to generate the CSR but also the BPR 'Draft Summary of Product Characteristics' report

Thank you

