

IT tool training

Biocides Day

25th of October 2018

9:30-11:15	IUCLID
11:30-13:00	SPC Editor
14:00-16:00	R4BP 3



Biocides IT tools



To manage your data and prepare dossiers



To create and edit your SPC



To submit and manage your dossiers

IUCLID 6

Biocides Day

25th of October 2018

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IUCLID Team
European Chemicals Agency



Agenda

- IUCLID 6.3
 - ✓ New web user interface
 - ✓ Improvements related to the biocides
- BPR dossier structure
- IUCLID Demo
 - ✓ How to create a biocidal product family in IUCLID?
 - ✓ How the new user interface looks like?
- Hands-on training (active substance generated *in situ*)
 - ✓ Launch IUCLID 6.3 and select the web user interface
 - ✓ Create a biocidal product dataset
 - ✓ Create biocidal product dossiers, and export them
 - ✓ Validate a biocidal product dataset, and correct an error

IUCLID 6.3



IUCLID 6.3

- Released on 24th of October 2018
 - ✓ format changes
 - ✓ new web user interface
- Biocides dossiers can be still submitted using any IUCLID 6 format
- I6z files prepared in IUCLID 6.3 can be exported to previous major version, so 6.2

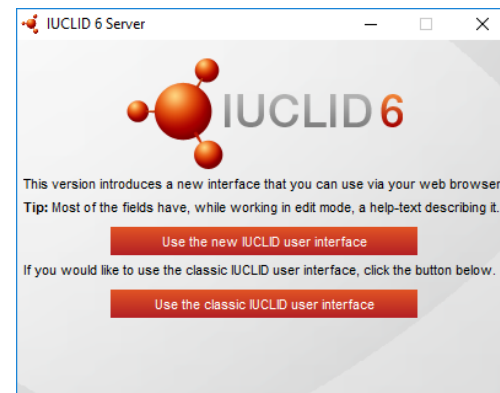
Export details

B:\FILES\427b3c8c-8bb7-4ee4-a8fe-084488456d1d.i6z Browse...

Export to previous major version

New web user interface

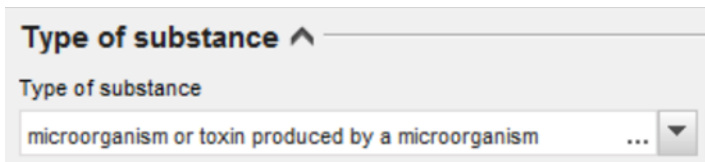
- Requires only a standard web browser
- Search any text on the screen (Ctrl + F)
- Zoom in/out
- Every document has an URL
- More windows/tabs can be open at the same time
- Page can be bookmarked
- Gaps between the 'classic' user interface, and the new one continuously reducing



More information
in the IUCLID demo

Microorganisms

- New submission type for a substance:
BPR Microorganisms
(requirements of Annex II, title 2 of the BPR)
- Dossier created based on:
 - ✓ BPR Active substance application (representative product)
 - ✓ BPR Biocidal product authorisation

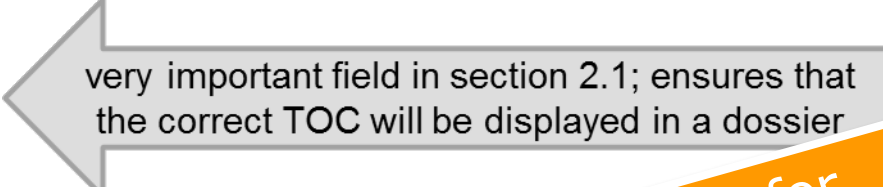


Type of substance ^

Type of substance

microorganism or toxin produced by a microorganism ...

substance dataset, section 2.1



very important field in section 2.1; ensures that the correct TOC will be displayed in a dossier

No change for the dossier

Microorganisms... continued

- New section (section 3 in BPR Microorganisms) dedicated to microorganisms
 - ✓ data required by section 3 Biological properties of the microorganism (Annex II, title 2)
 - ✓ data required by sections 5, 10 and 11 (Annex II, title 2) that cannot be reported elsewhere
 - ✓ data required by section *3.1 Biological properties of the microorganism in the biocidal product* (**Annex III**, title 2)

Microorganisms... continued

- IUCLID picklists updated where...
 - ✓ IUCLID document could be used to report microorganisms data, but an existing picklist did not contain microorganisms related options, e.g. 4. *Methods of detection and identification*

analytical methods



analytical methods
 analytical profile of batches
 methods, procedures and criteria used to establish the presence and identity of the microorganism
 methods used for monitoring purposes to determine and quantify residues (viable or non-viable)
 other:

- ✓ Units specific for microorganisms were missing, e.g. 2.7 Content of the microorganism

% (w/w)
 % (v/v)
 mg/L
 mg/kg
 ppm
 mg/m³



% (w/w)	CFU/mL
% (v/v)	CFU/L
mg/L	ITU/mg
mg/kg	ITU/mL
ppm	cells/mL
mg/m ³	cells/L
g/L	spores/g
g/kg	spores/mL
CFU/g	other:
CFU/kg	

Microorganisms... continued

Table 1. Information required by the Annex III, title 2 of the BPR and corresponding sections in IUCLID Mixture/Product dataset

Information required by the Annex III, title 2 of the BPR (MICROORGANISMS Core data and additional dataset)	In which IUCLID section of Mixture/Product dataset relevant data shall be reported
1. APPLICANT	2.1 Trade name or proposed trade name
1.1 Name and address	2.1 Trade name or proposed trade name
1.2 Contact person	2.1 Trade name or proposed trade name
1.3. Manufacturer and formulator of the biocidal product and the microorganism(s) (names, addresses, including location of plant(s))	1.3 Representative biocidal product manufacturer 1.3.1 Location of manufacturing plant(s)
2. IDENTITY OF THE BIOCIDAL PRODUCTS	2 Identity of the representative biocidal product
2.1 Trade name or proposed trade name	2.1 Trade name or proposed trade
3.1 Biological properties of the microorganism in the biocidal product	Substance dataset: 3. Biological properties of the microorganism
3.2 Appearance (at 20 °C and 101,3 kPa)	3.1 Appearance (at 20 °C and 101,3 kPa)
3.2.1 Colour (at 20 °C and 101,3 kPa)	
3.2.2 Odour (at 20 °C and 101,3 kPa)	
3.3 Acidity, alkalinity and pH value	3.2 Acidity, alkalinity

Annex 4 of the Biocides Submission Manual

Legal entity site reported separately

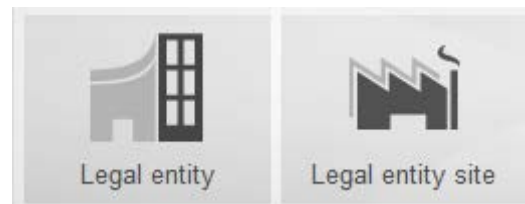
- 'Sites' document added to the BPR submission types for substances and products
- Legal entity site document now part of dossiers

▼ 1.3 Active substance manufacturer *

1.3.1 Location of manufacturing plant(s) *

▼ 1.3 Biocidal product manufacturer *

1.3.1 Location of manufacturing plant(s) *



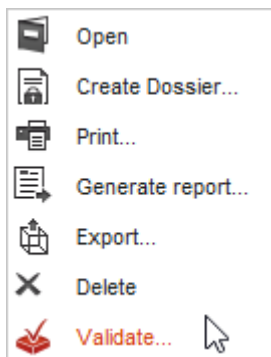
Validation of BPR data

- Two first validation rules are now available for BPR dossiers and datasets
- Rules previously included at the dossier creation stage are now transferred to the Validation Assistant

BR001: The selected Biocidal Product dataset is not valid for creating BPR Biocidal product authorisation dossier. Valid Biocidal Product dataset for this dossier type must contain at least one component with function 'active substance' and a linked substance dataset. If there is more components with function 'active substance', a relevant substance or mixture dataset must be linked to each one.

BR002: The selected representative Biocidal Product dataset is not valid for creating BPR active substance application (representative product) dossier. Valid representative Biocidal Product dataset for this dossier type must contain exactly one component with function 'active substance' and a linked substance dataset for one representative product. If there is more than one representative product, the same active substance has to be linked in all records.

Validation in the classic user interface



Validation assistant wizard

Validated entity: Product X
Time of validation: 2018/10/24 13:24:09
Validation scenario: BPR Active substance application (representative product)

Submission checks (1) Quality checks (0)

Business rules (1), Completeness check rules (0)

Re-check Open document Open document Copy report Copy selected row(s) Filter: All Rule level: All

Rule	Section nu... ^	Section name	Document name	Message	Rule type	Rule level
BPR002	2.3	Representative biocidal product composition		The selected representative Biocidal Product dataset is not valid for creating BPR active substance application (representative product) dossier. Valid representative Biocidal Product dataset for this dossier type must contain exactly one component with function 'active substance' and a linked substance dataset for one representative product. If there is more than one representative product, the same active substance has to be linked in all records.	Business rule	Failure

Validation assistant - Report

Validation in the web user interface

Submission Type:

BPR Biocidal product authorisation

[Submission type details](#)

 Validate

 Create dossier

Validation assistant report

Validation time
24/10/2018 13:31

 Re-validate

 Edit dossier settings



 Validate

! Submission checks **1**  Quality checks **0**

Business rules **1** Completeness check rules **0**
Business rule (BPR001)


 2.3 Biocidal product composition

The selected Biocidal Product dataset is not valid for creating BPR Biocidal product authorisation dossier. Valid Biocidal Product dataset for this dossier type must contain at least one component with function 'active substance' and a linked substance dataset. If there is more components with function 'active substance', a relevant substance or mixture dataset must be linked to each one.

Create dossier



 Create dossier

 You have 1 Submission rules which require fixing.
We highly recommend you fix these errors before creating and submitting your dossier.

Continue with dossier creation

View/fix errors

Biocidal product family

- Reference fields that allow to indicate for which product(s) and/or meta SPC(s) the provided document is relevant
- Products belonging to one family or meta SPC listed in the composition section of the meta SPC

Product Compositions

Product compositions

- ✓ Meta 1 Product 1
- ✓ Meta 1 Product 2
- ✓ Meta 2 Product 1
- ✓ Meta 2 Product 2

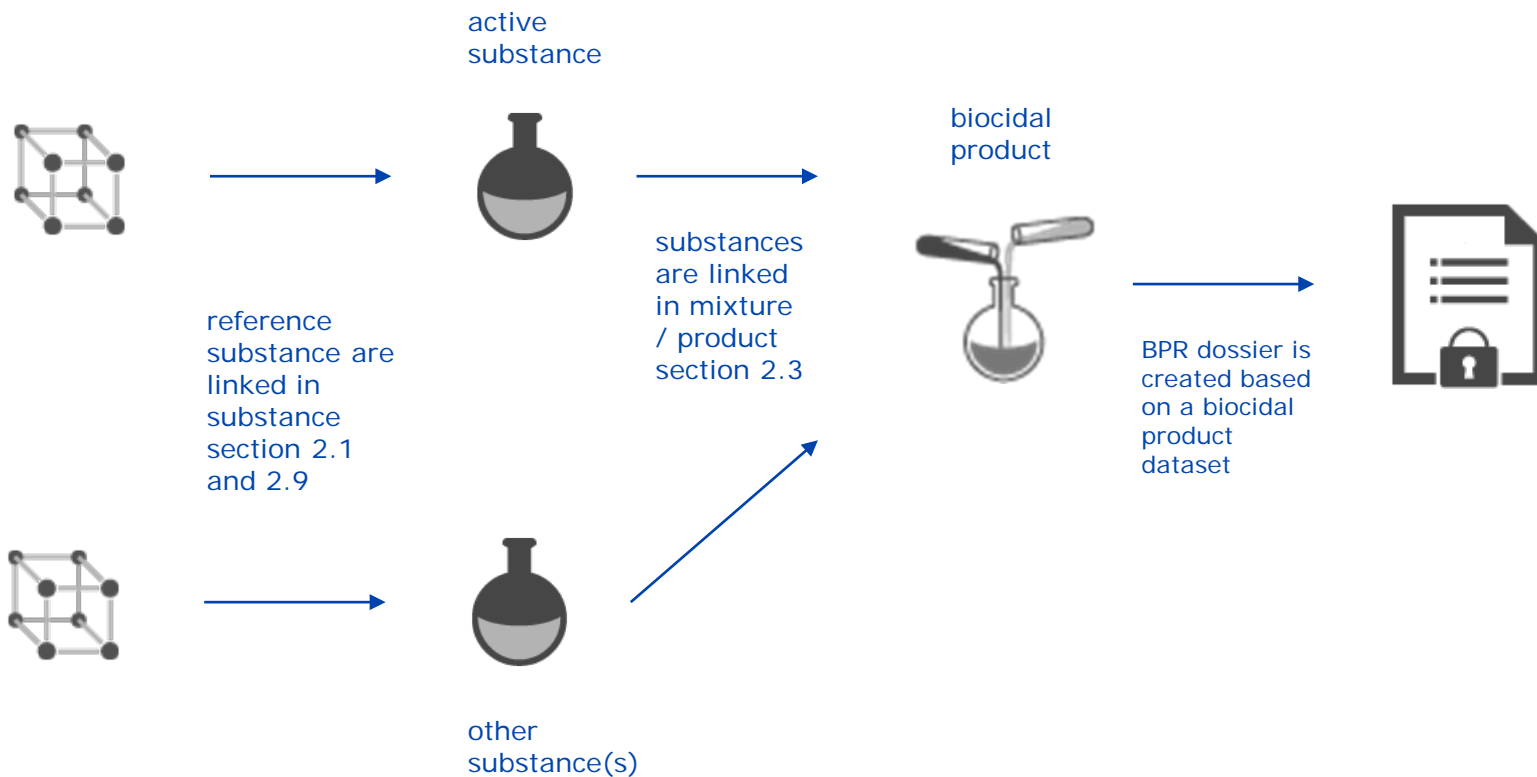
- Copying of summaries and records to build the family composition

More information
in the DEMO

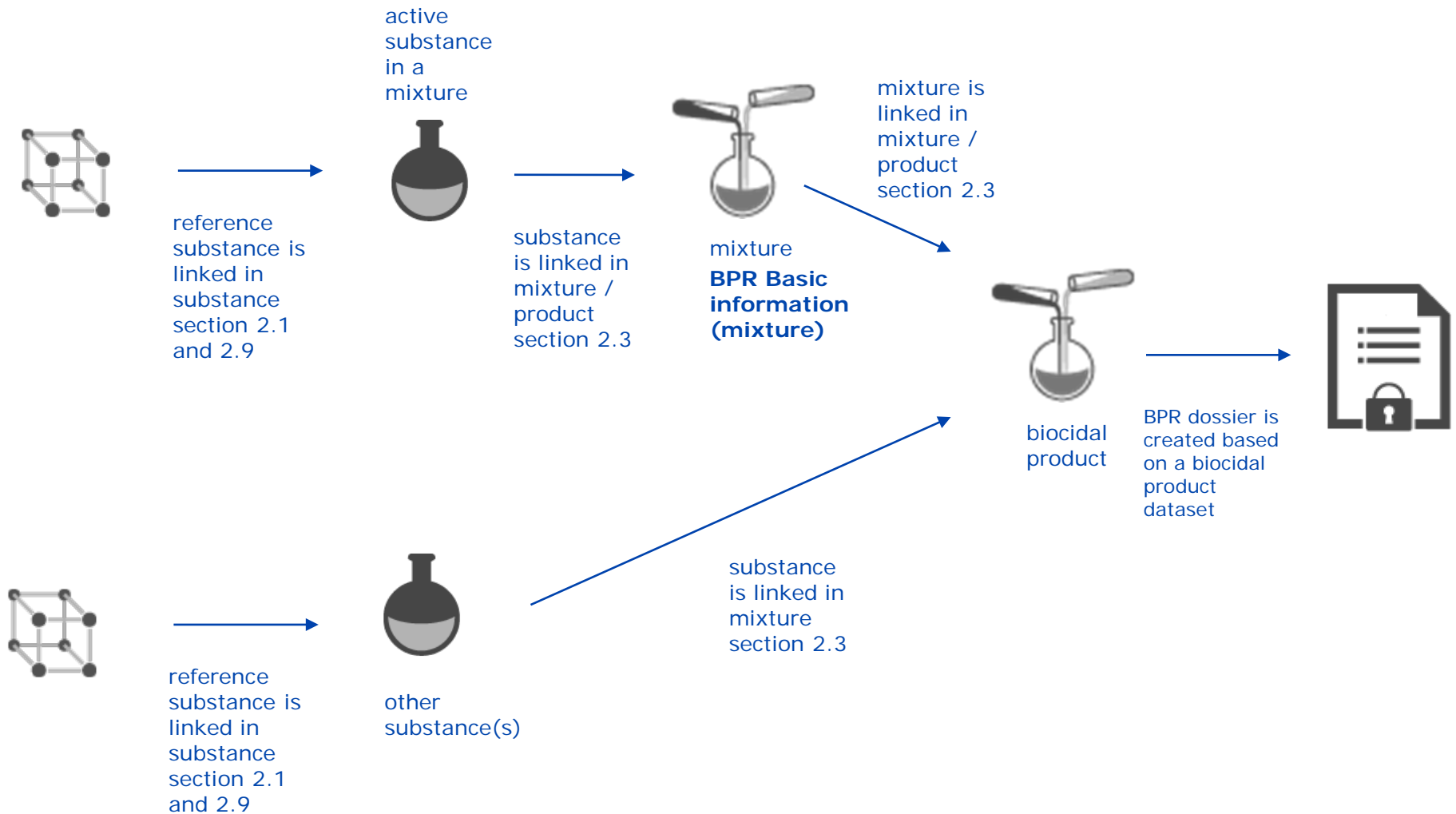
BPR dossiers



BPR dossier structure (substance-components only)



BPR dossier structure (including substance in mixture)



Components of a BPR dossier



- BPR Active substance information
- BPR Microorganisms
- BPR Basic information (substance)
- BPR Substance of concern



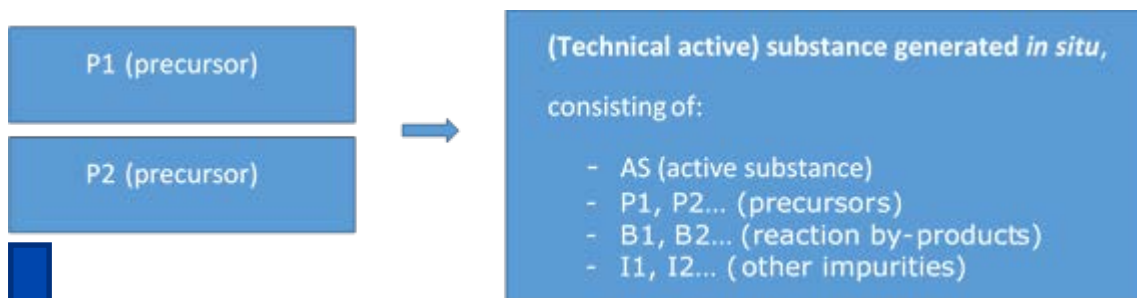
Function: active
substance



- BPR Active substance application
(representative product)
- BPR Biocidal product authorisation
- BPR Basic information (mixture)



In situ generated active substance



✓ 2.3 Representative biocidal product composition *

☰	☰	Composition of technical AS generated in situ	Last Modified:08/10/2018 15:34	100 %
☰	☰	Initial composition before precursors start to react	Last Modified:05/10/2018 13:13	100 %
☰	☰	Disinfection by products	Last Modified:08/10/2018 15:35	

Annex 2 to BSM
updated on 1st of
October

Reaction pathways described

Description

 Insert existing templates ▾

Option 1: Boundary composition of the substance

Option 2: Composition of a UVCB substance

Option 3: Microorganisms

Option 4: Technical active substance generated in situ

substance
composition
(section 2.9)

Attached description 



Description

 Insert existing templates ▾

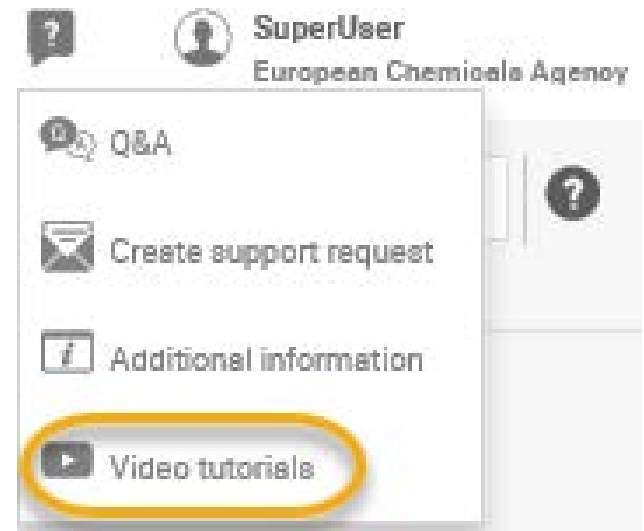
- The reaction pathways describing how the active substance is generated in situ:
- The reaction pathways describing how the disinfection by-product is generated; amounts of generated disinfection by-product:

More information



Help system

- Help system integrated in IUCLID itself in both user interfaces
- Handy links in the web user interface



IUCLID manuals and webinars

<https://iuclid6.echa.europa.eu/support>

<https://www.echa.europa.eu/web/guest/support>

<https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals>

IUCLID > Support

Support



Documentation

Find anything you want to improve or enhance your knowledge in many issues related to IUCLID 6.

[Read more](#)



> Publications



> Helpdesks

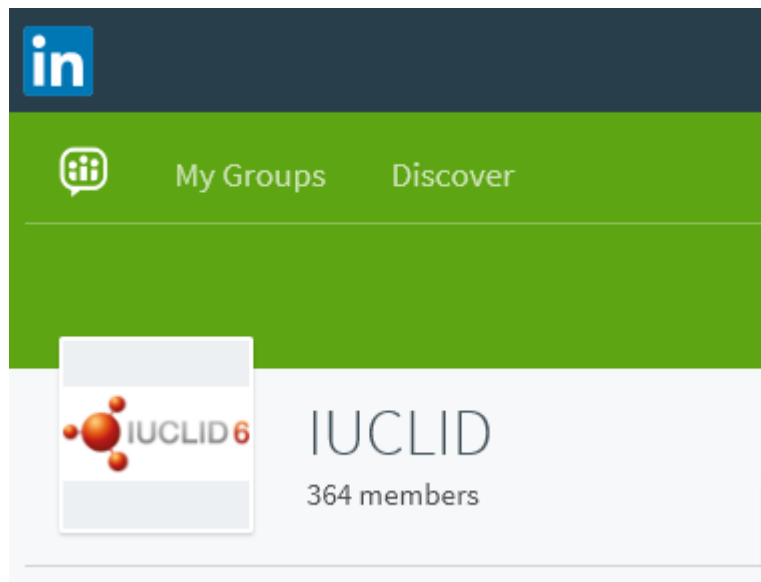


> Q&As Support
> Webinars

IUCLID LinkedIn group

IUCLID is the essential tool for any organisation or individual that needs to record, store, submit, and exchange data on chemical substances in the format of the OECD **Harmonised Templates**. Follow IUCLID on **LinkedIn** .

[iuclid6.echa.europa.eu](https://www.linkedin.com/groups/12043483)



<https://www.linkedin.com/groups/12043483>

Thank you!

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Demo

- How to create a biocidal product family in IUCLID?
- How the new web user interface looks like?



Hands on training

Creation and update of
a IUCLID dossier using the
web user interface



Scenario

- PART 1: Launch IUCLID 6 and select the web user interface to be used
- PART 2: Create a biocidal product dataset
- PART 3: Create a BPR Active substance application (representative product) dossier and a BPR Biocidal product authorisation dossier, and export them
- PART 4: Correct an error in a product dataset in order to successfully create a BPR dossier (validation)

Feedback

- Your feedback is important for us
- Feedback survey made available today

Programme continues

11:30-13:00 SPC Editor

14:00-16:00 R4BP 3

