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

- **IUCLID 6**: To manage your data and prepare dossiers
- **SPC Editor**: To create and edit your SPC
- **R4BP 3**: To submit and manage your dossiers
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

- Released on 24\textsuperscript{th} 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
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

substance dataset, section 2.1
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*

  ✔ Units specific for microorganisms were missing, e.g. 2.7 Content of the microorganism
Microorganisms... continued

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

<table>
<thead>
<tr>
<th>Information required by the Annex III, title 2 of the BPR (MICROORGANISMS Core data and additional dataset)</th>
<th>In which IUCLID section of Mixture/Product dataset relevant data shall be reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. APPLICANT</td>
<td>2.1 Trade name or proposed trade name</td>
</tr>
<tr>
<td>1.1 Name and address</td>
<td>2.1 Trade name or proposed trade name</td>
</tr>
<tr>
<td>1.2 Contact person</td>
<td>2.1 Trade name or proposed trade name</td>
</tr>
<tr>
<td>1.3. Manufacturer and formulator of the biocidal product and the microorganism(s) (names, addresses, including location of plant(s))</td>
<td>1.3 Representative biocidal product manufacturer 1.3.1 Location of manufacturing plant(s)</td>
</tr>
<tr>
<td>2. IDENTITY OF THE BIOCIDAL PRODUCTS</td>
<td>2 Identity of the representative biocidal product</td>
</tr>
<tr>
<td>2.1 Trade name or proposed trade name</td>
<td>2.1 Trade name or proposed trade name</td>
</tr>
</tbody>
</table>

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
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 each record.
Validation in the classic user interface
Validation in the web user interface

Submit type: BPR Biocidal product authorisation

Validation assistant report

Submission checks: 1
Quality checks: 0

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

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

<table>
<thead>
<tr>
<th>Product Compositions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product compositions</td>
</tr>
<tr>
<td>✔ Meta 1 Product 1</td>
</tr>
<tr>
<td>✔ Meta 1 Product 2</td>
</tr>
<tr>
<td>✔ Meta 2 Product 1</td>
</tr>
<tr>
<td>✔ Meta 2 Product 2</td>
</tr>
</tbody>
</table>

- Copying of summaries and records to build the family composition

More information in the DEMO
BPR dossiers
BPR dossier structure (substance-components only)

- Reference substance are linked in substance section 2.1 and 2.9
- Active substance
- Substances are linked in mixture / product section 2.3
- Biocidal product
- Other substance(s)
- BPR dossier is created based on a biocidal product dataset
BPR dossier structure (including substance in mixture)

- Reference substance is linked in substance section 2.1 and 2.9.
- Active substance in a mixture is linked in substance section 2.1 and 2.9.
- Substances are linked in mixture / product section 2.3.
- Mixture is linked in mixture / product section 2.3.
- BPR Basic information (mixture) is linked in mixture / product section 2.3.
- Biocidal product is created based on a biocidal product dataset.
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

(Technical active) substance generated in situ, consisting of:
- AS (active substance)
- P1, P2... (precursors)
- B1, B2... (reaction by-products)
- I1, I2... (other impurities)

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

- 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:

substance composition (section 2.9)
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

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

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