

Introduction

Webinar: Get ready for the
transition of SPC into IUCLID

15 February 2024

Roberto GILIOLI
European Chemicals Agency



What you can expect today

Time	Topic	Speaker
11.00	Presentation of the new SPC solution	Roberto GILIOLI
11.10	Outline of IUCLID functionalities for SPC	Dorota Burchard-Sosnowska
11.25	Overview of the supporting material	Heidi PIHOL
11.30	Webinar open for questions	

Q&A

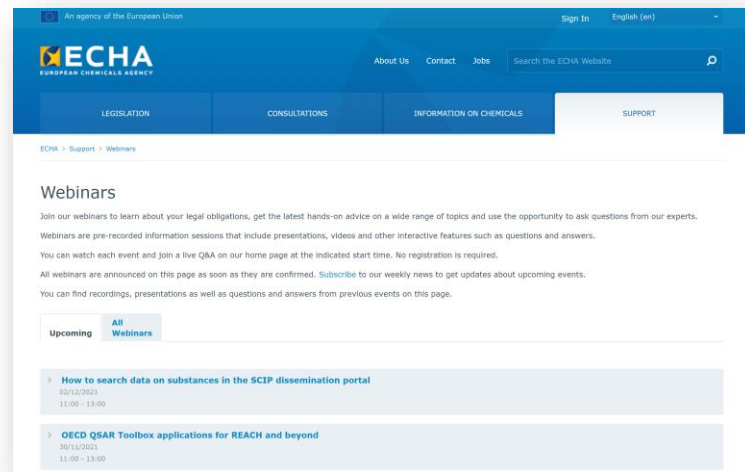
- Join Q&A at: [slido.com](https://www.slido.com)
Event code:
- Send questions until 29 February – we continue to reply after the webinar
- Only questions within scope
- Other questions?
Contact us: echa.europa.eu/contact



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Material available

- Video recording
- Presentations
- Q&A transcript (soon after the event)
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The new SPC solution

Webinar: Get ready for the
transition of SPC into IUCLID

15 February 2024

Roberto GILIOLI
European Chemicals Agency



SPC in IUCLID is now available

- **Summary of Product Characteristics (SPC):** mandatory document for biocidal product authorisations
- **In the past:** SPCs prepared with SPC editor
- **As of 12 February 2024:** SPCs must be prepared only in IUCLID format (.i6z)
- **No more access to SPC editor**



©Adobe Stock/ronstik

How to access SPC IUCLID?

Industry

- [ECHA Cloud Services](#)
- [IUCLID 6 download page](#)

Authorities

- [ECHA Cloud Services](#)



Features of SPC IUCLID

- **Same content** as in the SPC Editor
- Dedicated **IUCLID interface** for single products and product families
- **Validation rules** to check completeness and consistency
- **Translations**
- **Annotations** replacing comments
- **Plug ins:**
 - Comparison tool
 - Report generator



What changes in R4BP 3?

Only the format of SPC!

- Same R4BP 3 workflows
- SPCs in .i6z to be uploaded/downloaded in R4BP 3 tasks/cases as before
- Same way to disseminate data












Old SPCs migrated in new format

- **All SPCs** in R4BP 3 cases and assets **migrated automatically**
- Exception: **SPCs attached**
 - ad hoc communications
 - messages



How to download migrated SPCs?

- Go to relevant **case or task**
- Search for **SPC component**
- Click on relevant button:

el	en (Master)	es	et
 download to PDF	 download to PDF	 download to PDF	 download to PDF
 download to WORD	 download to WORD	 download to WORD	 download to WORD
 download in I6Z	 download in I6Z	 download in I6Z	 download in I6Z

Thank you

Roberto.GILIOLI@echa.europa.eu

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[EUchemicals](https://www.youtube.com/EUchemicals)

Outline of IUCLID functionalities for the SPC

Webinar: Get ready for the transition of SPC into IUCLID

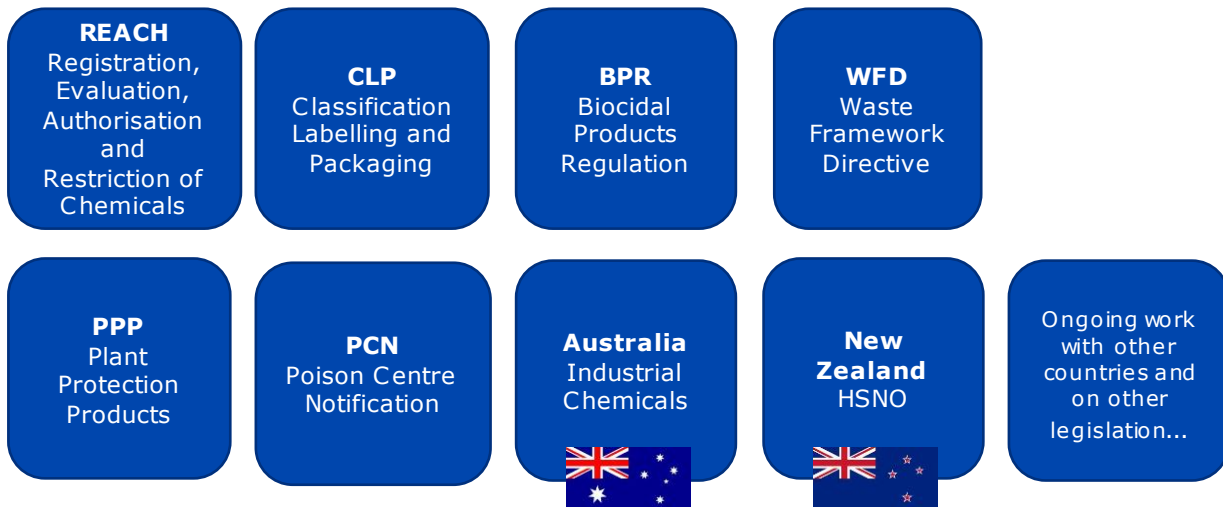
15 February 2024

Dorota BURCHARD-SOSNOWSKA
European Chemicals Agency



IUCLID - Introduction

The **I**nternational **U**niform **C**hemical **I**nformation **D**atabase is a tool to record, store and maintain data on intrinsic and hazard properties of chemical substances for different regulatory purposes.



IUCLID for biocides

- **2000** – IUCLID: software prescribed in EU Biocides Directive to notify existing active substances
- **2013** – BPR article 79 ensures all scientific data related to registered biocides are stored in IUCLID
 - IUCLID used to manage biocides data and prepare dossiers:
 - BPR biocidal product authorisation
 - BPR active substance application (representative product)
- **2024 – IUCLID used to prepare an SPC dossier**



SPC structure in IUCLID

The screenshot shows the IUCLID 6 interface for a 'Family of disinfection products'. The 'Working context' is set to 'BPR Summary of product characteristics (SPC)'. The main navigation menu lists several sections with their respective counts:

- Family of disinfection products (1)
- Manufacturers of the product (2)
- Product information (5)
- Hazard and precautionary statements (1)
- Authorised uses (1)
- General directions for use (1)
- Other information (1)

Two blue arrows point from the 'Manufacturers of the product' and 'Hazard and precautionary statements' sections in the menu to their respective expanded views on the right. The 'Manufacturers of the product' view shows a list of sub-sections: 'Manufacturer of the product', 'Location of manufacturing sites', and 'Location of manufacturing site'. The 'Hazard and precautionary statements' view shows a sub-section: 'Hazard and precautionary statements'.

Each section can be expanded to show relevant sub-sections or documents to be filled with data

SPC structure in IUCLID

Dashboard > Mixtures / Products > Family of disinfection products

Family of disinfection products
9120d867-e2e5-42a3-b301-c934d3247935

View Dossiers Validate Create dossier

Working context
BPR Summary of product characteristics (SPC)

Type at least 3 characters

- BPR Summary of product characteristics (SPC)
- Family of disinfection products
 - Manufacturers of the product 2
 - Product information 5
 - Hazard and precautionary statements 1
 - Authorised uses 1
 - General directions for use 1
 - General directions for use
 - Other information 1

General directions for use
UUID: 788c886f-a46c-4f0d-bbda-e51522c63118

Instructions for use
Treat the entire surface with the product, let act a few seconds and wipe.

Risk mitigation measures
To protect water & soil organisms it is not allowed to release residues of the treatment solution in the sewage, soil or surface water. Residues should be discharged to manure storage.

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
First aid: general information: immediately remove any clothing soiled by the product
After inhalation: Supply fresh air, consult doctor in case of complaints.
After skin contact: Generally the product does not irritate the skin.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: If symptoms persist consult doctor.

Instructions for safe disposal of the product and its packaging
To protect water & soil organisms it is not allowed to release residues of the treatment solution in the sewage, soil or surface water. Residues should be discharged to manure storage.

Conditions of storage and shelf-life of the product under normal conditions of storage
Protect from frost. Store in a tempered place, away from direct sunlight and out of reach from children. No particular precaution of use.

Documents open on the right side, can be filled, saved, edited

SPC structure in IUCLID

SPC type
single product

- Manufacturers of the product
 - Manufacturer of the product
- Location of manufacturing sites
 - Location of manufacturing site
- Product information
 - SPC name and legal entity
 - Disinfection product
 - Family, meta SPC, product
 - Product.001
- Hazard and precautionary statements
- Authorised uses
 - Use
 - Target organisms
 - Use-specific directions for use
 - Packaging
 - Method
- General directions for use
 - General directions for use
- Other information
 - Other information

SPC type
product family

- Product information
 - SPC name and legal entity
 - Family, meta SPC, product
 - Family of disinfection products
 - meta SPC 1
 - meta SPC 2
 - Product.001
 - Product.002
 - Product.003
 - Product.004

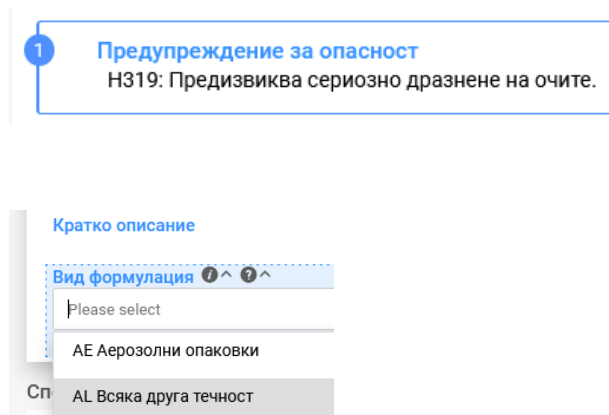
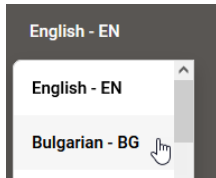
Related products

- Related products
 - Product.004
 - Product.003

Same working context to store data for a single product or a product family

Functionalities in IUCLID

→ Translations of the user interface



A screenshot of the IUCLID user interface. At the top, a blue-bordered box contains a warning message: "1 Предупреждение за опасност" (Warning for hazard) followed by "H319: Предизвиква сериозно дразнене на очите." (H319: Causes serious eye irritation). Below this, a section titled "Кратко описание" (Brief description) contains a dropdown menu labeled "Вид формулация" (Formulation type). The dropdown is open, showing the text "Please select" and two options: "AE Аерозолни опаковки" (AE Aerosol containers) and "AL Всяка друга течност" (AL Any other liquid). The "AL" option is currently selected.

Functionalities in IUCLID

→ Mandatory fields

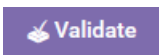
Trade names of the product

A screenshot of the 'Trade names of the product' form. The 'Country' field is highlighted with a red dashed border and a red error message: 'This field is mandatory.' Below the form, the text 'Trade name' and 'Iodine' are visible. A 'Save' button is present at the bottom right.

Trade names of the product

A screenshot of the 'Trade names of the product' form after successful completion. The 'Country' field is checked with a green checkmark and contains 'Ireland'. The 'Trade name' field contains 'Iodine'. A 'Save' button is present at the bottom right.

→ Validation

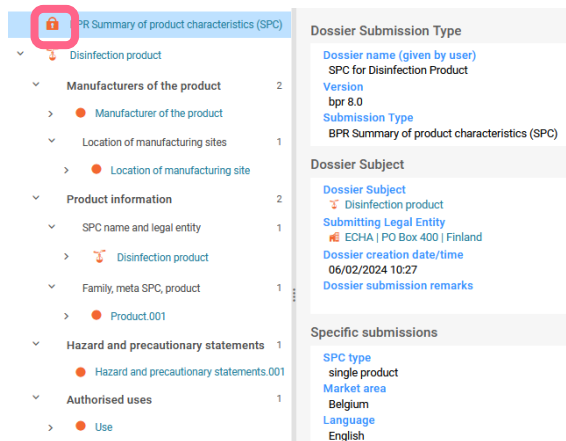
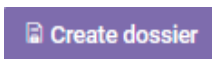


! Manufacturers of the product (👤 Family of disinfection products)

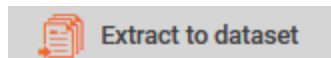
At least one complete 'Manufacturer of the product' must be provided

Functionalities in IUCLID

→ Dossier creation

A screenshot of the IUCLID interface. On the left is a tree view of dossier sections: "BPR Summary of product characteristics (SPC)" (highlighted with a red box and lock icon), "Disinfection product", "Manufacturers of the product" (2), "Location of manufacturing sites" (1), "Product information" (2), "SPC name and legal entity" (1), "Family, meta SPC, product" (1), "Hazard and precautionary statements" (1), and "Authorised uses" (1). On the right is a form for "Dossier Submission Type" and "Dossier Subject". The "Dossier Submission Type" section includes fields for "Dossier name (given by user)" (SPC for Disinfection Product), "Version" (bpr 8.0), and "Submission Type" (BPR Summary of product characteristics (SPC)). The "Dossier Subject" section includes "Dossier Subject" (Disinfection product), "Submitting Legal Entity" (ECHA | PO Box 400 | Finland), "Dossier creation date/time" (06/02/2024 10:27), and "Dossier submission remarks". Below these is a "Specific submissions" section with "SPC type" (single product), "Market area" (Belgium), and "Language" (English).

→ Extract to dataset



→ Distinction between datasets and dossiers



Functionalities in IUCLID

- SPC documents generated in IUCLID (with the report generator)
- For a single product or for a product family
 - Report format: .rtf (compatible with Microsoft Word or OpenOffice for example) and .pdf

1. ADMINISTRATIVE INFORMATION	3
1.1. Trade name(s) of the product	3
1.2. Authorisation holder	3
1.3. Manufacturer(s) of the product	3
1.4. Manufacturer(s) of the active substance(s)	3
2. PRODUCT COMPOSITION AND FORMULATION	4
2.1. Qualitative and quantitative information on the composition of the product	4
2.2. Type(s) of formulation	4
3. HAZARD AND PRECAUTIONARY STATEMENTS	5
4. AUTHORISED USE(S)	6
4.1. Use description	6
5. GENERAL DIRECTIONS FOR USE	8
5.1. Instructions for use	8
5.2. Risk mitigation measures	8
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	8
5.4. Instructions for safe disposal of the product and its packaging	8
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	8
6. OTHER INFORMATION	9

Functionalities in IUCLID

→ Translations of generated SPC documents (.rtf, .pdf)

Market area

Germany

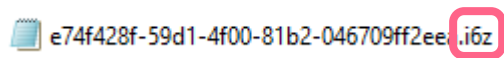
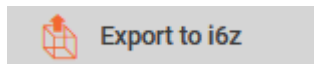
Language

German

1. ADMINISTRATIEVE INFORMATIE	3
1.1. Handelsnaam (-namen) van het product	3
1.2. Toelatingshouder	3
1.3. Fabrikant(en) van het product	3
1.4. Fabrikant(en) van de werkzame stof(fen)	3
2. PRODUCTSAMENSTELLING EN -FORMULERING	4
2.1. Kwalitatieve en kwantitatieve informatie over de samenstelling van het	

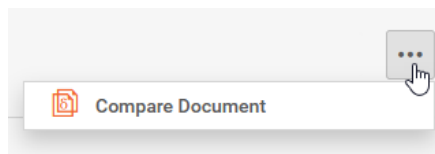
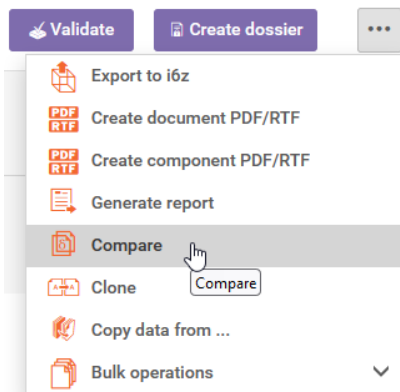
Functionalities in IUCLID

→ Export to .i6z



Functionalities in IUCLID

- Compare two SPC versions (two dossiers)
- Compare selected documents



Document Comparison Report

● BioIntendedUsesExposure: **Use.001**

Field	Source	Target
Document name	Use.001	Spraying
Field of use <i>i</i> Intended uses and exposure > Intended use and exposure	• outdoor use	• indoor use

IUCLID distributions

Desktop



- Single machine with no network connection
- Multiple users allowed but only one user at a time
- Database integrated into IUCLID application
- Targeted to small and medium sized companies

Server



- IUCLID runs in an application server over a network
- Concurrency of users
- Access restricted per document, per user and per groups of users
- For large organisations

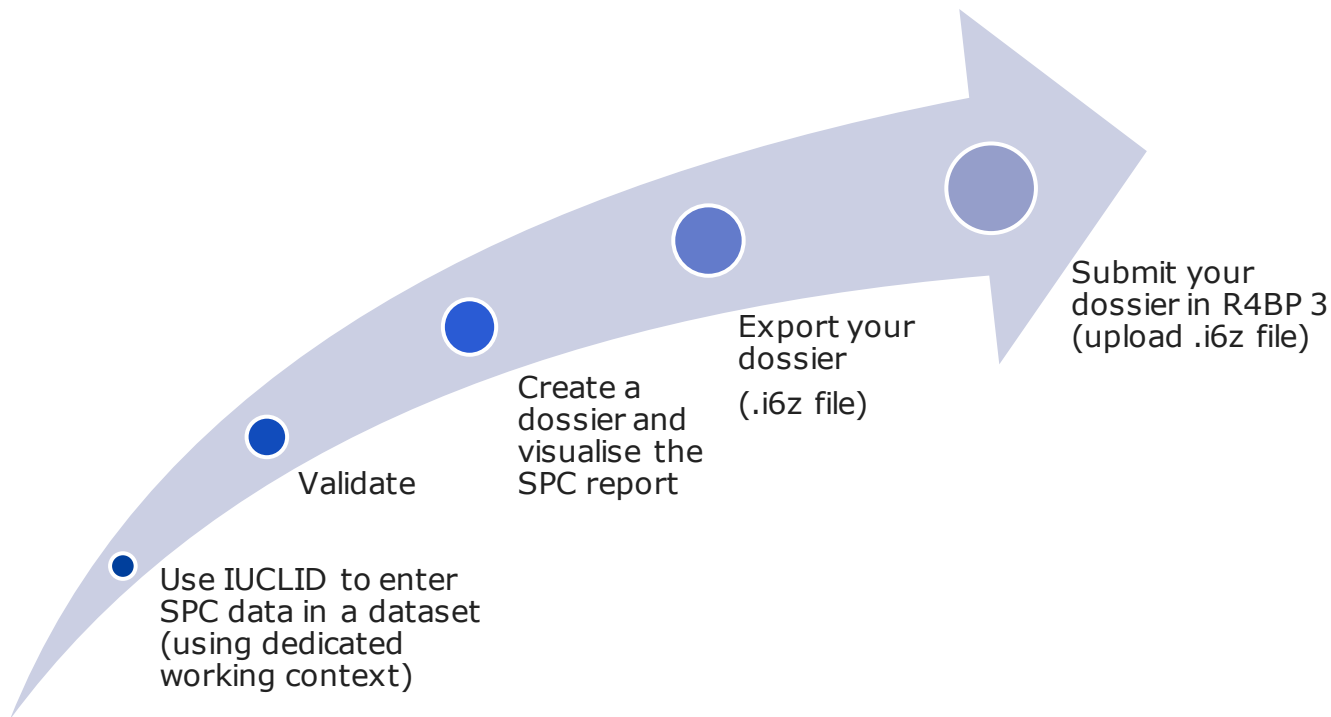
Cloud



- No installation or maintenance needed
- ECHA keeps system updated with latest version available
- Backups and data migration by ECHA
- Work from anywhere
- Free of charge

- Cloud, desktop or server - which version of IUCLID is best for me? iuclid6.echa.europa.eu/download
- v7.12.4 of IUCLID 6 published **5 February** available in each distribution

SPC creation with IUCLID



Training page on IUCLID website

→ You will find:

- An introduction to IUCLID
- Exercises and relevant IUCLID files
- Recordings of the solutions of the exercises
- Training Q&A document from 24 October 2023

SPC training session for industry, online event (24/10/2023)

This training session is organised in the context of the transition from the SPC Editor to IUCLID to prepare the Summary of Product Characteristics under the EU BPR.

The recording of the training session is available on the [IUCLID 6 YouTube channel](#).

You will find below all necessary materials needed to complete the IUCLID-relevant parts of this training:

- [Introduction to IUCLID](#) for SPC users (2.5 MB, .pdf)
- [Exercise instructions](#) (1.73 MB, .pdf)
- Relevant IUCLID 6 files (~300 KB per file, .i6z)
 - [Part 3, authorised dossier](#)
 - [Part 5, dossier for validation](#)
- Solutions to the exercises (on the IUCLID YouTube channel)
 - [Part 1](#)
 - [Part 2](#)
 - [Part 3](#)
 - [Part 4](#)
 - [Part 5](#)
- [Conclusions](#)

From the training session on 24/10/2023, until the 14/11/2023, a SiDo session was kept opened to collect any questions related to the training. The questions and answers have been gathered in this [document](#).

iuclid6.echa.europa.eu/training-material

Thank you

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[EUchemicals](https://www.youtube.com/EUchemicals)

Supporting material

Webinar: Get ready for the
transition of SPC into IUCLID

15 February 2024

Heidi PIHOL
European Chemicals Agency



Support landing page



ECHA > Support

Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

Questions and answers








Visit our Q&A page to find out more about our processes and regulations. We have created an extensive database divided into **topics**, **scopes** and **chapters** to help you easily find answers to your questions.

You can **filter** by the question's ID number, questions developed with national helpdesks, question field and answer field.

Search for Q&As

TOOLS

 CHESAR	 ECHA CHEM	 ECHA Cloud Services
 ePIC	 EU Observatory for Nanomaterials	 EUSES
 Interact Portal	 IUCLID 6	 Poison Centres
 Q&A Toolbox	 R4BP 3	 REACH-IT
 S2S	 SCIP	

The first version of our new Chemicals database, ECHA CHEM makes available information from all REACH registrations received by the European Chemicals Agency (ECHA). See for more information on the transition to ECHA CHEM. [More](#)



Are you an SME?

- Getting started with the EU chemicals legislation
- SME fees under REACH and CLP
- SME fees under Biocidal Products Regulation

How to register under REACH

- Your obligations
- Identify your substance
- What you need to submit
- What to consider for your business

Are you from a company or a member of the public?

- **Regulatory support**
REACH, CLP, BPR, PIC, WFD (SCIP), POPs, DWD, EUON, EUCLEF ...
- **Technical support**
IUCLID, REACH-IT, R4BP3, chemical data on ECHA website...
- **Additional support**
Invoicing, access to documents, speaking requests, visits to ECHA...

Are you from an EU/EEA national authority?

- Get support

Check submission manuals

The screenshot shows the ECHA website interface. At the top, there is a navigation bar with 'SEARCH FOR CHEMICALS' and 'SUPPORT' buttons. The left sidebar contains a menu for 'Dossier Submission Tools' with sub-items: Manuals, REACH-IT, IUCLID, CHESAR, SPC, and R4BP 3. Under R4BP 3, 'Biocides Submission Manuals' is highlighted. The main content area is titled 'Biocides Submission Manuals' and contains a paragraph about the BSM series. Below this is a 'Technical guides' section with two links: 'BSM Technical guide: How to prepare a biocides dossier [PDF] [EN]' and 'BSM Technical guide: How to use R4BP 3 [PDF] [EN]'. The first link is highlighted. A table lists the document 'How to prepare a biocides dossier' with a page count of 53. The document content includes a section header '4.2. Preparing a mixture/product dataset for 'BPR Summary of product characteristics (SPC)'' and a paragraph explaining that IUCLID is replacing SPC Editor. It also lists two types of datasets: 'A Product family' and 'A Single product'.

An agency of the European Union

SEARCH FOR CHEMICALS SUPPORT

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LEGISLATION

ECHA > Support > Dossier Submission Tools > R4BP 3

Dossier Submission Tools

- Manuals
- REACH-IT
- IUCLID
- CHESAR
- SPC
- R4BP 3
 - Biocides Submission Manuals**
 - Supporting documents
 - Active substances
 - National authorisations
 - Technical equivalence
 - Union authorisations
 - Simplified authorisations

Biocides Submission Manuals

The aim of the Biocides Submission Manual (BSM) series is to provide industry users with detailed and illustrative technical assistance. The BSM series describes how to build IUCLID dossiers for the various Biocidal Product Regulation applications and how to submit and manage those applications in R4BP 3 until a successful outcome is achieved.

Technical guides

- BSM Technical guide: How to prepare a biocides dossier [PDF] [EN]
- BSM Technical guide: How to use R4BP 3 [PDF] [EN]

How to prepare a biocides dossier	53
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4.2. Preparing a mixture/product dataset for 'BPR Summary of product characteristics (SPC)'

This chapter outlines how to prepare a dataset containing summary of product characteristics (SPC).

IUCLID is replacing SPC Editor. The SPC s can be created and edited only in IUCLID since the SPC Editor was decommissioned and the SPC xml files cannot be uploaded to R4BP3 anymore.

A new 'BPR Summary of product characteristics (SPC)' can be created for:

- A Product family:** A set (family) of biocidal products sharing similar properties and same mixture components with compositions comprised within defined ranges.
- A Single product:** An individual biocidal product with a specifically defined composition.

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Look for Q&As



ECHA > Support

Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

Questions and answers



Visit our Q&A page to learn about our processes and created an extensive database of questions and answers on various topics, scopes and chapters to help you easily find answers to your questions.

You can filter by the question's ID number, questions developed with national helpdesks, question field and answer field.



ECHA > Support > Questions and answers

Search for Q&As

Questions and answers

This database has questions and answers about all our processes and regulations. We have divided our content in topics, scopes and chapters to help you easily find answers to your questions. You can also filter by the question's ID number, questions developed with the national helpdesks, question field and answer field.

FURTHER INFORMATION

- Video tutorial

BPR [dropdown] SPQ [dropdown] Search Chapter... [dropdown]

Reset filters [button] [button] Search... [input]

↑ ID NHD Question Answer
[input] (All) [input]

TOOLS

CHESAR	ECHA CHEM
ePIC	EU Observatory for Nanomaterials
Interact Portal	IUCLID 6
QSR Toolbox	R4BP 3
S2S	REACH-IT
SCIP	

- Regulatory support**
REACH, CLP, BPR, PIC, WFD (SCIP), POPs, DWD, EUON, EUCLEF ...
- Technical support**
IUCLID, REACH-IT, R4BP3, chemical data on ECHA website...
- Additional support**
Invoicing, access to documents, speaking requests, visits to ECHA...

Are you from an EU/EEA national authority?

- Get support

Contact ECHA for dedicated support

LEGISLATION

CONSULTATIONS

SEARCH FOR CHEMICALS

SUPPORT

ECHA > Contact > Technical support

Contact

Regulatory support

Technical support

Additional support

Technical support

I need support with:



Chemical data published by ECHA



ePIC



R4BP 3

Contact form - R4BP 3



Release of the new SPC solution

Please be aware that R4BP 3 will not be available from Wednesday, 7 February 2024 (9:00 EET) until new SPC solution.

Please also keep in mind that after Monday, 12 February 2024, the SPC Editor will be no longer available.

Your request

Request type *

Please select...

Please select...

Log in issues and account management

Submission

Technical support

SPC IUCLID

Username

Legal Entity UUID

Question *

Please describe your situation in detail so that we can provide a fast and comprehensive answer. For technical support, please include the SPC ID and the chemical name.



Interact Portal



IUCLID 6



Poison Centres



QSAR Toolbox



R4BP 3



REACH-IT



S2S



SCIP

Are you from a company or organization?

- Regulatory support
REACH, CLP, BPR, PIC, WFD
- Technical support
IUCLID, REACH-IT, R4BP3,
- Additional support
Invoicing, access to documents

Are you from an EU/EEA national government?

- Get support

Conclusions

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15 February 2024

Heidi PIHOL
European Chemicals Agency



Key takeaways

- Benefit from IUCLID standard functionalities
- Seek for support and ECHA supports you
- Submit SPCs in IUCLID format



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Q&A

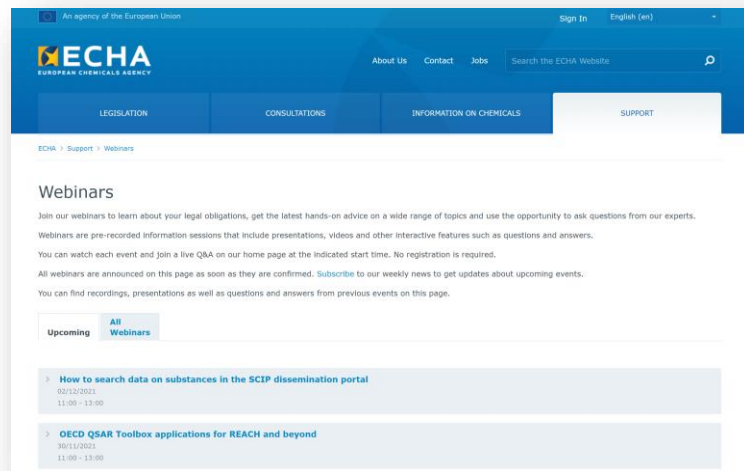
- Join Q&A at: [slido.com](https://www.slido.com)
Event code:
- Send questions until 29 February – we continue to reply after the webinar
 - Other questions?
Contact us: echa.europa.eu/contact



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Material available

- Video recording
- Presentations
- Q&A (soon after the event)



The screenshot shows the ECHA website's 'Webinars' page. The header includes the ECHA logo and navigation links for 'About Us', 'Contact', and 'Jobs'. Below the header, there are tabs for 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The main content area is titled 'Webinars' and contains the following text:

Join our webinars to learn about your legal obligations, get the latest hands-on advice on a wide range of topics and use the opportunity to ask questions from our experts. Webinars are pre-recorded information sessions that include presentations, videos and other interactive features such as questions and answers. You can watch each event and join a live Q&A on our home page at the indicated start time. No registration is required. All webinars are announced on this page as soon as they are confirmed. [Subscribe](#) to our weekly news to get updates about upcoming events. You can find recordings, presentations as well as questions and answers from previous events on this page.

Below the text, there is a filter for 'All Webinars' and a list of upcoming webinars:

Upcoming	All Webinars
3	How to search data on substances in the SCIP dissemination portal 02/12/2021 11:00 - 13:00
3	OECD QSAR Toolbox applications for REACH and beyond 30/11/2021 11:00 - 13:00

echa.europa.eu/webinars

Thank you

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