

Available support

Biocides Stakeholders' Day

1 September 2015

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Secretariat
European Chemicals Agency





Overview



1. Where to go when you have a question?
2. Support on IT tools
3. Biocides guidance
4. Particular topics of interest



Overview



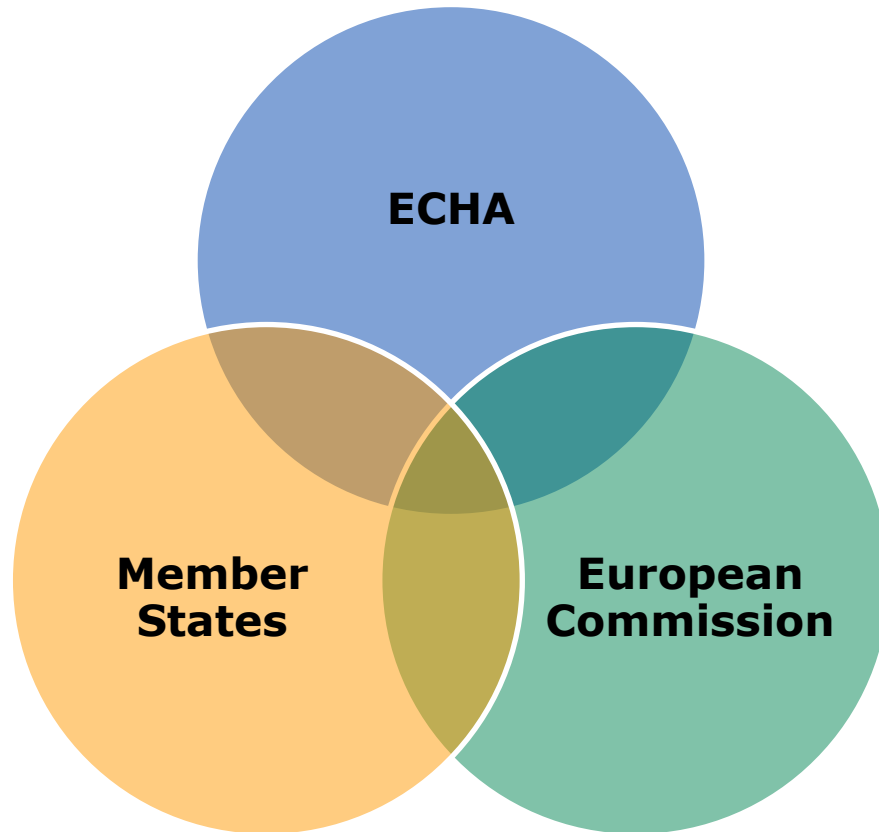
- 1. Where to go when you have a question?**
2. Support on IT tools
3. Biocides guidance
4. Particular topics of interest

**Check
available
information**



- Relevant information is available from:
 - Guidance, Q&As, newsletter, videos and webinars – all on ECHA’s website
 - Commission’s website and CIRCA BC
 - National competent authority websites
 - Stakeholder organisations

It's a joint effort



We have a network



Getting started pages

- Entry point to EU chemicals legislation for companies not yet familiar with it
- Companies can easily identify their **role** in the supply chain

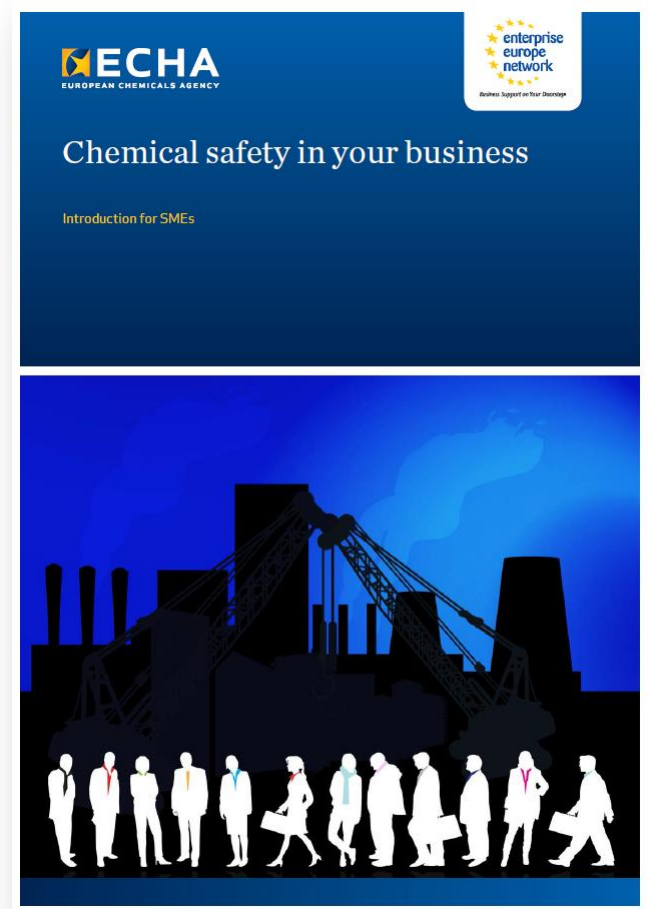
[echa.europa.eu>support>getting started](https://echa.europa.eu/support/getting_started)



 <p><i>Do you make substances?</i></p> <p>> Manufacturer</p>	 <p><i>Do you buy chemicals, raw materials or finished products from outside the EEA?</i></p> <p>> Importer</p>	 <p><i>Do you represent a non-EEA company selling chemicals and/or goods to the EEA?</i></p> <p>> Only representative</p>
 <p><i>Do you store and distribute chemicals and/or finished products?</i></p> <p>> Distributor</p>	 <p><i>Do you mix chemicals and use them in your industrial or professional activities?</i></p> <p>> User of chemicals</p>	 <p><i>Is your company based outside the EEA?</i></p> <p>> Manufacturer outside the EEA</p>
 <p><i>Do you trade very hazardous chemicals internationally?</i></p> <p>> Trader in very hazardous chemicals</p>	 <p><i>Do you handle biocides?</i></p> <p>> Biocides supplier or user</p>	

SME guide

- Overview of EU chemicals legislation: it explains REACH, CLP and BPR in 23 languages
- Practical advice:
 - How to find your way through the legislation
 - Provides links on EU and national funding
 - Lists useful sources of information
- echa.europa.eu>support>getting started



**Contact
ECHA:**

echa.europa.eu/en/contact



Remit of the ECHA Helpdesk



Regulatory advice:

- Active substance approval
- Low risk active substances, Annex I to the BPR
- Union authorisation
- Article 95
- Technical equivalence and chemical similarity check
- Review Programme management

Remit of the ECHA Helpdesk



Regulatory advice:

- BPC procedures
- Classification, labelling and packaging (Active substances)
- Data requirements
- Data sharing, including the inquiry process
- Dissemination
- ECHA fees

Remit of the ECHA helpdesk



IT tools support:

- R4BP 3, IUCLID 5 and SPC functionalities
- Dossier preparation
- Industry submission questions e.g. invoices, submission status and requirements
- R4BP2 data migration status
- Account management
- Bugs

Contact your national helpdesk

echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks



- National biocides helpdesks are the first contact point for **regulatory advice**
- Also non-EU companies need to identify the relevant national helpdesk to contact
- If your submission step is with your national authority, please contact them

Go to your national helpdesk

- I have a biocidal product but I do not know to what product type it belongs to
- I make a product available on the market but I do not know if it is a biocidal product or a plant protection product
- Is my product a treated article or a biocidal product? (Article 3(3))
- Should I apply for mutual recognition or parallel trade?



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BPR IT tools support

R4BP 3 - Register for Biocidal Products

R4BP 3 is the central hub through which all biocides applications are made. It provides functions which enable the industry and the authorities to comply with the legislative requirements and exchange information between them.

Biocides submissions under the Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012) started on 1 September 2013.

IUCLID 5 is used to collect, organise and store the data on active substances and biocidal products. For an application, you create a IUCLID 5 dossier and submit it to ECHA and the national authorities through R4BP 3. IUCLID 5 can be downloaded from the IUCLID website.

The migration of assets and applications from previous version of R4BP2 to R4BP3 has been completed.

If you cannot find in R4BP 3 the asset corresponding to your authorisation which was recorded in R4BP2, this means that the record of your authorisation in R4BP2 did not contain a valid LE UUID for the authorisation holder. To be able to perform the final migration from R4BP2 to R4BP 3, such assets have been attributed to a virtual legal entity and are currently not accessible to you or any real company ('orphan' asset). In order to get access to the 'orphan' asset in R4BP 3, please follow the instructions available under the specific links on this page. **For further information, please refer to the 'Q&A on migration' section on the ECHA website.**

How to submit applications



- › National authorisations
- › Active substances
- › Technical equivalence and chemical similarity

Biocides Submission Manuals



- › [More](#)

Tools



- › [R4BP 3](#)
- › [IUCLID](#)
- › [SPC Editor](#)

"Orphan" cases & assets

- › [Instructions to industry users to get access to their "orphan" cases and assets in R4BP 3 \[PDF\]](#)
- › [Template to claim access to "orphan" cases \[XLS\]](#)
- › [Template to claim access to "orphan" assets \[XLS\]](#)

See also

- › [Guidance](#)
- › [Video tutorials](#)
- › [Webinars](#)
- › [Supporting documents](#)
- › [Q&A](#)
- › [Q&A on migration](#)
- › [ECHA Accounts manual \[PDF\] \[EN\]](#)
- › [List of biocidal active substances](#)



Biocides submission manuals

▼ Technical guides

- › [BSM Technical guide: using IUCLID](#) [PDF] [EN]
- › [BSM Technical guide: using R4BP 3](#) [PDF] [EN]
- › [BSM Technical guide: using SPC](#) [PDF] [EN]

▼ Application instructions

- › [BSM Application instructions: active substances](#) [PDF] [EN]
- › [BSM Application instructions: technical equivalence and chemical similarity](#) [PDF] [EN]
- › [BSM Application instructions: national authorisations](#) [PDF] [EN]
- › [BSM Application instructions: simplified authorisations](#) [PDF] [EN]
- › [BSM Application instructions: Union authorisations](#) [PDF] [EN]

▼ Process manuals

- › [BSM Process of invoicing in R4BP 3](#) [PDF] [EN]
- › [BSM Process of confidentiality requests for biocide applications](#) [PDF] [EN]




Video tutorials


About Us
Regulations
Addressing Chemicals of Concern
Information on Chemicals
Chemicals in our Life
Support

ECHA > Press > Video library

Video library

Note: By going to ECHA YouTube, you are leaving the ECHA website and going to a third party site. That site may have a privacy policy different from ECHA.





Working with the SPC: drafting &

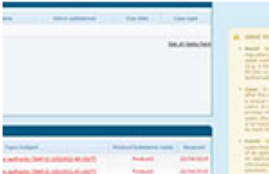
The video describes how to work with a SPC for initial applications, how to use a draft SPC or

ion or a single product as

ents

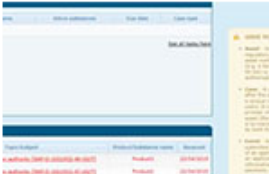
et with a complete SPC

oduct family SPC




Processes in R4BP 3: Merging assets

Conversion from a frame formulation to a biocidal product covers the practical steps you need to




Processes in R4BP 3: Asset transfer

Authorisation holder transfer for national, simplified and union authorisations in R4BP 3: technical




Who is a downstream user

Users of chemicals don't always know when they are "downstream users" under the REACH



ECHA Accounts for R4BP 3 users

This video provides an overview of how ECHA account management works for R4BP 3 users. It





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ECHA Guidance on BPR

- How to fulfil the information requirements (A) and perform the required assessments (B)
- Principles for the evaluation of applications (C)

	Volume I Identity/phys-chemical/analytical methodology	Volume II Efficacy	Volume III Human health	Volume IV Environment
Part A	Guidance	Guidance	Guidance	Guidance
Part B	Under development	Under development	Guidance	Guidance
Part C	Under development	Under development	Under development	Under development
Volume V Specific Guidance				
	Active substances and suppliers (Article 95 list)			Guidance
	Technical equivalence			Guidance
	Micro-organisms			Just published!



Planned publication dates

	Volume I Identity/phys-chemical/analytical methodology	Volume II Efficacy	Volume III Human health	Volume IV Environment
Part A	Guidance	Guidance	Guidance	Guidance
Part B	Under development	By end 2016	Guidance	Guidance
Part C	Under development	By end 2016	Under development	Under development
Volume V Specific Guidance				
	Active substances and suppliers (Article 95 list)			Guidance
	Technical equivalence			Guidance
	Micro-organisms			Just published!

The rest ready by
the beginning of
2017





Planned Guidance updates

- Volume III Human health, Part B: Sept/Oct 2015
- Volume IV Environment, Part B: By end of 2016
- Volume V Micro-organisms: By mid 2016

<http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-bpr>

Ongoing BPR guidance consultations

If ECHA identifies a need for updating existing guidance or for developing new guidance, it will prepare a corresponding draft document. A consultation procedure will be initiated based on this first draft and that will follow the following steps:

- › Consultation of a Partner Expert Group (PEG);
- › Consultation of ECHA's Committees and/or Forum, where relevant;
- › Concluding consultation of the European Commission and the relevant Competent Authorities.

In order to ensure that the guidance updating process is kept transparent and open to participation by relevant partners, drafts of the texts and feedback from the different consultation steps will be published on this webpage.

See also



› [Consultation procedure for Guidance \[PDF\]](#)

› [Guidance feedback form](#)



Transitional Guidance

- Initiated under the BPD; valid until relevant new documents are ready
- New Transitional Guidance for disinfectants PTs 1-5 to be published in Dec 2015/Jan 2016

 [Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives](#)

[> Transitional Guidance on Evaluation of Environmental RMM for Disinfectants Product Type 1-5](#)

[> Transitional Guidance on Efficacy Assessment for Product Type 22 Embalming Products](#)

[> Transitional Guidance on Efficacy Assessment for Product Type 21 Antifouling Products](#)

[> Transitional Guidance on Efficacy Assessment of Preservatives](#)

[> Transitional Guidance on mixture toxicity assessment for biocidal products for the environment](#)

Practical guides

Practical guides on REACH and CLP

Practical guides on BPR

- › [The complete Practical Guide](#) [PDF]
- › [Practical Guide cover page](#) [PDF]
- › [Practical Guide chapter on approval of active substance](#) [PDF]
- › [Practical Guide chapter on renewal of an approval of active substance](#) [PDF] (*available in December*)
- › [Practical Guide chapter on review of an approval of active substance](#) [PDF] (*available in December*)
- › [Practical Guide chapter on Article 95: List of active substances and suppliers](#) [PDF]
- › [Practical Guide chapter on technical equivalence](#) [PDF]
- › [Practical Guide chapter on national authorisation](#) [PDF]
- › [Practical Guide chapter on mutual recognition](#) [PDF]
- › [Practical Guide chapter on renewal of national authorisation and authorisations subject to mutual recognition](#) [PDF]
- › [Practical Guide chapter on Union authorisation](#) [PDF]
- › [Practical Guide chapter on simplified authorisation](#) [PDF]
- › [Practical Guide chapter on changes of biocidal products](#) [PDF]
- › [Practical Guide chapter on data sharing](#) [PDF]
- › [Practical Guide chapter on research and development](#) [PDF] (*available in December*)
- › [Practical Guide chapter on appeals](#) [PDF]



Practical guides: data sharing

- Special series published in April 2015
- Include e.g. templates for letters of access and data-sharing agreements
- Translations are on their way

- › [Introduction to the BPR and SME considerations](#) [PDF]
- › [Data Sharing](#) [PDF]
- › [Letters of Access](#) [PDF]
- › [Consortia](#) [PDF]



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Data sharing

- Practical guide - special series on data sharing
- Web page on data sharing
- ECHA decisions on data-sharing disputes under BPR

echa.europa.eu/regulations/biocidal-products-regulation/data-sharing

echa.europa.eu/regulations/biocidal-product-regulation/data-sharing/echa-decisions-on-data-sharing-disputes-under-bpr

- Further tips to negotiations

echa.europa.eu/regulations/reach/registration/data-sharing/practical-advice-for-data-sharing-negotiations



Biocidal product family

- Note for Guidance
 - Implementing the new concept of biocidal product families (CA-Nov14-Doc.5.8 - Final.rev1 - Implementing the new BPF concept)
- SPC template
 - Updated SPC template for biocidal product families
- Application instructions for R4BP 3
 - Addendum to the Biocides Submission Manuals: specific instructions for biocidal product family applications

echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals



Treated articles

- Note for Guidance
 - Frequently asked questions on treated articles

echa.europa.eu/regulations/biocidal-products-regulation/treated-articles

- Article 3(3) Commission decisions

echa.europa.eu/regulations/biocidal-products-regulation/legislation

Article 3(3) BPR Commission decisions

Commission Implementing Decision (EU) 2015/411 of 11 March 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on cationic polymeric binders with quaternary ammonium compounds incorporated in paints and coatings.

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[ro](#) [sk](#) [sl](#) [sv](#)

Commission Implementing Decision (EU) 2015/655 of 23 April 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a polydimethylsiloxane-based formulation placed on the market to control mosquitoes.

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[ro](#) [sk](#) [sl](#) [sv](#)

- › Corrigendum to Commission Implementing Decision (EU) 2015/655 of 23 April 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a polydimethylsiloxane-based formulation placed on the market to control mosquitoes (OJ L 107, 25.4.2015).

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Commission Implementing Decision (EU) 2015/646 of 23 April 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on bacterial cultures intended to reduce organic solids and to be placed on the market for that purpose.

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