

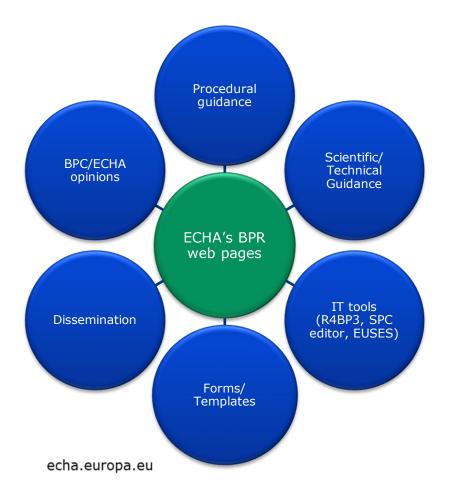
# Navigating through Biocidal Products Regulation (BPR) information on ECHA's website

#### Safer Chemicals Conference 6 October 2021





#### What is available?





#### **Procedural guidance – general information**

- Accessible by clicking on 'BPR' under the 'LEGISLATION' tab
- Most Biocidal Products Regulation (BPR) processes covered

https://echa.europa.eu/regulations/bi ocidal-productsregulation/understanding-bpr

LEGISLATION	PUBLIC CONSULTATIONS	INFORMATION ON CHEMICALS			
CHA > Legislation > BPR > Understandin	g BPR				
			REGULATIONS		
PR	Understanding BPR	Biocidal Products     Regulation			
Understanding BPR	The Biocidal Products Regulation (BPR, Re				
Upcoming deadlines	placing on the market and use of biocidal humans, animals, materials or articles ag	Regulation (EU) 528/2012			
Approval of active substances	bacteria, by the action of the active substi				
E Authorisation of biocidal products	This regulation aims to improve the functi in the EU, while ensuring a high level of p				
E Technical equivalence	environment.				
In situ generated active substances	The text was adopted on 22 May 2012 an 2013, with a transitional period for certain	ABOUT US			
Annex I amendment	Products Directive (Directive 98/8/EC).		Biocidal Products		
Product-types	All biocidal products require an authorisati market, and the active substances contain	Committee			
Active substances and suppliers	previously approved. There are, however,	certain exceptions to this principle. For	- Working groups		
Treated articles	example, biocidal products containing acti Programme can be made available on the				
BPR Legislation	laws) pending the final decision on the ap				
Data sharing	to 3 years after). Products containing new assessment may also be allowed on the r	SEE ALSO			
Chemical similarity check service	authorisation is granted.	Getting started with EU chemicals			
Substitution to safer chemicals	The BPR aims to harmonise the market a		legislation European Commission - Biocides		
	active substances and authorisation of bio for Member State evaluations, opinion-for				
	promotes the reduction of animal testing obligations and encouraging the use of al	<ul> <li>Biocidal Products Directive (Directive 98/8/EC)</li> </ul>			
	As in the previous directive, the approval	Biocides Relevant Document Links			
	Union level and the subsequent authorisa State level. This authorisation can be exte	<ul> <li>R4BP 3 user manuals</li> </ul>			
	mutual recognition. However, the new regu possibility of a new type of authorisation a	Guidance documents			
		<ul> <li>Technical agreements on Biocides</li> </ul>			
	A dedicated IT platform, the Register for I for submitting applications, exchanging da	<ul> <li>Forms and templates</li> <li>Practical Guides</li> </ul>			
	applicant, ECHA, Member State competent	Practical Guides     Working Group Documents			
	Commission. Another IT tool, IUCLID, is u	Emission scenario documents			
			Coordination Group public		
	RELATED		documents CA meeting documents		
	<ul> <li>Approval of active substances</li> </ul>		Enforcement		
	Authorisation of biocidal products				
	Technical equivalence				
	Active substance suppliers     Data sharing				



#### **Procedural guidance – practical guides**

- Various chapters describing the main processes and data-sharing rules in a concise and practical way
- Start here if you are not very familiar with the regulation

https://echa.europa.eu/practicalguides/bpr-practical-guides

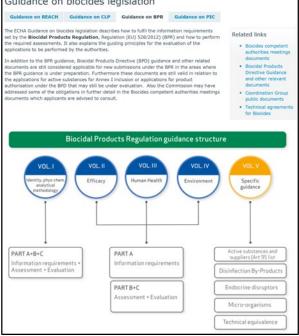
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LEGISLATION	CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT					
ECHA > Support > Guidance > Practical Gu	ides > Practical Guides on BPR					
Practical Guides	Practical Guides on BPR					
	These documents provide practical information on BPR requirements and best practice on how to fulfil them.					
	Practical guides on REACH and CLP Practical guides on BPR					
	The complete Practical Guide (DPT)     Practical Guide Coper page [DPT]     Practical Guide Coper page [DPT]     Practical Guide Coper page [DPT]     Practical Guide Coper on Reference of an approval of active substance [DPT]     Practical Guide Coper on Reference of an approval of active substance [DPT]     Practical Guide Coper on Reference of an approval of active substance [DPT]     Practical Guide Coper on Reference of an approval of active substance [DPT]     Practical Guide Coper on Reference of an approval of active substance [DPT]     Practical Guide Coper on Reference of an approval of active substance [DPT]     Practical Guide Coper on Reference of Temp approval of active substance [DPT]     Practical Guide Coper on Reference of Temp approval of active substance subjects [DPT]     Practical Guide Coper on Reference of Temp approval of active substances subject to mutual recognition [DPT]     Practical Guide Coper on Reference on Reference of Temp approval of Tem					
	Practical Guide: Special Series on Data Sharing  Introductors by BRF and SME considerations [D07]  So and a few of an and the Disk on the first of the prime of the Constraint [D07]  Latter of Access [D07]  So and the one and the Disk on the one of the Constraint [D07]  So and the one and the Disk on the one of the Constraint [D07]  So and the one and the Disk on the of the prime of the Constraint [D07]  So and the one and the Disk on the of the prime of the Constraint [D07]  So and the one and the Disk on the of the prime of the Constraint [D07]  So and the one and the Disk on the of the prime of the Constraint [D07]  So and the one and the Disk on the of the prime of the Constraint [D07]  So and the one and the Disk on the Oil Disk of the prime of the Constraint [D07]  So and the one and the Disk on the Oil Disk of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the prime of the Constraint [D07]  So and the one and the Disk of the prime of the prim of the prime of the prime of the prime of					



# Scientific/technical guidance – formal guidance

- Divided into five volumes covering different scientific areas
- Scientific assistance for active substance/biocidal product applications

https://echa.europa.eu/guidancedocuments/guidance-on-biocideslegislation





# Scientific/technical guidance – technical agreements on biocides

- Available on S-CIRCABC (link available on ECHA's website)
- Agreements made by the working groups of Biocidal Products Committee BUT not yet implemented in ECHA's guidance
- Five documents, with decisions made by the different BPC working groups that provide scientific assistance for active substance/biocidal product applications.

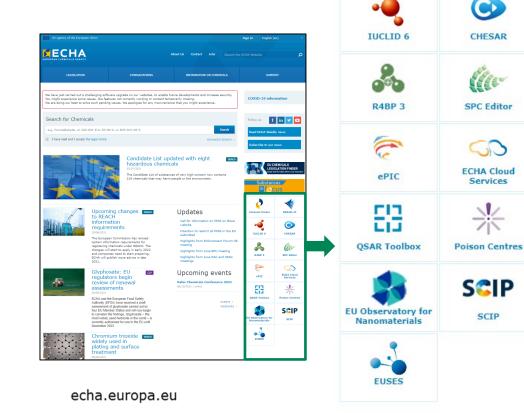
Documents agreed at BPC WG meetings - Public 🍼	Library > TAB - Technical Agreements for Biocides Library The Library is the space where contents are stored, managed ar	d abased		Http   Back
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	Archive Efficacy		10 July 2020 08:24	目心
Advanced Search	Archive Environment		21 July 2021 10:24	目心
V Clipboard	Archive Human Health		9 August 2021 11:43	目心
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S-CIRCABC online training course	APCP-TAB_version_2_0.pdf	704.08 KB	20 February 2020 09:17	🖻 🏚 🖏
W3C WAI-A MCAG 1.0	Cross-cutting-TAB_version_1.pdf	699.59 KB	3 June 2020 11:20	🗎 🏥 🗳
	EFF-TAB_version_2_2.pdf	312.62 KB	10 July 2020 08:25	i 💼 💼 🛍
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	4 TOX-TAB-09_08_2021.pdf	426.16 KB	9 August 2021 11:46	目 🏚 🛍
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https://webgate.ec.europa.eu /scircabc/w/browse/4047dcc1ff35-45e1-894c-8647639f9ae8



### **ECHA's IT tools**

 Accessed through ECHA's home page



Interact Portal

REACH-IT



### **Submission manuals for support**

- Technical guides
- Application instructions
- Process manuals

https://echa.europa.eu/support /dossier-submissiontools/r4bp/biocidessubmission-manuals

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LEGISLAZIONE	CONSULTAZIONI	INFORMAZIONI SULLE SOSTANZE CHIMICHE	ASSISTENZA				
ECHA > Assistenza > Strumenti per la presenta	tione del fascicoli > R4BP 3 > Biocides Submission Man	iuals					
R4BP 3	Biocides Submission	Manuals					
Biocides Submission Manuals	The aim of the Biocides Submission Manual						
Supporting documents	assistance. The BSM series describes how t to submit and manage those applications in		Biocidal Product Regulation applications and achieved.				
Active substances	-						
National authorisations	Y Technical guides						
Technical equivalence and chemical	BSM Technical guide: How to prepare a biocides dossier (pop) [EN]     BSM Technical guide: How to use R4BP 3 (pop) [EN]						
similarity							
Union authorisations Simplified authorisations	<ul> <li>BSM Technical guide: How to use the SPC Editor [POF] [EN]</li> </ul>						
Simplified authorisations							
	Application instructions						
	<ul> <li>BSM Application instructions: How to submit an application for Active Substance (PDF) (EN)</li> </ul>						
	BSM Application instructions: How to submit an application for Technical Equivalence and Chemical Similarity [POF] [E						
	<ul> <li>BSM Application instructions: How to</li> </ul>	o submit an application for National Au	thorisation (PDF) (EN)				
	<ul> <li>BSM Application instructions: How to</li> </ul>	o submit an application for Simplified A	withorisation [PDF] [EN]				
	<ul> <li>BSM Application instructions: How to</li> </ul>	o submit an application for Union Autho	orisation (PDF) (EN)				
	Process manuals						
	BSM Process of invoicing in R4BP 3	[PDF] [EN]					
	<ul> <li>BSM Process of confidentiality reque</li> </ul>	ists for biocide applications (PDF) (EN)					
	<ul> <li>BSM Process of dissemination</li> </ul>						
	<ul> <li>Part 1 - IUCLID sections 1 -</li> </ul>						
	- Part 2 - IUCLID sections 5 -	- 7 [PDF] [EN]					
	<ul> <li>Part 3 - IUCLID section 8 (P)</li> </ul>	OF] [EN]					



#### **Forms and templates**

- Various forms and templates that help when preparing applications
- Revised Product Assessment Report (PAR) template recently published



https://echa.europa.eu/s upport/guidance-onreach-and-clpimplementation/formats



#### **Information available on biocides**

#### **BPR - Biocidal Products Regulation**

- Biocidal active substances
- Biocidal products
- List of active substances and suppliers
- Consultation on candidates for substitution (ongoing)
- Consultation candidates for substitution (previous)
- Consultations on derogations to exclusion criteria (ongoing)
- Consultations on derogations to exclusion criteria(previous)

- List of notifications
- Article 94 for treated articles
- Renewal of active substances
- Deadlines for Union authorisation applications

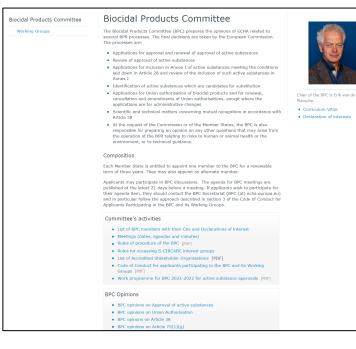
#### https://echa.europa.eu/information-on-chemicals

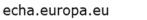


### **Biocidal Products Committee (BPC) web page**

- Working procedures and opinions on:
  - Active substance approval
  - Union authorisation
  - Articles 38 and 75
- Links to:
  - The BPC's Working Groups
  - The Enforcement Forum
  - The Board of Appeal

#### https://echa.europa.eu/about-us/whowe-are/biocidal-products-committee







## Thank you! claudio.putzu@echa.europa.eu

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