

Industry Experience of Navigating Through the Biocidal Products Regulation

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Support available to industry to assist compliance with the BPR

1st September 2015

Chemours

- Spun-off from DuPont on 1st July 2015
- US\$ 6 billion sales in 2014
- Three business units – Titanium Technologies, Fluoroproducts and Chemical Solutions
- Products include Ti-Pure™, Teflon™, Opteon™, Viton™, cyanides, Virkon™
- Impact of BPR
 - active substance importer and supplier
 - biocidal product formulator and reseller

Questions

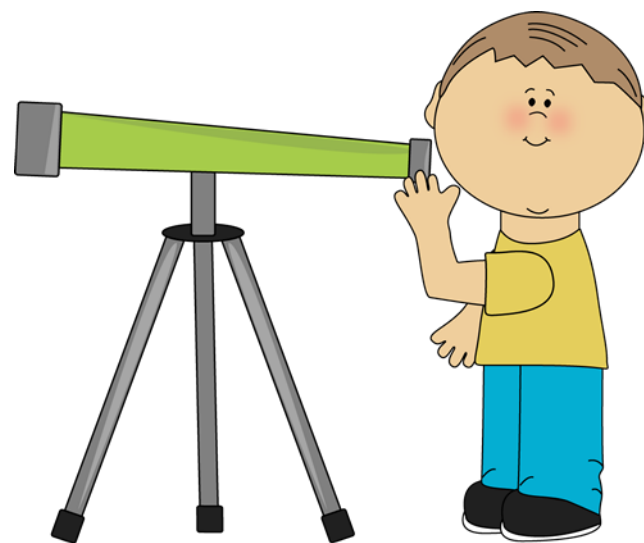
- What, when, where, which, why, how?
- Needs include:
 - General information on the BPR
 - Guidance on requirements and processes
 - Help with problems
 - Interpretation of specific issues
- Questioners may have no or little knowledge, some awareness, various levels of experience or be an expert



Answers

- European Commission
- ECHA
- National Helpdesks

- Colleagues
- Trade associations
- News services
- Consultants
- Contract Research Organisations
- Lawyers



Official European Support

- European Commission
- ECHA

- Primarily information on websites



- *situation as of mid-August 2015
- *English language versions shown
- *personal experience and views



European Commission

1st September 2015

European Commission

The screenshot shows the European Commission website for Biocides. The browser address bar displays http://ec.europa.eu/environment/chemicals/biocides/index_en.htm. The page features the European Commission logo and the word "ENVIRONMENT". A navigation menu includes "Home", "About us", "Policies", "Funding", "Legal compliance", and "News & outreach". A left sidebar lists various topics such as "REACH", "Classification and labelling", "Biocides", "Endocrine disruptors", and "Nanomaterials". The main content area is titled "Introduction" and contains the following text:

Introduction

Biocides are chemicals used to suppress organisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials. These harmful organisms include pests and germs (i.e. moulds and bacteria). Examples of biocidal products are insect repellents, disinfectants and industrial chemicals like anti-fouling paints for ships and material preservatives. However, because of their intrinsic properties biocides can pose risks to humans, animals and the environment.

The new [Regulation](#) entered into force on 1 September 2013. It repeals Directive 98/8/EC and aims to provide a high level of protection for humans, animals and the environment.

Last updated: 07/08/2015 [Top](#)

On the right side of the page, there are social media icons (Facebook, Twitter, YouTube, LinkedIn, RSS) and buttons for "NEWS", "LINKS", "REACH", "BIOCIDES", and "Endocrine Disruptors". The ECHA logo (European Chemicals Agency) is also present.



European Commission

- Located at DG Environment, not DG Sante
- Generally, an overview of the main provisions of the BPR
- Contains links to legislation and to ECHA website
- Some use as an introduction to the BPR, but lacks details
- <http://ec.europa.eu/environment/chemicals/biocides>



Official Journal

1st September 2015

Official Journal

The screenshot displays the EUR-Lex website interface. At the top, the EUR-Lex logo and "Access to European Union law" are visible, along with navigation links like "About EUR-Lex", "Site map", and "A-Z". The main navigation bar includes "Home", "Official Journal", "EU law and related documents", "National law", "Legislative procedures", and "More". A search bar is prominently featured in the center, with a "SEARCH" button. Below the search bar, there are sections for "Find results by" (with filters for Document number, CELEX number, Year, Number, and Type) and "Recently published" (with filters for Legislation, International agreements, EU case law, COM and JOIN documents, SWD documents, Consolidated legislation, and Legislative procedures). A sidebar on the right contains "My EUR-Lex" options (Sign in, Register), RSS feeds, Webservice registration, Guided Tour, Statistics, and User community. A Twitter feed is also visible at the bottom right, showing tweets from @EURLex.

Official Journal

- Provides formal, comprehensive texts of Decisions, Regulations and Judgements
- Powerful search tool
- Includes many documents of peripheral interest
- Does not include guidance documents or databases
- Available in all official EU languages

- Legal texts often not easy to comprehend due to legal language and cross-references

- <http://eur-lex.europa.eu>



EUR-Lex search function

The screenshot displays the EUR-Lex search interface. At the top left is the EUR-Lex logo with the text "Access to European Union law". The top right contains navigation links: "About EUR-Lex", "Site map", "A-Z", "FAQ", "Help", "Links", "Legal notice", "Cookies", "Contact", and a language dropdown set to "English (en)". A search bar contains the term "biocid" and a search icon. Below the search bar is a breadcrumb trail: "EUROPA > EU law and publications > EUR-Lex > Search results". A navigation menu includes "Home", "Official Journal", "EU law and related documents", "National law", "Legislative procedures", and "More".

The main content area is titled "Refine query" and includes several filters:

- By domain:** EU law and related documents (1094), Official Journal (888), National law (252), Legislative procedures (5).
- By subdomain:** All (1015), Legislation (460), Preparatory acts (409), National implementing measures (241), EU case law (84).
- By year of document:** 2015 (32), 2014 (130), 2013 (145), 2012 (119), 2011 (94).
- By type of procedure:** Codetermination procedure (COD) (167), Ordinary legislative procedure (COD) (42), Consultation procedure (CNS) (32), Non-legislative procedure (NLE) (17), Cooperation procedure (SYN) (6).

The search criteria are: "Search for: biocid, Search language: English". Below this are options to "Save to My searches", "Create in My RSS feeds", and "Save to My items". The results are sorted by "Default" in "Descending" order, showing "Results 1 - 10 of 1644".

The first result is: **32012R0528: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance**. It includes the text: "OJ L 167, 27.6.2012, p. 1-123 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV). This document has been published in a special edition(s) (HR)".

The second result is: **32006R1907: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC**. It includes the text: "OJ L 396, 30.12.2006, p. 1-848 (NL), OJ L 396, 30.12.2006, p. 1-850 (ET, LV, LT, MT, SK), OJ L 396, 30.12.2006, p. 1-849 (EN, FR, IT, SL, FI, SV), OJ L 396, 30.12.2006, p. 1-851 (CS, DE, HU), OJ L 396, 30.12.2006, p. 1-853 (EL), OJ L 396, 30.12.2006, p. 1-852 (ES, DA), OJ L 396, 30.12.2006, p. 1-794 (PL), OJ L 396, 30.12.2006, p. 1-854 (PT)".

Additional information for the first result includes: "Direct text access: PDF, HTML", "Author: European Parliament, Council of the European Union", and "Date of document: 22/05/2012".

On the right side, there is a "My EUR-Lex" section with "Sign in" or "Register" buttons, and a list of "My searches (0)", "My items (0)", and "My RSS feeds (0)". Below this is an "RSS feeds" section with links for "Webservice registration", "Guided Tour", "Statistics", "User community", and "We'd like to hear from you".



CIRCABC

1st September 2015



[EUROPA](#) > [European Commission](#) > [CIRCABC](#) > [SANTE](#) > [BPR - Public](#)

Biocides - Regulation 528/2012 - Public

- ▶ Information
- ▶ Library
- ▶ Events
- ▶ Newsgroups

Search



[Advanced Search](#)

Main Menu

- [Browse categories](#)
- [Login](#)
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- [eLearning](#)

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Biocides - Regulation 528/2012 - Public

Welcome to the Interest Group 'Biocides - Regulation 528/2012 - Public'.



This group contains information of public interest relating to the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

▶ [Join this Group](#)

▼ [Contact information](#)

sante-biocides@ec.europa.eu

▼ [What's new](#)

Title	Path	Size	Modified
No items to display.			

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[Top of the page](#)



V.3.7.2 / Rev: 7606 / N1
CIRCABC is open source



Chemours™

BPR support

1st September 2015

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CIRCABC

- Indirect navigation
- <https://circabc.europa.eu>
- “Browse categories”, “Health and Food Safety”, “Biocides”, “Library”
- Navigation between pages is peculiar
- Public access to biocides information but much of the CIRCABC site has restricted access, *e.g.* “Information”
- Not easy to identify new documents
- Mixture of the useful and the obsolete so be careful – information may be outdated or only proposals

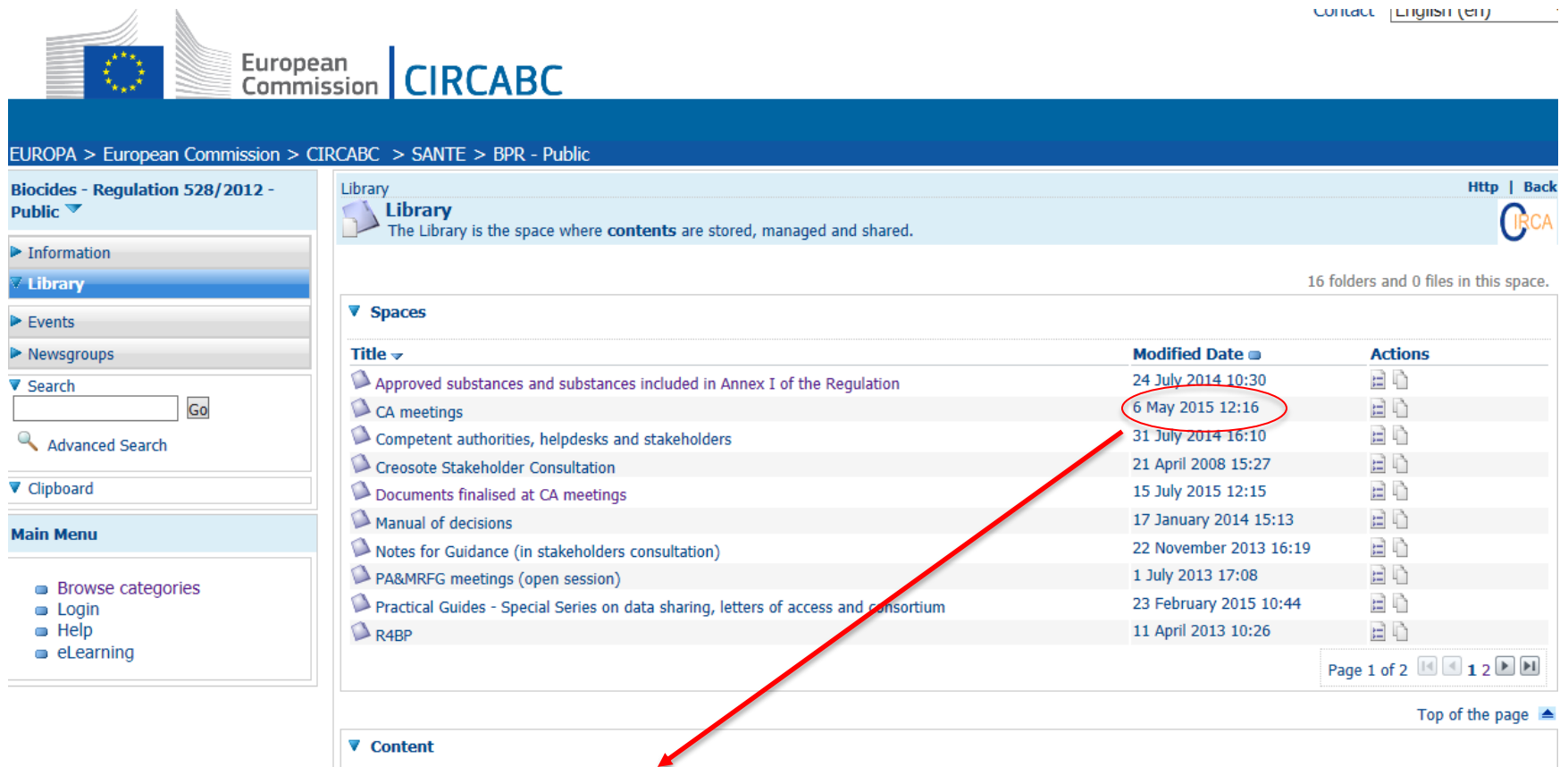


CIRCABC – only parts are public

The screenshot shows the CIRCABC website interface. At the top right, there are links for 'Contact' and 'English (en)'. The breadcrumb trail reads: 'EUROPA > European Commission > CIRCABC > SANTE > BPR - Public'. On the left sidebar, under 'Biocides - Regulation 528/2012 - Public', the 'Information' link is circled in red. The main content area displays a yellow error message: 'Access Denied. You do not have the appropriate permissions to perform this operation. You are redirected to the space: 'BPR - Public''. Below the error message, there is a section for 'Biocides - Regulation 528/2012 - Public' with a welcome message and a description of the group's purpose. A 'Join this Group' button is visible. Further down, there is a 'Contact information' section with the email 'sante-biocides@ec.europa.eu' and a 'What's new' section with a table header (Title, Path, Size, Modified) and the text 'No items to display.' At the bottom right of the page, there is a pagination control showing 'Page 1 of 1'.



CIRCABC – look for subfolder updates












EUROPA > European Commission > CIRCABC > SANTE > BPR - Public

Biocides - Regulation 528/2012 - Public

Library
The Library is the space where **contents** are stored, managed and shared.

16 folders and 0 files in this space.

Title	Modified Date	Actions
Approved substances and substances included in Annex I of the Regulation	24 July 2014 10:30	 
CA meetings	6 May 2015 12:16	 
Competent authorities, helpdesks and stakeholders	31 July 2014 16:10	 
Creosote Stakeholder Consultation	21 April 2008 15:27	 
Documents finalised at CA meetings	15 July 2015 12:15	 
Manual of decisions	17 January 2014 15:13	 
Notes for Guidance (in stakeholders consultation)	22 November 2013 16:19	 
PA&MRFG meetings (open session)	1 July 2013 17:08	 
Practical Guides - Special Series on data sharing, letters of access and consortium	23 February 2015 10:44	 
R4BP	11 April 2013 10:26	 

Page 1 of 2

Top of the page

Contains sub-folders; 60th CA meeting folder last modified 10th June



CIRCABC Library – useful information

- Approved substances and substances included in Annex I of the Regulation **assessment reports**
- Substances not approved.....
- CA meetings **policy discussions at CA meetings**
- Competent authorities, helpdesks and stakeholders
- Documents finalised at CA meetings **agreed positions on some specific topics, including under BPD!**
- Practical Guides - Special Series on data sharing, letters of access and consortium
- Review programme for existing active substances
- Study reports **miscellaneous documents including information on fees and sustainable use**



CIRCABC Library – outdated information

- Creosote Stakeholder Consultation
- Manual of decisions
- Notes for Guidance (in stakeholders consultation)
- PA&MRFG meetings (open session)
- R4BP
- Reports in accordance with Art 24
- Study on the implementation of 98/8
- Treated articles



European Chemicals Agency

1st September 2015

An agency of the European Union | Document library | News and Events | Press | Contact | English (en)

ECHA
EUROPEAN CHEMICALS AGENCY

Search the ECHA Website | Advanced search >

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

ECHA > Homepage

22/07/2015 - Press release
First applications for Union authorisation submitted to ECHA
The first two applications for Union authorisation of biocidal products have recently been submitted to ECHA according to the procedure established by the Biocidal Products Regulation.

News

11/08/2015 - News item
Guidance on substance identification for essential oils now available
The European industry associations for essential oils have published new guidance to help industry to fulfil their registration obligations under REACH. This is the result of intensive work by stakeholders, in consultation with ECHA, to establish practical solutions for the identification of this specific group of substances.

22/07/2015 - News item
REACH Guidance on information requirements updated
ECHA has updated two sections in Chapter R7a of the Guidance on Information Requirements and Chemical Safety Assessment: Section R.7.2 on Skin corrosion/irritation, serious eye damage/eye irritation and respiratory tract corrosion/irritation and Section R.7.6 on Reproductive Toxicity.

08/07/2015 - News item
ECHA follows up on registrants' obligations to consider alternative tests
ECHA has analysed why registrants submitted 295 new higher tier studies on vertebrate animals without first seeking the Agency's decision to permit such tests.

06/07/2015 - News alert
The Summary of Product Characteristics (SPC) editor goes multilingual
An updated version of the Summary of Product Characteristics (SPC) editor to support biocidal product authorisations is now available in 23 EU languages as well as Norwegian.

Search for Chemicals
 I have read and I accept the legal notice
Name, EC or CAS No

BIOCIDES Stakeholders' Day
1 September 2015, Helsinki, Finland

REACH 2018

CLP 2015: ACT NOW!

BIOCIDES 1-SEPT 2015
APPLY NOW TO STAY ON THE MARKET

- REACH-IT
- IUCLID 5
- CHESAR
- R4BP 3



ECHA

- Comprehensive website
- Covers not only BPR but also REACH, CLP and PIC
- Provides a lot of useful guidance, databases, process descriptions and helpful documents
- Describes work of Biocidal Products Committee
- Regularly updated
 - **SIGN UP FOR WEEKLY NEWSLETTER**
- Can be difficult to find what you want



ECHA BPR information - Regulations

- Understanding BPR – describes major concepts
- Legislation – consolidated version of BPR, subsidiary legislation, specific decisions, BPD legal texts
- Processes – active substance approval, biocidal product authorisation, technical equivalence, Article 95 compliance, data sharing,
- Links to IT tools
- Nanomaterials
- Treated articles
- Research and Development



ECHA BPR information – other pages

- Home page - news headlines, public consultations, events, new guidance, webinars
- Addressing Chemicals of Concern - active substances which are candidates for substitution
- Information on Chemicals – databases on active substances, biocidal products and Article 95 list
- Support – guidance documents (look for the BPR information, as mostly REACH)
- Support – emission scenario documents, R4BP3 links, SME information



ECHA - Finding Information

- Website reflects ECHA approach based on data and processes
- Will only tell what is known – will not (cannot) answer unresolved issues
- When trying to find something:
 - search box often not very helpful
 - easier to look at each main page for required information
 - keep clicking and look for likely useful links down, left and right
 - outline of site structure at bottom of each page
 - REACH and CLP pages can provide useful information on substances



ECHA - Helpdesk

- The ECHA Helpdesk advises on BPR, CLP, PIC and REACH, although national helpdesks are first point of contact
- Helpdesk supports ECHA IT tools, such as R4BP 3
 - Learn how to use R4BP3 (and that includes authorities) or pay somebody who knows what they are doing
 - R4BP3 needs to work 24/7 (with limited maintenance windows) with support every business day
- Helpdesk needs to provide same-day solutions to simple errors or problems
- Default 15 day message irritates users and discredits ECHA



Help me!

- Everybody has different needs
- Different knowledge, problems, questions, language, approach
- Some questions have no answers or several answers
 - Experience from BPD carried over to BPR, but policies and processes mainly developed for rodenticides, insecticides and wood preservatives may not be applicable to disinfectants and preservatives or in the new legislative framework
 - Little previous consideration of issues specific to disinfectants such as efficacy and commodities
 - No experience of new features of BPR such as *in situ* generation of active substances, biocidal product families and treated articles



Conclusions

- A great deal of information is available on-line
- Knowing where to look is sometimes a problem
- Keeping up to date is important
- Specific cases will always raise questions – need to discuss with relevant evaluating authority
- Need workable solutions to unresolved issues and guidance available when needed
- It's improving!



Thank you

1st September 2015