Confidentiality requests Dissemination

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Biocides
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Content

1. Legal framework
2. Confidentiality requests
    - Current practices under BPD
    - Workflow envisaged under BPR
    - Proposal
3. Dissemination
    - Current practices under BPD
    - Proposal under BPR
    - Progress

Article 66: Confidentiality

- 66(1): Reference to Access to Documents legislation ("ATD"– EC/1049/2001)
- 66(2): Information normally not to be disclosed under ATD - it may undermine protection of commercial interests or persons privacy/safety such as
  - CBI: Full composition, precise tonnage, links in the supply chain
  - Names of persons involved in animal testing
  - However, it may be disclosed if urgent action needed to protect environment, human/animal health
- 66(3): Information always to be disclosed under ATD
- 66(4): Framework for making and justifying a request for non-disclosure of certain information in active substance dossiers and in product dossiers

Article 67: Electronic public access

Information always published

Art 67(1) - Active Substance	Art 67(2) Product
(a)(b) ISO – IUPAC- EINEC names	(a) Terms & conditions of the authorisation
(c) C&L	(b) SPC
(d) Phys-chem endpoints & data on pathways & fate & behaviour	(c) Analytical methods
(e) Results of (eco)-toxicological studies	
(f) Accepted exposure level or PNEC	
(g) Guidance on safe use	
(h) Analytical methods	

Article 67: Electronic public access

Information that may be claimed confidential when adequately justified

Art 67(3) - Active Substance	Art 67 (4) - Product
(a) (if essential to C&L) Degree of purity, identity of impurities and/or additives known to be dangerous	(a) Study summaries or robust study summaries of studies submitted to support approval…
(b) Study summaries or robust study summaries of studies submitted to support approval…	(b) Assessment Report
(c) [certain] information in the Safety Data Sheet	
(d) Trade name of substance	
(e) Assessment report	

Article 67: Electronic public access

- Time for making information publicly available, free of charge
  - from date of approval of the active substance, from date of authorisation of the product
- Assessment of confidentiality requests
  - Justification in accordance with Art 66(4) accepted as valid by the CA or Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned

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Current practices under BPD

Legal provisions

- Article 19
  - Confidentiality can be requested for CBI reasons
  - Full justification is needed
  - Assessment done by the MSCA receiving the application
    - If accepted, information to be treated as confidential by the other MSCAs and the Commission
  - Information never confidential specified in Art 19(3)
    - similar to BPR
  - Provisions and format for making information publicly available to be decided in accordance with the procedures set in Art 28(2), i.e. part of the matters referred to the Standing Committee

Current practices under BPD

Assessment of confidentiality requests

- Carried out by the MSCAs for active substances and biocidal products
- Active substance dossiers
  - Requests assessed during the evaluation work by the receiving CA ("RMS"), especially for preparing the final assessment report (AR)
    - HSE: *"The RMS prepares a draft assessment report, based on the template developed by the COM, and the information within Document I of the RMS evaluation on the specific active substance. The final version will become a public document so confidential information in Document I will not be transferred into the assessment report."*
  - Final AR is published on public CIRCA
    - *"This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC"*
    - Examples – see next slide
  - Technical dossier (i.e. robust study summaries) is not published

Extracts of one Assessment Report published on CIRCA

2.1.1.2 Biocidal product:

Identification of the product

Trade name	Goliath gel	
Ingredient of preparation	*Function*	*Content*
Fipronil	Active substance	0.05 % w/w
Formulants	Details on the composition of the product are confidential.	
Physical state of preparation	Aqueous based gel	
Nature of preparation	Ready to use gel bait	

APPENDIX III: LIST OF STUDIES

A2.6/01	Besnoin, J.M.	2001	MB46030 – Manufacturing Process of the Technical Active Substance Aventis CropScience SA, Lyon; France GLP (unpublished) (BASF DocID C016926) **Business Confidential Information – See BCI folder**	Y*	BASF
A2.6/02	Foerster R.	2005	Fipronil, starting material - Data regarding the purity and source of the starting material BASF AG Agrarzentrum Limburgerhof, Limburgerhof; Germany GLP (unpublished) (BASF DocID 2005/1008413 **Business Confidential Information – See BCI folder**	Y*	BASF

Current practices under BPD

Assessment of confidentiality requests

- Biocidal products
  - Work done at national level
  - Publication of information
    - Depends on the MSCAs
    - Some MS publish general information such as list of products authorised, C&L, SDS data
    - No underlying technical dossier or AR found so far on MSCA websites

Workflow envisaged under the BPR

1. Applicant flags relevant information in their application
   - in the IUCLID dossier for the parts to which IUCLID applies.
     - Fields under identification in dissemination project. Industry manuals to be completed for biocides sections
   - In the draft Assessment Report (AR - section 13 of Annex II & III)
   - *Note: The AR may be claimed confidential for active substances and products (see Art 67(3) & (4)) – but we assume that the full report cannot be claimed confidential - some parts of it only*
2. Applicant submits dossier and pays relevant invoice
3. Evaluation of approval (active)/authorisation (product) begins
4. Assessment of confidentiality requests done in parallel (CA or Agency?)
   - It may require interaction with the applicant to confirm certain aspects, e.g. the purity/impurities chemical profile (see document on tech. equivalence)
   - Output is to be taken into account in the final AR prepared by the CA
4. Final Evaluation leading to approval/authorisation
5. Publication of non confidential information [IUCLID & AR] by ECHA

Assumptions

- Assessment of confidentiality requests to be done as an integral part of the evaluation work done by the MSCA for the following reasons:
  - Type of work: Decision whether the degree of purity is essential for C&L, identity of impurities/additives must be disclosed due to hazardous properties, etc. This is part of the evaluation work
  - Timing:
    - Outcome is to be reflected in the final AR prepared by the MSCA
    - Publication must be done from date of approval/authorisation, i.e.the assessment should be concluded before that date to enable timely dissemination
  - Workability: It may require interaction with the applicant which should be carried at the same time of other request for information done by the MSCA in accordance with Art 8 (1&2)

Proposal

	Active substance requests	Product requests
MSCA	• Assess claim(s) in parallel to evaluation of application	
ECHA	• Disseminate accordingly • IT support - alert on confidentiality requests flagged in the IUCLID - collect decisions on the validity of the confidentiality requests • Harmonisation role (*if felt needed by the MSCAs*): - provide support for deciding on common criteria based on REACH experience – prepare manuals for industry based on these criteria	

Reasons for the proposal

- Workability and efficiency considerations
  - Assessment by MSCA:
    - interaction with applicant is done by one institution only
    - interaction ECHA/MSCA at end of process for publication
  - Assessment by ECHA:
    - interaction between applicant and ECHA needed while MSCA is also interacting with applicant possibly on same topics, e.g. clarification of purity or identity of impurities to assess whether request is justified or not (this can be modified as a consequence of the tox/ecotox profile)
    - multiple interactions needed between ECHA and MSCA during evaluation, e.g. to agree to accept or not certain requests, and to provide the outcome of the assessment for preparing the final assessment report

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Current practice under BPD - recap

Active Substance	Product
Final AR is published on public CIRCA http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/assessement_directive&vm=detailed&sb=Title	Depends on the MSCAs: some MS publish general information such as list of products authorised, C&L, SDS data
Technical dossier (i.e. robust study summaries) is not published	No underlying technical dossier or AR found so far on MSCA websites

Proposal under BPR – Workflow for AS

1. ECHA transfers Dossier to MSCA via R4BP3
2. MSCA starts Evaluation, interacts with applicant, accepts/rejects the confidentiality requests
3. From approval: ECHA receives list of accepted requests and public version of the AR, via R4BP3
4. ECHA filters the IUCLID dossier from confidential information based on the list received
5. AR and IUCLID dossier are published on ECHA website

Dissemination page for AS – draft

Search Results - Active Substances

The results of your search query are displayed below. You can download the full list of search results as a .csv file, or browse the list online.
From the list of search results there are links to further information for each substance:

Open the dossier for an active substance in a new window.

Link to the BP

Link to the AR & Doc IIIA

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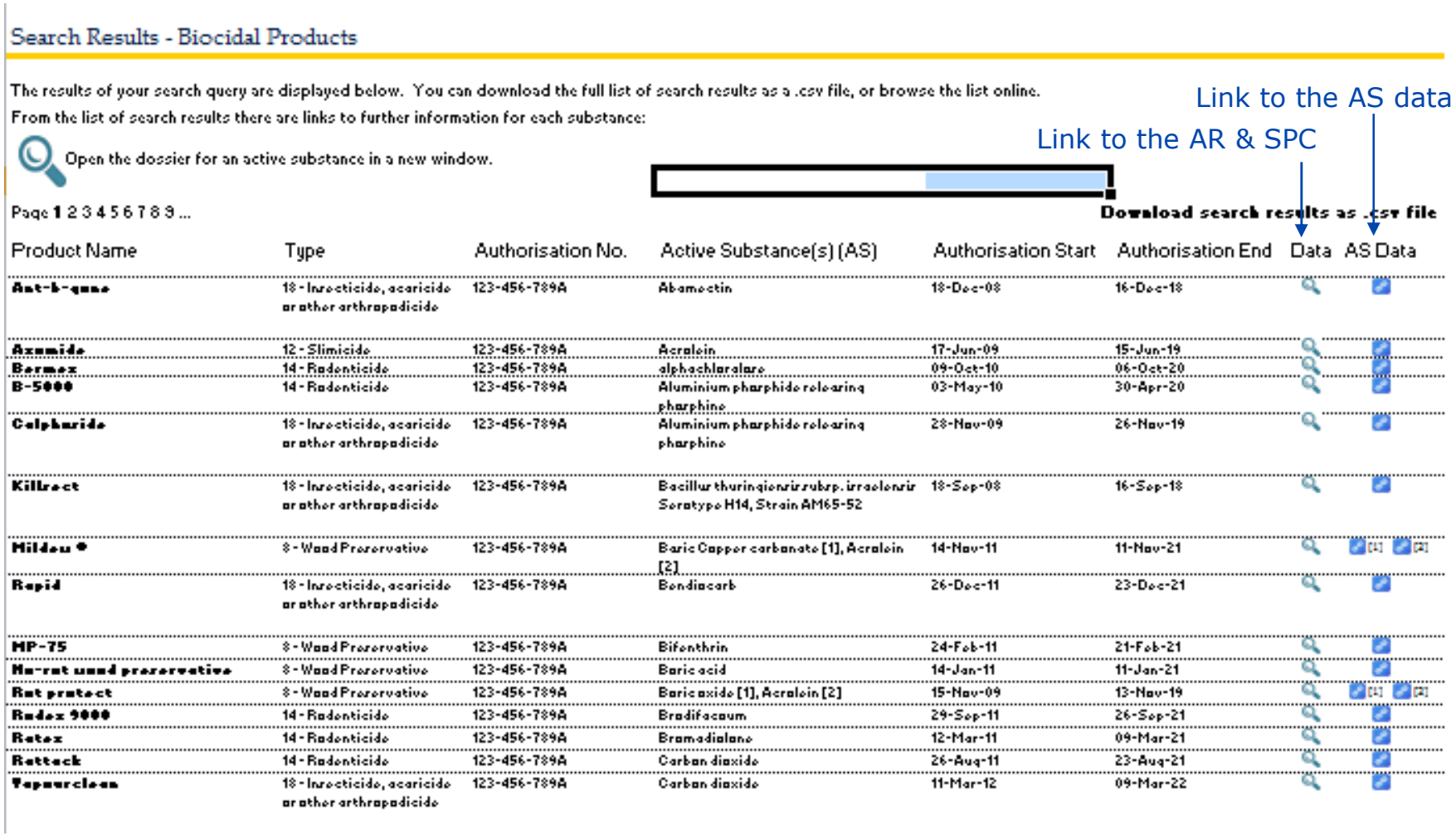
Download search results as .csv file

EC No.	CAS No.	Name	Type	Inclusion Directive	Inclusion Date	Expiry Date	Data	Products
-	71751-41-2	Abamectin	18 - Insecticide, acaricide or other arthropodicide	2011/67/EU	18-Dec-08	16-Dec-18		
203-453-4	107-02-8	Acrolein	12 - Slimicide	2010/5/EU	17-Jun-09	15-Jun-19		
240-016-7	15879-93-3	alphachloralose	14 - Rodenticide	2009/93/EC	09-Oct-10	06-Oct-20		
244-088-0	20859-73-8	Aluminium phosphide releasing phosphine	14 - Rodenticide	2009/95/EC	03-May-10	30-Apr-20		
244-088-0	20859-73-8	Aluminium phosphide releasing phosphine	18 - Insecticide, acaricide or other arthropodicide	2010/9/EU	28-Nov-09	26-Nov-19		
-	-	Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52	18 - Insecticide, acaricide or other arthropodicide	2011/78/EU	18-Sep-08	16-Sep-18		
235-113-6	12069-69-1	Basic Copper carbonate	8 - Wood Preservative	2012/2/EU	14-Nov-11	11-Nov-21		
245-216-8	22781-23-3	Bendiocarb	18 - Insecticide, acaricide or other arthropodicide	2012/3/EU	26-Dec-11	23-Dec-21		
-	82657-04-3	Bifenthrin	8 - Wood Preservative	2011/10/EU	24-Feb-11	21-Feb-21		
233-139-2	10043-35-3	Boric acid	8 - Wood Preservative	2009/94/EC	14-Jan-11	11-Jan-21		
215-125-8	1303-86-2	Boric oxide	8 - Wood Preservative	2009/98/EC	15-Nov-09	13-Nov-19		
259-980-5	56073-10-0	Brodifacoum	14 - Rodenticide	2010/10/EU	29-Sep-11	26-Sep-21		
249-205-9	28772-56-7	Bromadiolone	14 - Rodenticide	2009/92/EC	12-Mar-11	09-Mar-21		
204-696-9	124-38-9	Carbon dioxide	14 - Rodenticide	2008/75/EC	26-Aug-11	23-Aug-21		
204-696-9	124-38-9	Carbon dioxide	18 - Insecticide, acaricide or other arthropodicide	2010/74/EU	11-Mar-12	09-Mar-22		

Proposal under BPR – Workflow for BP

1. Same as AS
2. Same as AS
3. From date of authorisation, ECHA receives list of accepted requests and public versions of the AR & SPC via R4BP3
4. IUCLID dossier (when it exists) is filtered from confidential information based on the list received
5. Terms & conditions, public SPC and AR from R4BP, and IUCLID dossier (when it exists) are published

Dissemination page for BP – draft



Search Results - Biocidal Products

The results of your search query are displayed below. You can download the full list of search results as a .csv file, or browse the list online.
From the list of search results there are links to further information for each substance:

Open the dossier for an active substance in a new window.

Link to the AS data

Link to the AR & SPC

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Download search results as .csv file

Product Name	Type	Authorisation No.	Active Substance(s) (AS)	Authorisation Start	Authorisation End	Data	AS Data
Ant-b-gone	18 - Insecticide, acaricide or other arthropodicide	123-456-789A	Abamectin	18-Dec-08	16-Dec-18		
Axamide	12 - Slimicide	123-456-789A	Acrolein	17-Jun-09	15-Jun-19		
Barmax	14 - Rodenticide	123-456-789A	alphachloralose	09-Oct-10	06-Oct-20		
B-5000	14 - Rodenticide	123-456-789A	Aluminium phosphide releasing phosphine	03-May-10	30-Apr-20		
Calphazide	18 - Insecticide, acaricide or other arthropodicide	123-456-789A	Aluminium phosphide releasing phosphine	28-Nov-09	26-Nov-19		
Killract	18 - Insecticide, acaricide or other arthropodicide	123-456-789A	Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52	18-Sep-08	16-Sep-18		
Mildew ●	8 - Wood Preservative	123-456-789A	Boric Copper carbonate [1], Acrolein [2]	14-Nov-11	11-Nov-21		[1] [2]
Rapid	18 - Insecticide, acaricide or other arthropodicide	123-456-789A	Bendiocarb	26-Dec-11	23-Dec-21		
MP-75	8 - Wood Preservative	123-456-789A	Bifenthrin	24-Feb-11	21-Feb-21		
No-rot wood preservative	8 - Wood Preservative	123-456-789A	Boric acid	14-Jan-11	11-Jan-21		
Rot protect	8 - Wood Preservative	123-456-789A	Boric oxide [1], Acrolein [2]	15-Nov-09	13-Nov-19		[1] [2]
Radex 9000	14 - Rodenticide	123-456-789A	Brodifacoum	29-Sep-11	26-Sep-21		
Ratex	14 - Rodenticide	123-456-789A	Bromadiolone	12-Mar-11	09-Mar-21		
Rattack	14 - Rodenticide	123-456-789A	Carbon dioxide	26-Aug-11	23-Aug-21		
Vapourclean	18 - Insecticide, acaricide or other arthropodicide	123-456-789A	Carbon dioxide	11-Mar-12	09-Mar-22		

Timelines

- 1 Sep 2013 – Manual publication process
  - AS
    - List of active substances approved, with date of approval
    - Assessment reports (public version) – same as current CIRCA
    - Doc IIIA redacted by applicants – submitted to ECHA
    - Searchable per substance identifiers and name
  - BP
    - List of authorised products, date, country, authorisation holder (no AR and no Doc III) – Excel file taken from R4BP2
    - Not searchable
- From November 2013 – enrichment of information related to BP
  - Information extracted from R4BP3 (migrated from R4BP2 for authorised products under BPD)
  - Search functionality
  - Enrichment over time with IUCLID dossiers and ARs

Progress

- IUCLID 5.5 – release 2 April 2013
  - Applicant can indicate requests for confidentiality on items listed in Art 67 (3) & (4)
- Stakeholders' consultation
  - Workshop 15 January 2013
  - Participants from ECHA, Commission, MSCAs, NGOs, Industry
  - Presentation focused on interpretation of Article 67 and rules for filtering the IUCLID dossier
- Robust study summaries for AS
  - Doc IIIA will be used
  - First applicants contacted on 1 February 2013 to redact their data – deadline for submission: 1 July 2013
- Study launched for adapting our Dissemination systems to information received via R4BP

Discussion