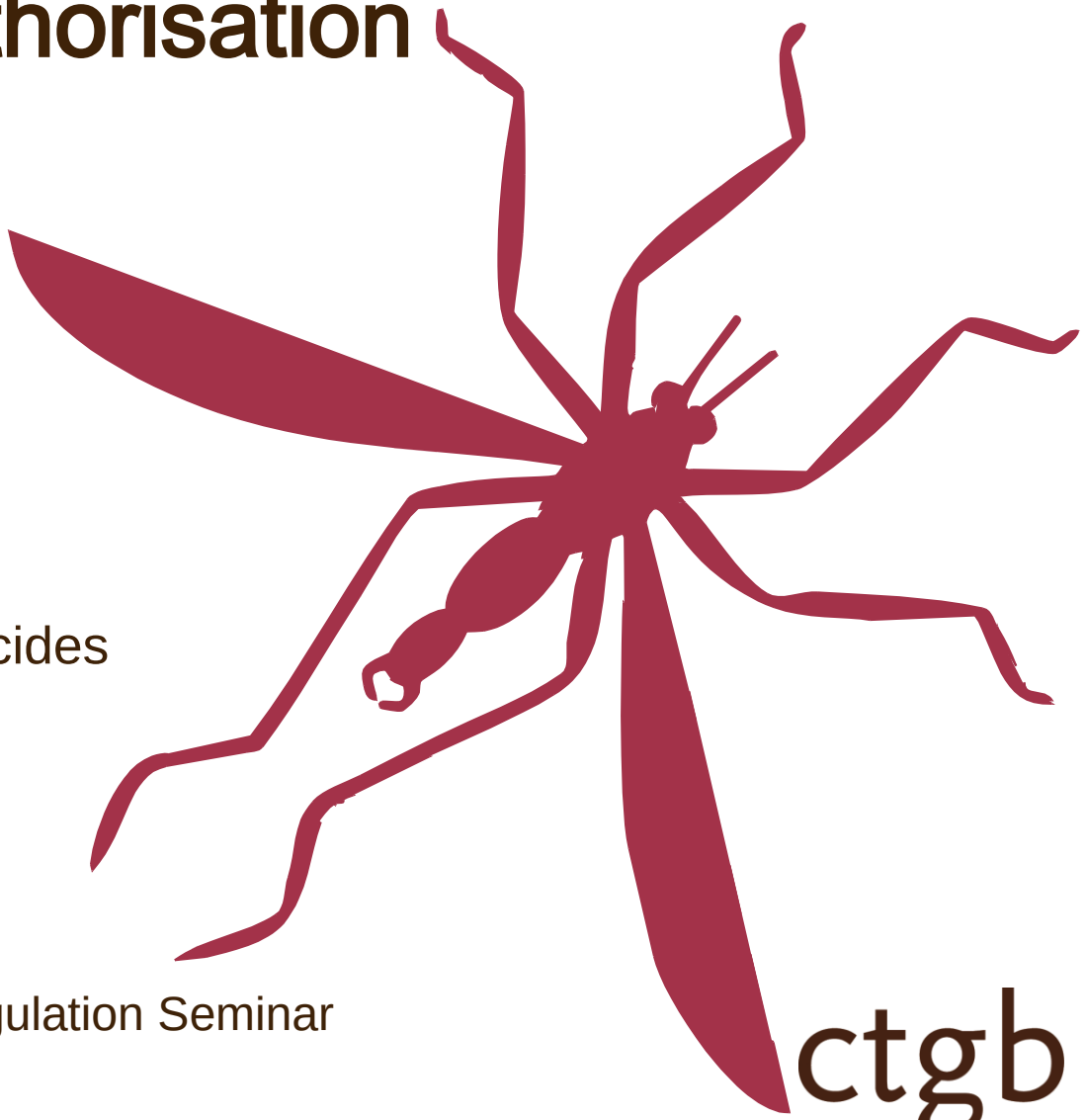
Key member state issues for product authorisation



Joost van Galen
Projectmanager Biocides

Annual Chemicals Regulation Seminar

April 2015

ctgb

Contents

- Introduction to Ctgb
- Biocides in the Netherlands
- Ctgb's experience with BPR product authorisations
- Transition from national law to BPR
- BPR IT tools

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Board for the authorisation of plant protection products and biocides

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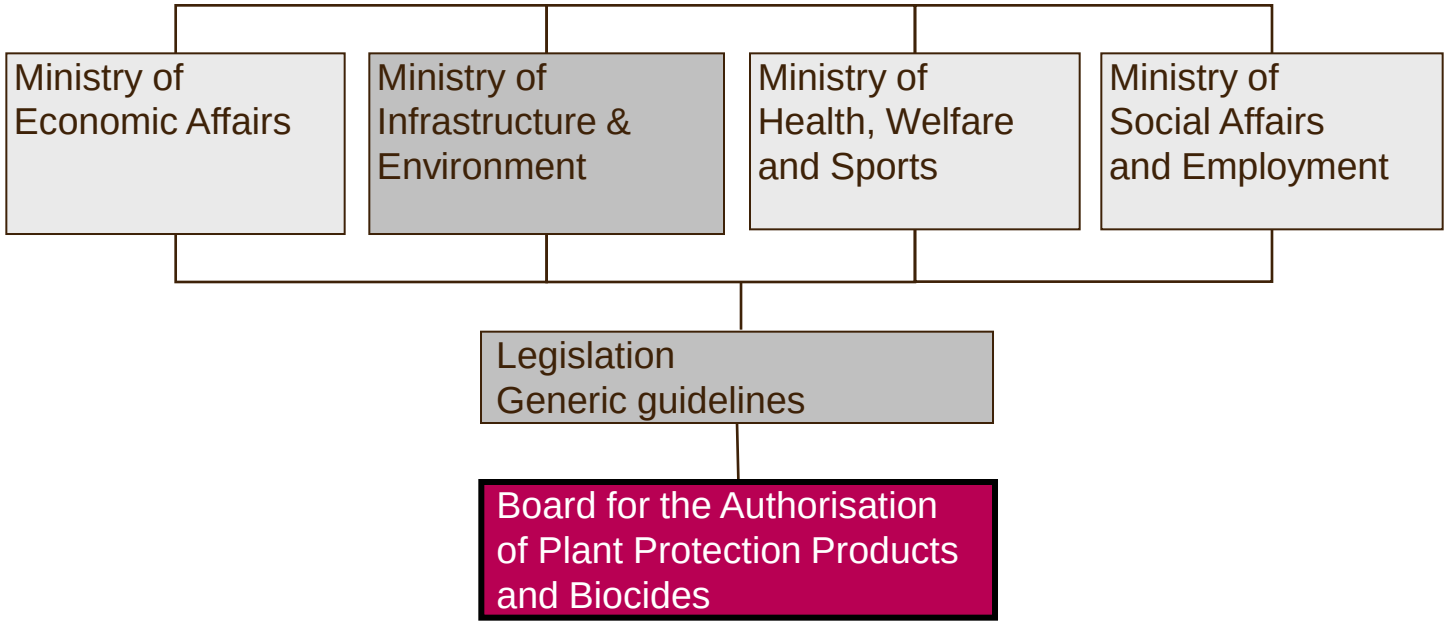
Organisation chart of Ctgb



Ctgb is the independent legal entity for authorisation and a semi-autonomous rate-controlled agency (ZBO in Dutch)

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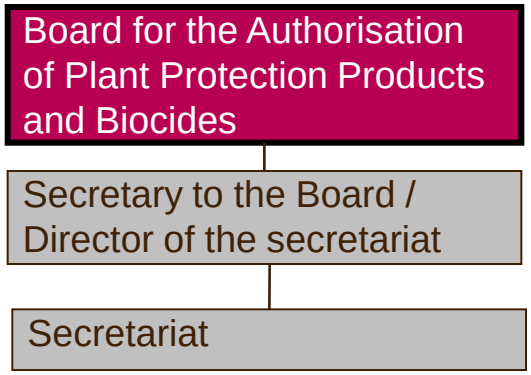
Relation Board and Secretariat



The Secretariat is responsible for the assessment of applications, and drafting the advice to the Board

The Board discusses this advice and:

- adopts or rejects the advice or
- asks for clarification of certain issues

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Biocides in the Netherlands

National legislation and BPR

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Authorisation of biocidal products

- 20+ years of experience in biocide authorisations
- Total of 1400 authorised products

- Dutch (transitional) law
  - Authorisation requirements for all PT's are quite similar to the BPR requirements.

- BPR
  - Authorisation requirements as laid down in BPR.

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Our experience with product authorisation under BPR

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Be prepared

- Avoid surprises at later stage, know what you want/need in advance!

- For example:
  - Union authorisation
  - National authorisation with MR
  - Fees (annual fees), timelines, same biocidal products, specific products per market area

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An SPC for every authorisation

- SPC editor – possibility for database with all authorised biocides
- Biocidal products should be classified, packaged and labelled in accordance with the SPC

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National authorisations (mutual recognitions)

- Build on experience from the BPD
- BPR offers some extra's
- Possibility for MR in parallel
- Disagreements occur in >50% cases
- Most disagreements resolved among MSs (Coordination Group)
- More experience gained per PT: less problems occur

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National experience

- ± 135 BPR/BPD authorisations:
  - ± 35 authorisations as RMS
  - ± 100 mutual recognitions/same biocidal products
- In general we are able to keep to the timelines
- Possibility to deviate for problem resolution
  - Keeping to timelines?
  - Best interest of applicant?

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Same biocidal product

- Straight forward procedure, very useful for SME's and private label companies

- Experience until now:
  - Proof that your product is 'the same' as the reference product
  - When relevant: only administrative changes
  - Letter of Access to all data of reference product and active substance

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Union authorisation

- Pre-submission phase with ECHA
- Discussions:
  - Is product within scope of BPR?
  - The right PT?
  - MSs may have different interpretations

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Union authorisation – the story until now

- Not many applications received yet:
  - High tariff to be paid to ECHA (and eCA)
  - Not available for all PTs yet
  - Limited number of approved active substances

- National same biocidal product from a Union family-member not possible yet

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Biocidal product families

- Defining the family
  - Similar use?
  - Similar composition?
  - Similar levels of risk and efficacy?
- Guidance is final, Q&A documents under development
- Family SPC, Meta SPC, product SPC. IT tools to be adjusted

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Biocidal product family - developments

- SME: consortia formation to share costs
- Advantage to make the family as big as possible?

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Simplified authorisations

- Active substance on Annex I
- Efficacy needs to be proven
- Complete SPC needs to be proven (shelf life)

- No LoA for product approval: no incentive to put new substances on Annex I?

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Transition of biocidal products from national law to BPR

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Approved active substances

- All active substances approved for all PTs a product is intended for → BPR

- Otherwise → national law

- Transition from national law to BPR within 3 years of approval final a.s./PT combination

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After active substance approval

- Products can remain on the market only if authorisation under BPR is applied for
- No new product authorisations under national law

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IT tools take centre stage?

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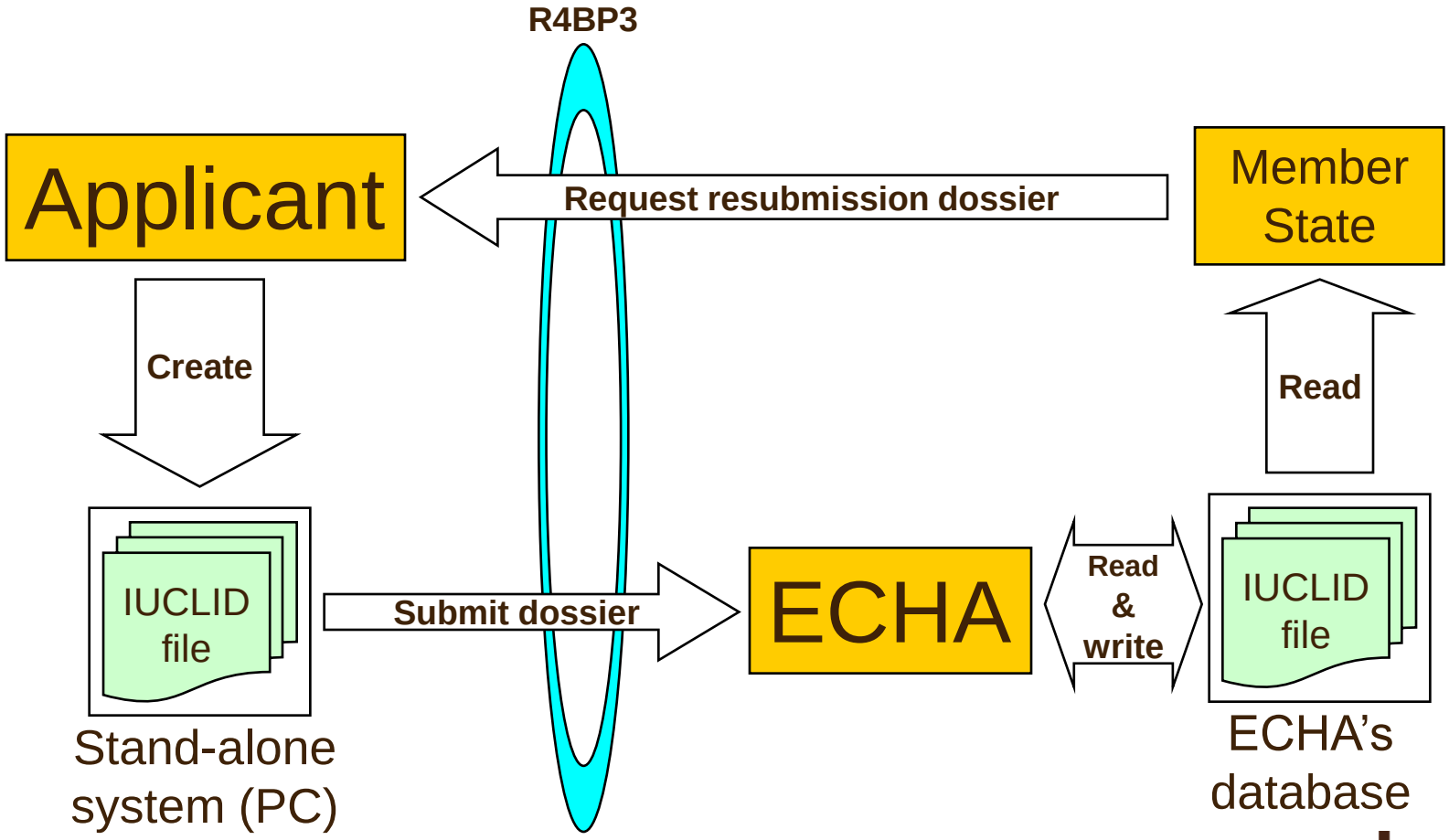
Handling of applications



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Consequence of IT architecture

- CA can not amend the IUCLID dossier
- Applicant is completely responsible for the dossier
- Evaluation of the provided information by applicant

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ECHA provides guidance for applicant's tasks

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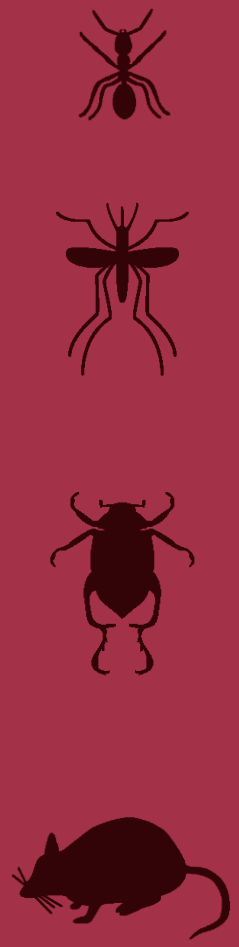
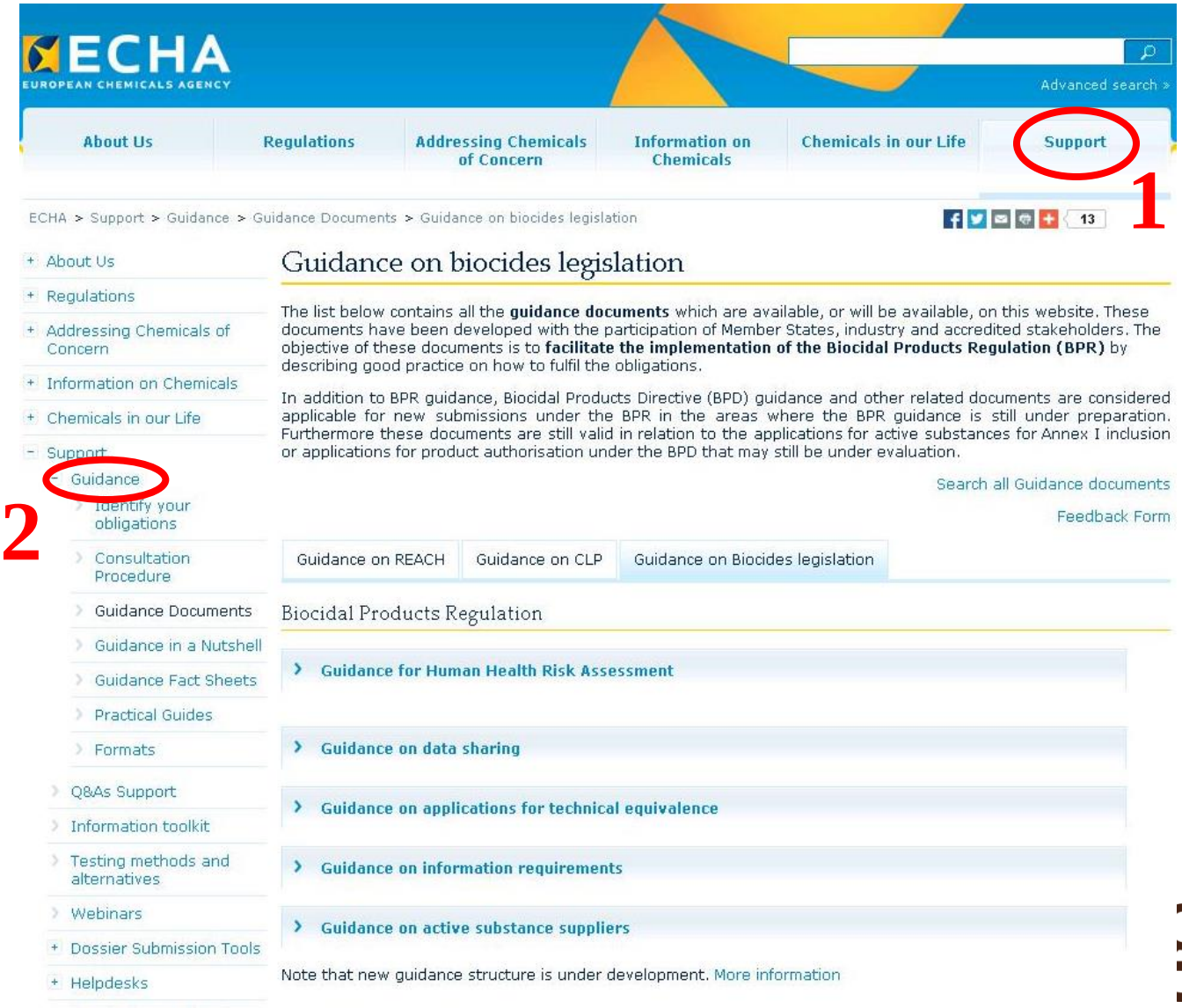
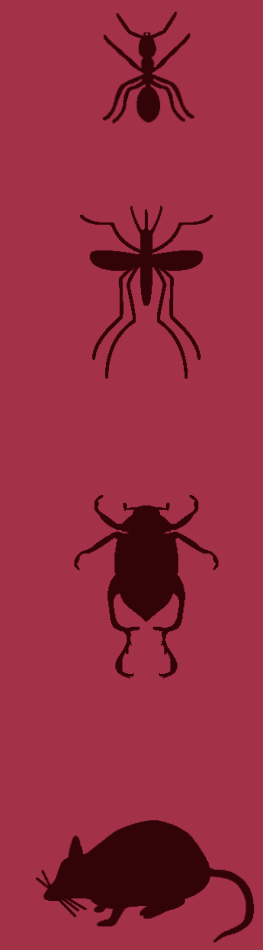
ECHA provides guidance at http://echa.europa.eu/





ECHA provides submission manuals, supporting documents etc.



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  - Practical examples of exposure scenarios
  - Small and Medium-sized Enterprises (SMEs)
  - Restriction

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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.

Submission manuals

- Biocides Submission Manual 1: Using IUCLID for biocide applications [PDF]
- Biocides Submission Manual 2: Using R4BP 3 for biocide applications [PDF]
- Biocides Submission Manual 3a: Active substances Part A, Initial submissions [PDF]
- Biocides Submission Manual 3b: Biocides Submission Manual 3b: Active substances Part B, Technical equivalence and Chemical similarity [PDF]
- Biocides Submission Manual 4a: Biocidal products Part A, Initial submissions [PDF]
- Biocides Submission Manual 4b: Biocidal products Part B, National authorisation changes on request [PDF]
- Biocides Submission Manual 5: Invoicing in R4BP 3 [PDF]
- Biocides Submission Manual 6: Confidentiality requests for biocide applications [PDF]

Questions?

Questions after the meeting:

Contact ECHA at

http://echa.europa.eu/contact/helpdesk-contact-form

Contact Ctgb at

servicedesk@ctgb.nl

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