ECHA
EUROPEAN CHEMICALS AGENCY

Webinar on Article 95 of the Biocidal Products Regulation

Information requirements and dossier evaluation

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Corrigendum (02/10/2014)

- Due to further development of the Article 95 process, slides 7, 8 and 11 have been amended in the present version of the presentation.

Overview

- Types of applications
- Information requirements
  - General
  - Letters of access
  - Complete substance dossiers
- Evaluation process

Types of applications

Types of applications

- A letter of access (LoA) to a 'Complete substance dossier'
- A 'complete substance dossier' complying with the requirements of Annex II to the BPR

- [A reference to a 'complete substance dossier' for which all data protection periods have expired]
- ['Mixed application' - both an LoA and data for the endpoints not covered by the LoA]

Information requirements I

General

Identity of the active substance

- Article 95 does not require prior establishment of technical equivalence

- Information regarding the identity of the active substance needs to be provided according to the requirements of Annex II of the BPR (not requested for LoA to a complete substance dossier)

Submission of an application

- Submit through the Register for Biocidal Products (R4BP)
- Submission manual: http://echa.europa.eu/documents/10162/14938692/bsm_03a_active_subst_init_subm_en.pdf
- A supporting document should be completed – **specify role of applicant**
- **Product-type** (PT) should be given in IUCLID 5 (section 7) for a complete substance dossier or mixed application, otherwise in the LoA
- All data should be submitted in IUCLID 5 for complete substance dossier or mixed application

Information requirements II

Letter of access (LoA)

Content of a Letter of Access

- According to the Biocidal Products Regulation, an LoA should contain at least (Article 61):
  - "the name and contact details of the data owner and the beneficiary;
  - the name of the active substance or biocidal product for which access to the data is authorised;
  - the date on which the letter of access takes effect;
  - [a list of the submitted data to which the letter of access grants citation]"

Letter of access

- For the purposes of an Article 95 application, a list of submitted data is not necessary if the LoA refers to a 'complete substance dossier' in its entirety
- Attach LoA in R4BP (together with the Supporting document)
- No IUCLID file is needed
- In addition:
  - Product-type, applicant's role

Information requirements III

Complete substance dossier

Complete substance dossier

- In compliance with Annex II of the Biocidal Products Regulation

Content of dossier:

- All core datasets
- A summary, evaluation and draft risk assessment (section 13)
- PT-specific additional datasets will be required

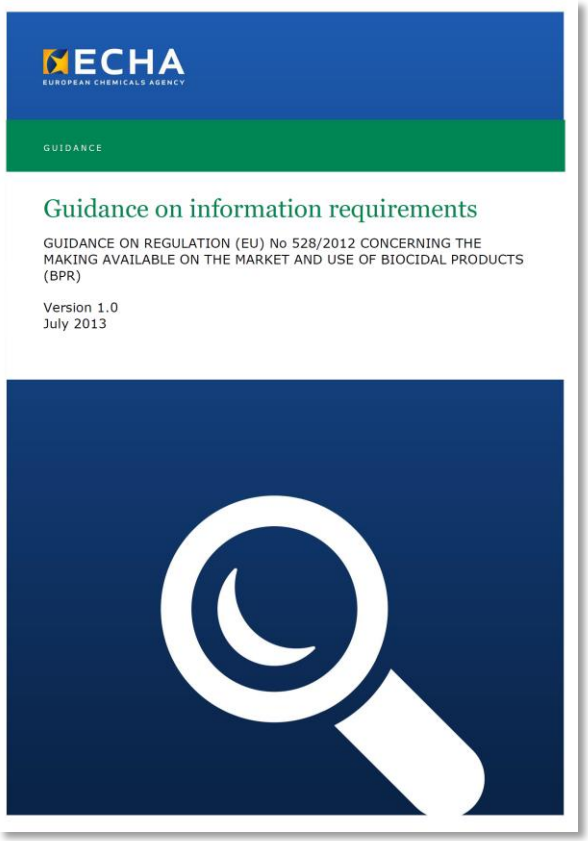
  (Part V of the Guidance on information requirements)

- Full study reports need to be provided!

Guidance on information requirements

- Information on:
  - Which endpoints to cover;
  - Which tests to provide;
  - Testing protocols;
  - Quality issues;
  - Waivers;
  - etc…

http://echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf



Evaluation process

Evaluation process

- Time for comments on draft decision 1 (+2) months
- Only one possibility to update application
- No legal deadline
- Total evaluation time depends on application type, level of complexity and ECHA's workload

Apply as soon as possible!

To ensure inclusion on the Article 95 list before 1 September 2015

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