What applicants need to know about technical equivalence and chemical similarity

Conclusions

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11:00 - 12:35 Helsinki Time (EET, GMT +2)

Key messages – Technical equivalence

- Active substances which have been approved and included in Annex I of the Directive 98/8/EC or in the Union list of approved active substances
- Two application types:
  - Tier I
  - Tier II
- Information requirements and assessment criteria depend on the application type

Key messages – Chemical similarity check

- Chemical similarity check focuses on the substance identity and chemical composition
- CSC is intended for active substances for which the decision on approval has not (yet) been adopted
- Two application types
  - Individual application
  - Joint application
- Information requirements and assessment criteria are the same as for technical equivalence Tier I

Key messages – general

- To ensure the smooth assessment of your application, it is recommended to provide all information in a clear and consistent manner

Information material (1)

Web pages

Technical equivalence general page

http://echa.europa.eu/regulations/biocidal-products-regulation/technical-equivalence

Chemical similarity check general page

http://echa.europa.eu/regulations/biocidal-products-regulation/chemical-similarity-check-service

Information material (2)

Web pages

Guidance documents

Guidance on applications for technical equivalence

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=guidance_applications_technical_equivalence

Guidance on information requirements

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=guidance_information_requirements

Guidance for identification and naming of substances under REACH and CLP

http://echa.europa.eu/guidance-documents/guidance-on-reach

Submission manual

Biocides Submission Manual 3b: Active substances Part B, Technical equivalence and Chemical similarity

http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

Upcoming webinars and events (1)

How to ensure the safe use of nanomaterials under REACH - Part III: current best practices for human health and environmental exposure assessment and risk characterisation for nanomaterials
31 March 2013

Ninth Stakeholders Day
21 May 2014

Biocides Stakeholders Day
Q3 2014

Upcoming webinars and events (2)

How to bring your registration dossier in compliance with REACH – Tips and Hints (part 6)
Q4 2014

Webinar on Article 95
2014

Webinar on Union Authorisation
2014

http://echa.europa.eu/en/support/training-material/webinars

Questions and Answers

- Questions will still be answered through the Q&A panel
  - You can continue to submit questions until the end of this presentation
  - Panelists will continue to answer your questions until 13:35 Helsinki time (EET, GMT +2) via the Q&A panel (first come, first served)
  - The event will close at 13:35 Helsinki time (EET, GMT +2)
  - If by then no answer is provided to your question, please send your question to the ECHA Helpdesk using the contact form: http://echa.europa.eu/contact

- If you use the ECHA contact form:
  - You will receive an acknowledgement of receipt
  - Answer within 15 working days

Feedback questionnaire

- Once the event has ended, you will be automatically directed to a post-event questionnaire page

- Your feedback is important to us and helps us make the content of future webinars more relevant for your needs

- Please take the time to fill out the questionnaire

Thank you