



Revision of the Biocides Directive

Simplified procedures and data requirements

by
Karola Maxianova
European Commission
DG Environment, Unit B.3

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Current situation

- Together with PPP Directive has the most stringent data requirements
 - Lack of clarity on applying the data waiving
 - Need to adapt BPD to the REACH Regulation
 - Avoid discrimination between active substances
- Low risk substances
 - Need to reform the ‘low risk’ and basis substances concepts and make them more attractive
- Frame formulations
 - So far no experience, but identified need to clarify the provisions and make the concept more flexible



Data requirements - waiving

- Objective: reduce vertebrate animal testing
- Clarify the data waiving provisions:
 - Align grounds for waiving with REACH and clarify these in the regulatory text
 - Oblige the Member States to inform applicants of their right to request a waiver including the grounds for such waiver and provide assistance to applicants
 - Clarify that both core and additional data can be waived
- Changes applicable to new active substances and to product stage



Low risk substances

- Annex IB (basic substances) was never used and shall be, therefore, repealed
 - Annex IA ('low risk') needs a fundamental reform:
 - Alternative I: Reform the 'low risk' in line with REACH exemptions
 - Alternative II: Direct authorisation of low risk products at the EU level
 - Need to find the right balance between risks and making the concept more attractive
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Frame formulations

- Need to clarify the scope and procedures
- Moving from frame formulations to variations:
 - More flexibility through minor, major and administrative variations to the authorisation
 - Authorisations for unique or variable composition of products
- Variations in a mutual recognition procedure



Conclusion

Thank you for your attention!

More information about the revision is available at:
<http://ec.europa.eu/environment/biocides/revision.htm>

ENV-biocides@ec.europa.eu