



Revision of the Biocides Directive

3 July 2009

Chantal Bruetschy
European Commission
DG Environment, Unit B.3



Introduction : reasons for revision

1. Close loopholes and promote best practice for environmental and human health protection
2. High costs of compliance, in particular for SMEs
3. Need for simplification, clarification and addressing shortcomings





Revision Process

- Mini-revision (COM (2008) 618)
 - Prolongation of the review programme until 2014
- Major revision (COM(2009) 267)
 - Consultation with MS (Ljubljana, Bonn)
 - Stakeholder consultation meeting (May 2008)
 - Impact Assessment
 - Proposal for a new Biocides Regulation (June 2009)



Impact Assessment

- Five policy issues
 - Scope, product authorisation, data sharing, data requirements, fees
- Failure of mutual recognition and absence of data sharing – very high costs
- Overall cost savings of the preferred options for the industry: as of €2.7 billion over a period of 10 years



New elements under consideration

- Regulation vs. Directive
- Scope
- Product authorisation
- Data sharing
- Data requirements
- Fees



Extension of the scope

1. Treated materials and articles
2. *In situ* generated active substances
3. Biocidal products in food contact materials
4. Use of biocidal products
5. Exemptions from the scope (e.g. food/feed, processing aids)



Safety provisions

- Exclusion criteria for active substances (Art. 5)
- Comparative assessment / candidates for substitution
 - 2-step approach (substances + products)
- Cumulative assessment



Product authorisation - 1

- Streamlined procedures and deadlines
- Strengthening of mutual recognition
- Unique authorisation vs. frame formulations
- Amendments, cancellations, parallel trade



Product authorisation - 2

- Community authorisation
 - Low-risk biocidal products and products based on new active substances
- Roles of MS, ECHA and the Commission
- Annex IA and IB repealed



Data sharing and data protection

- Alignment with REACH Regulation
 - Obligatory sharing of vertebrate animal studies
 - Voluntary sharing of other studies
- Address shortcomings identified in the Guidance on data protection
 - Commitment under mini-revision (free-riders)



Data requirements

- Revise the data requirements and establish a 2-tiered system
- Strengthen data waiving provisions
- Revised concept of 'low risk' biocidal products



Fees

- Partially harmonised structure of fees
 - Fee reductions and waivers (SMEs, joint submissions, etc.)
 - Annual fees
 - Subsidiarity and proportionality
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Involvement of ECHA

- Coordination role for the evaluation of active substances
 - Community authorisation - opinion
 - Dispute settlement (mutual recognition + data sharing)
 - Scientific and technical support
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Conclusions

<http://ec.europa.eu/environment/biocides/revision.htm>

ENV-Biocides@ec.europa.eu