



Revision of the Biocides Directive

Product authorisation and fees

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Product authorisation

- Current situation: national authorisations and mutual recognition
- No practical experience of the biocides product authorisation and mutual recognition procedures is available
- Other regulatory frameworks (e.g. Plant Protection Products, Medicinal Products)
- 50.000 products to be authorised/re-authorised in the next 10 years



Policy options

- Improved guidance and informal approaches
- Mutual recognition and conflict resolutions strengthened
- Single Community authorisation
- Centralised authorisation



Mutual Recognition

- Clarification of the current procedure, in particular concerning the dispute resolution.
- Mutual Recognition could also be reinforced by allowing/obliging :
 - MS to initiate mutual recognition
 - Applicants to submit their applications at the same time in the different MS where authorisation is applied for.



Single Community authorisation

- After being authorised by one MS, products could be placed on the market of other MS.
- No need for further administrative procedures, other than complying with labelling rules.
- System could include a safeguard clause to allow MS to object in pre-defined circumstances.
- Dispute resolution via a Community procedure with legal effects.



Centralised authorisation system

- One single authorisation, granted at Community level, and valid in the entire EU market
- Procedural steps
 - Assessment (Agency, ECB-type, RMS)
 - Commission decision
- Products
 - Products containing new active substance
 - Products used in industrial applications
 - Low risk products



Current situation on fees

- Article 25 of the Directive states that Member States shall establish systems of fees
- Fees to cover costs in carrying out the different procedures
- Varying and high fees
 - Ranging from 10.000 to 354.000 EUR for active substance evaluation and from 1.000 to 70.000 for product authorisation.
 - Up to 1 million to be paid for a substance supported in 13 product-types.



Policy options for fees

- No action but increased transparency on fee levels and structures
- Harmonised fee structure
 - Full fee charged for first PT, reduced fee for subsequent PTs
 - Instalment systems for payments
- A centralised fee system
- Specific provisions for SMEs



Conclusion

Thank you for your attention!

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

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