AGENDA

11. May, 9:00
- Practical handling of application dossiers
- Administration of fees
- Guidance Documents Overview: TNsG and TGD
- Dossier Structure: Administrative handling of the “All-in-one Approach”
  Lunch Break
- Information and data requirements for applications for inclusion of an active biocidal substance in Annex I/IA of the BP-Directive;
  Prerequisites for authorisation or registration of a biocidal product
 Speakers: Ingrid Hauzenberger, Martin Paparella

12. May, 9:00
- Completeness check and waiving issues
- Toxicological and ecotoxicological effects assessment
  Lunch Break
- Overview on human Exposure, models
- Development of environmental emission scenario documents with specific focus on biocides
- Exposure estimation, Overview on environmental models
 Speakers: Roland Solecki, Ingrid Hauzenberger, Margrit Grimm, Jorgen Larsen, Bernd Kneidinger

13. May, 9:00
- Environmental exposure scenarios for rodenticides
- Human and environmental risk assessment
- Experiences gained in the pilot project with special focus on the evaluation of a wood preservative
  Lunch Break
- Decision procedures at national and EU level
- Environmental risk characterisation: Practical example
 Speakers: Jorgen Larsen, Roland Solecki, Edmund Plattner, Bernd Kneidinger, Margrit Grimm

14. May, 9:00
- Efficacy assessment under the BP- Directive
  Lunch Break
- Toxicological assessment: Steps in animal welfare
- Impact of geographic, demographic and bioclimatic conditions
- Considerations for the responsible use of biocides – Example: disinfectants
 Speakers: David Dillon, Martin Paparella, Ingrid Hauzenberger
Accession to European Union requires that the Slovak Republic has its national legislation fully compliant with that of the EU. As of July 1, 2003, the Act No. 217/2003 L.C. on Placing Biocidal Products on the Market came into force. The Act is a transposition of the Directive 98/8/EC concerning the placing of biocidal products on the market and of the Commission Regulations (EC) 1896/2000 and 1687/2002. With respect to the requirements of the Commission Regulations (EC) 1896/2000, (EC) 1687/2002 and 2032/2003 it is expected that the New Member States would take over their responsibilities following their accession to EU, in particular in the framework of the EU 10-year-Review Programme for the evaluation of existing active biocidal substances. It is therefore deemed necessary to strengthen the capacity of Slovak institutions so that they become fully compliant with other Member States. The respective experts from institutions dealing with the Act No. 217/2003 L.C. are strongly encouraged to attend the Training Workshop “Evaluation of Biocides in the EU Review Programme” organised within the Twinning Project SR 01 10 01 01 0010 Strengthening the Capacities for Management of Biocidal Products in the Slovak Republic.

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REGISTRATION

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NO REGISTRATION FEE IS REQUIRED

DEADLINE: APRIL 9, 2004

TOPICS

- Structure and handling of dossiers for applications for inclusion of an active biocidal substance in Annex I/IA of the Biocidal Products Directive 98/8/EC
- The basis for the technical work on biocides: overview on Guidance Documents
- Information and data requirements for applications for inclusion of an active biocidal substance in Annex I/IA of the Biocidal Products Directive
- Authorisation or registration of a biocidal product
- Toxicological and ecotoxicological effects assessment
- Efficacy assessment
- Environmental and human exposure estimation
- Impact of geographic, demographic and bioclimatic conditions
- Human and environmental risk characterisation
- Decision procedures at national and EU level
- Toxicological assessment: Animal welfare
- Considerations for the responsible use of biocides – Example: disinfectants

With contributions from:

David Dillon, The UK’s Health and Safety Executive, United Kingdom, Head of Efficacy and Chemistry Section
Jorgen Larsen, Danish EPA, Denmark, Head of the Biocides and Chemicals Assessment Section
Roland Solecki, Federal Institute for Risk Assessment, Germany, Scientific Director, Section Head in the Pesticides and Biocides Division
Edmund Plattner, Federal Ministry for Agriculture, Forestry, Environment and Water Management, Austria, Head of the Department
Margrit Grimm, Federal Environment Agency, Austria, Ecotoxicologist in the Expert Centre Biocides
Ingrid Hauzenberger, Federal Environment Agency, Austria, Ecotoxicologist in the Expert Centre Biocides
Bernd Kneidinger, Federal Environment Agency, Austria, Chemist in the Expert Centre Biocides
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