OECD Task Force on Biocides
US EPA Office of Pesticide Programs Perspective

US/Global Biocides Regulation Conference     April 12, 2016
OECD Task Force on Biocides (TFB)

• Objectives
  • Attain a harmonized regulatory approach.
  • Increased efficiency in the registration of biocides for both governments & industry.
  • Help countries to reduce risks associated with biocides use.

• Structure
  • 14 member countries; representatives from the European Commission; observers from the biocide industry, i.e., European Chemical Industry Council (CEFIC) and American Chemical Council (ACC)
  • TFB Chair, United States
  • Reports directly to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology
  • Work closely parallels the work on agricultural pesticides
OECD TFB: Activities

Areas of Focus

• Harmonization of methods for efficacy testing to ensure the validity of label claims
• Harmonization of physical/chemical test methods
• Harmonization of exposure assessment approaches
• Identifying effective biocide risk reduction measures
• Work sharing
OECD TFB: Collaboration within OECD

• National Co-ordinators of the Test Guidelines Programme (WNT) consulted on any Test Guidelines and Guidance Documents developed by the TFB
• Task Force on Hazard Assessment (TFHA)
• Task Force on Exposure Assessment (TFEA)
• Working Group on Pesticides (WGP)
• Working Party on Manufactured Nanomaterials (WPMN)
• Bio-Pesticides Steering Group (BPSG)
OECD TFB: Work Programme

Work Programme for 2017-2020 is under development

Highlights of Work Programme for 2013-2016

• Work sharing - development of OECD dossier guidance for biocides, i.e. harmonised templates for dossier submission as well as an approach for joint reviews
• Development of OECD guidance/guidelines (details - next slide)
• Performance standards and label claims for biocides
• Aggregate exposure/risk to human health
• Risk Reduction
OECD TFB: Guidance Documents & Test Guidelines

Under Development
• Guidelines on physical/chemical properties (storage stability and flammability)
• Guidance on the efficacy of insecticides against bed bugs
• Guidance Document for Tier 2 evaluations of efficacy of biocides used to treat articles

Recent Publications
• Guidance Document for a Tier 1 quantitative method for evaluating antibacterial activity of porous and non-porous antibacterial treated materials
• Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants and Field Testing
• Guidance Document on Assays for Testing the Efficacy of Baits against Cockroaches
• Guidance Document on the Testing of Efficacy of Baits, for Indoor Use, Against Garden Ants
• Guidance Document on Quantitative Methods for evaluating the activity of Microbicides used on hard non-porous surfaces (bactericidal, mycobactericidal, fungicidal and virucidal methods).
• Guidelines on physical/chemical properties (pH, Acidity and Alkalinity; density and viscosity)
• Guidance Document for single laboratory validation of quantitative analytical methods Test Guideline on Determination of Revised Emission Scenario Document for Wood Preservatives
OECD TFB: US Priorities

• US proposal for work sharing
• Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-porous Surfaces
• Tier 2 Quantitative method for evaluating antibacterial activity of porous and non-porous antibacterial treated materials and label claims
• Efficacy methods for insecticides - bed bugs priority
• Special sessions to exchange information and identify areas for future harmonization
  • 2015 Treated Articles
  • 2016 under consideration
Quantitative Methods: US EPA Role

Guidance Document on Quantitative Methods for Evaluating the Activity of Microbiocides used on Hard Non-porous Surfaces

- EPA is committed to the development and use of harmonized international quantitative test methods for measuring the efficacy of disinfectants
- Following review and consultation with OECD member countries U.S. EPA seeks ultimate adoption of the Guidance Documents as Test Guidelines
  1. Provide leadership of a new OECD Validation Management Group – to facilitate input and consensus building on test conditions/parameters
  2. Provide stewardship (e.g., periodic revisions) of the existing Guidance Documents
  3. Additional data collection – lead collaborative studies and collect data from users
  4. Use contemporary statistical procedures to devise best practices for use of methods based on known levels of variability
OECD Expert Group on Efficacy of Microbicides on Hard Surfaces

• U.S. EPA scientist leading the group
• Overarching goals of the workgroup
  • Develop a multi-year strategy with short and long-term goals
  • Interface and report to the OECD TFB and WNT
  • Seek review and concurrence on proposed editorial and technical improvements to the methods
  • Review and consider information (e.g., survey-based information) from regulatory authorities on current product testing requirements and labeling, and
  • Work with member countries on the identification and resolution of regulatory issues (e.g., test conditions, test microbes, product performance standards)
• Identify and resolve remaining technical issues and to facilitate the adoption of the Guidance Documents as Test Guidelines
US Proposals for OECD work sharing: 2014 and 2015 TFB meetings

• Goals of Work Share: Streamline biocide submission and study review processes and facilitate information sharing across regulatory authorities. Support independent risk assessments and decisions by regulatory authorities.

• Benefits: Coordinating processes and sharing knowledge between governments will enhance our scientific assessments and result in more efficient government approval of safe, efficacious biocides and resource savings for governments and industry.

• Conceptual Framework
  • Work with industry to facilitate and coordinate submissions to multiple regulatory authorities to maximize opportunities for information sharing between governments.
  • OECD Guidance for industry data submissions (dossier guidance), in particular for efficacy studies
  • Build OECD data review templates for study reviews (monograph guidance for government use) to enable and facilitate knowledge sharing between regulatory authorities conducting independent reviews, beginning with acute toxicity studies.