

US EPA ARCHIVE DOCUMENT

Cumulative Risk Assessment: Developing the Methods Available Papers and Where They May be Located

THE BEGINNING

The Food Quality Protection Act (FQPA), which became law in August 1996, requires EPA to consider the cumulative effects to human health that can result from pesticides and other substances that have a common mechanism of toxicity. Through cumulative risk assessment EPA will be able to determine if the risks posed by a group of pesticides that act in the same way in the body meet the current safety standard.

HOW HAS THE CUMULATIVE RISK ASSESSMENT PROCESS COME ABOUT?

The Office of Pesticide Programs has developed a framework for conducting cumulative risk assessments on pesticides. Achieving this framework has required the development of new methods and tools. EPA began with consideration of what constitutes common mechanism of toxicity, then moved on to methods for conducting aggregate exposure and risk assessments, and finally to the cumulative risk assessment process.

Grouping Pesticides by Common Mechanism of Toxicity

A common mechanism of toxicity group consists of chemicals for which scientifically reliable data demonstrate that the same toxic effect occurs in or at the same organ or tissue by essentially the same sequence of major biochemical events.

- ✓ EPA participated in a workgroup by the International Life Sciences Institute (ILSI) to discuss issues surrounding common mechanism as it applies to the organophosphate pesticides. The ILSI workgroup recommended that the organophosphates be classified as a common mechanism group. EPA accepted that recommendation. (Common Mechanism of Toxicity: A Case Study of Organophosphorus Pesticides, Toxicological Sciences, 41:8-20 (1998))
- ✓ EPA published draft guidance on common mechanism of toxicity for comment on August 6, 1998.
- ✓ The revised guidance was published February 5, 1999 (64 FR 5795)BAGuidance for Identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity.@*
- ✓ EPA has consulted the FIFRA Scientific Advisory Panel regarding various aspects of the Agency=s approach to common mechanism of toxicity**
 - ▶ March 19-20, 1997BCommon Mechanism of Toxicity: The Grouping of a Series of Chloroacetanilide Pesticides Based on a Common Mechanism of Toxicity
 - ▶ March 24-25, 1998BCommon Mechanism of Action of Organophosphates
 - ▶ March 24-25, 1998BSuggested Probabilistic Risk Assessment Methodology for Evaluating Pesticides that Exhibit a Common Mechanism of Action

- ▶ September 21-24, 1999BThe Carbamate Pesticides and the Grouping of Carbamates with the Organophosphate Pesticides

Aggregate Exposure and Risk Assessment

As part of the individual chemical risk assessment, EPA performs an aggregate risk assessment. The aggregate risk assessment includes consideration of exposures to the pesticide from food, drinking water, and residential/non-occupational sources.

- ✓ International Life Sciences Institute (ILSI) has held workshops with presentations and panel discussions by EPA and other scientists on topics related to aggregate exposure. Publications include:***
 - ▶ Assessment of Methods to Estimate Pesticides in Drinking Water (1998)
 - ▶ Aggregate Exposure Assessment Workshop Report (1998)
 - ▶ A Framework for Estimating Pesticide Concentrations in Drinking Water for Aggregate Exposure Assessments (1999)
 - ▶ Aggregate Exposure Assessment: Model Evaluation and Refinement Workshop (2001)
- ✓ EPA published draft guidance on aggregate risk assessment for comment on November 10, 1999.*
- ✓ EPA has published several guidance documents related to drinking water exposure assessment:*
 - ▶ Estimating the Drinking Water Component of a Dietary Exposure Assessment was published for comment on January 4, 1999. The revised version was published on November 10, 1999.
 - ▶ Standard Operating Procedure for Incorporating Screening-Level Estimates of Drinking Water Exposure in Aggregate Risk Assessments was published for comment October 11, 2000.
 - ▶ Drinking Water Screening-Level Assessments, Part ABGuidance for Use of the Index Reservoir in Drinking Water Exposure Assessments was published for comment October 11, 2000.
- ✓ EPA has published guidance on conducting residential exposure assessments:*
 - ▶ Standard Operating Procedures for Residential Exposure Assessment was published for comment January 4, 1999.
 - ▶ Framework for Assessing Non-occupational/Non-dietary Exposure to Pesticides was published for comment January 4, 1999.
- ✓ EPA has consulted the FIFRA Scientific Advisory Panel regarding various aspects of the Agency=s approach to aggregate risk assessment**
 - ▶ March 19-20, 1997BAggregate Exposure Assessment as Required by FQPABInterim Approach
 - ▶ September 9-10, 1997BStandard Operating Procedures (SOPs) for Residential Exposure Assessments
 - ▶ December 10-11, 1997BEstimating Drinking Water Exposure as a Component of the Dietary Risk Assessment
 - ▶ October 14-15, 1998BProposed Methods for Basin-Scale Estimation of Pesticide Concentrations in Flowing Water and Reservoirs for Tolerance Reassessment

- ▶ March 24-25, 1998B Policy for Review of Monte Carlo Analyses for Dietary and Residential Exposure Scenarios
- ▶ February 23-24, 1999B Guidance for Performing Aggregate Exposure and Risk Assessments; Questions on the Development of Aggregate Exposure and Risk Assessment Guidance
- ▶ May 25-27, 1999B Proposed Methods for Determining Watershed-Derived Percent Crop Areas and Considerations for Applying Crop Area Adjustments to Surface Water Screening Models
- ▶ September 21-24, 1999B Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment
- ▶ September 21-24, 1999B The Lifeline™ Project to Model Aggregate Exposures to Pesticides (Hampshire Research Institute)****
- ▶ February 29-March 3, 2000B Dietary Exposure Evaluation Model (DEEM™) and DEEM™ Decompositing Procedure and Soft (Novigen Sciences, Inc.)****
- ▶ February 29-March 3, 2000B Development and Use of Distributions of Pesticide Concentrations in Drinking Water for FQPA Exposure Assessments: A Consultation
- ▶ September 26-29, 2000B Assessing Aggregate and Cumulative Risk Using LifeLine™ (Hampshire Research Institute)****
- ▶ June 6-9, 2000B Monitoring Strategies for Pesticides in Surface-Derived Drinking Water
- ▶ September 26-29, 2000B CALENDEX™ Calendar-Based Dietary and Non-dietary Aggregate and Cumulative Exposure Software System (Novigen Sciences, Inc.)****
- ▶ September 26-29, 2000B ModelsB Residential ExposureBREX Model (Infosciences)****
- ▶ September 26-29, 2000B Progress Report on Estimating Pesticide Concentrations in Drinking Water

Assessing Cumulative Risk

Assessing cumulative risk involves developing ways to combine exposures to different substances that may have differing degrees of toxicity and be used in various ways at various times of the year. EPA=s guidance has to address how these factors will be handled. EPA has pursued an open, peer-reviewed process to develop cumulative risk assessment methods and approaches.

- ✓ International Life Sciences Institute (ILSI) has held workshops with presentations and panel discussions by EPA and other scientists on topics related to cumulative risk assessment. Publications include:***
 - ▶ A Framework for Cumulative Risk Assessment Workshop Report (1999)
- ✓ EPA published draft guidance on cumulative risk assessment for comment on June 30, 2000.*
- ✓ In July 2000, EPA held a technical briefing to help explain the methods and issues addressed in the guidance.
- ✓ EPA has consulted the FIFRA Scientific Advisory Panel regarding various aspects of the Agency=s approach to cumulative risk assessment**
 - ▶ December 8-9, 1999B Issues Pertaining to Exposure Assessment and Estimating Cumulative Risk

- ▶ December 8-9, 1999BChapter 4BExposure Assessment and Characterization; Chapter 6BEstimation and Characterization of Cumulative Risk
- ▶ September 21-24, 1999BProposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals that have a Common Mechanism of Toxicity
- ▶ September 21-24, 1999BIssues Pertaining to Hazard and Dose-Response Assessment
- ▶ September 26-29, 2000BEndpoint Selection and Determination of Relative Potency in Cumulative Hazard Assessment: A Pilot Study of Organophosphate Pesticide Chemicals
- ▶ September 26-29, 2000BAssessing Aggregate and Cumulative Risk Using LifeLine™ (Hampshire Research Institute)*
- ▶ September 26-29, 2000BCALENDEX™ Calendar-Based Dietary and Non-dietary Aggregate and Cumulative Exposure Software System (Novigen Sciences, Inc.)****
- ▶ December 7-8, 2000BCase Study of the Cumulative Risk of 24 Organophosphate Pesticides; Cumulative Risk Assessment Method for Dietary (Food) Exposure; Cumulative Risk Assessment for Residential Exposure; Cumulative Risk Assessment for Drinking Water; Integrated Cumulative Risk Assessment

* Science policy documents available on EPA=s web site:

www.epa.gov/oppfead1/trac/science

** Background documents and reports from the FIFRA SAP available on EPA=s web site:

www.epa.gov/scipoly/sap/

*** Information on reports by the International Life Sciences Institute available at

www.ilsil.org/publications/

**** Model presented by the company developing it, not by EPA