5º CONGRESO LATINOAMERICANO DE RESIDUOS DE PLAGUICIDAS
Alimentos y Medio Ambiente

LAPRW2015

EVALUACIÓN DE RIESGO - PLAGUICIDAS - MEDIO AMBIENTE - TOXICOLOGÍA

CURSO PRE-CONGRESO LAPRW2015:

"1er Seminario Internacional Aplicación de la Evaluación de Riesgo Ecológico por el uso de Plaguicidas para una Agricultura Sustentable"

9-10 MAYO 2015

Hotel Plaza San Francisco
Av. Libertador Bernardo O´Higgins Nº 816
Santiago Centro, CHILE

¡CURSO CON TRADUCCIÓN SIMULTÁNEA!

Taller patrocinado por IUPAC (Miembro del Consejo Internacional de Ciencias-Comité Asesor en Protección Química de Cultivos), CropLife Internacional-ACS Agro

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Fundación para la Innovación Agraria
02 JUL 2015
RECEPCION

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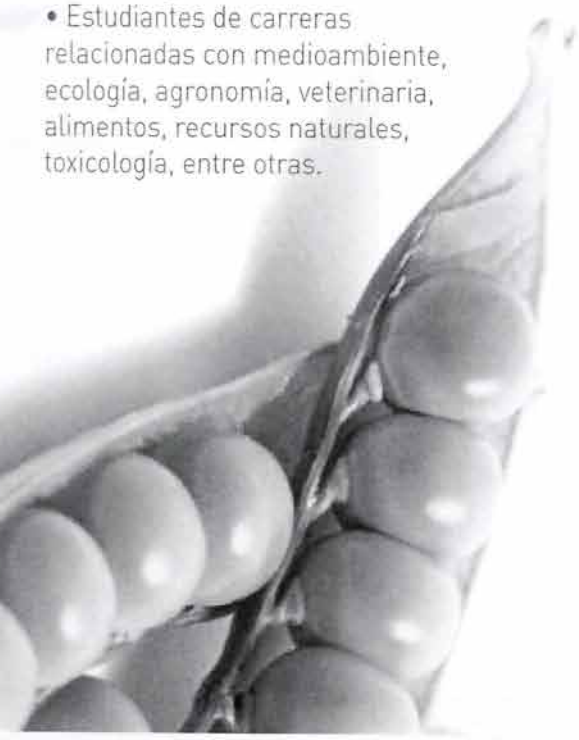
¿POR QUÉ ASISTIR?

- Taller con expertos en evaluación de riesgos en plaguicidas y medioambiente.
- Posibilidad de actualizarse con la información más reciente en el tema de evaluación de riesgos en plaguicidas e impacto a nivel medioambiental.
- Para definir, entender, tipificar y mitigar riesgos específicos.
- Debatir temas y conocimiento entre expertos y asistentes al Taller.

TALLER DIRIGIDO A

- Organismos reguladores de medio ambiente y alimentos
- Responsables de registros de productos químicos en entidades gubernamentales y privadas
- Encargados de asuntos regulatorios y normativos en empresas
- "Académicos y científicos en toxicología ambiental y alimentos".
- Estudiantes de carreras relacionadas con medioambiente, ecología, agronomía, veterinaria, alimentos, recursos naturales, toxicología, entre otras.



GENERALIDADES

Con el fin de aumentar la producción de alimentos para abastecer a la creciente población internacional, ha habido un gran incremento en el uso de plaguicidas para proteger los campos de cultivos de diferentes partes del mundo. Con el aumento del uso de plaguicidas, el potencial impacto ecológico es una creciente preocupación. Si bien en algunos países se realizan evaluaciones rutinarias de los riesgos ecológicos antes de utilizar los plaguicidas, la ciencia y uso de dichas evaluaciones aún se encuentra en sus primeras etapas. Las evaluaciones de riesgos ecológicos pueden variar de muy simples a extremadamente complejas, por lo que es importante entender las ventajas y desventajas de los distintos enfoques de la situación reglamentaria. El Taller de Evaluación de Riesgos Ecológicos está diseñado para abordar temas como:

(**I**) Definir los riesgos potenciales.
(**II**) Entender qué hay que proteger.
(**III**) Tipificación de los riesgos.
(**IV**) Riesgos específicos de cada región.
(**V**) Empleo de medidas de mitigación de riesgos.
(**VI**) Comprensión de los riesgos.

TEMAS RELEVANTES

Generalidades/Formulación de Problemas

- Marco regulatorio
- Marco regulatorio en evaluación de riesgos
- Objetivos de protección y su implementación en evaluación de riesgos
- Ensayos de ecotoxicidad
- Requisitos internacionales de ensayos

Caracterización del riesgo

- Evaluación de la exposición
- Incertidumbres en la estimación del riesgo
- Caracterización
- Mitigación del riesgo
- Principios para el desarrollo de escenarios regionales de exposición
- Integración de condiciones locales en evaluación de riesgos.
- Implementación y aplicación
- Percepción, comunicación y gestión del riesgo.
- Hoja de ruta para conducir una evaluación de riesgos.

LOS EXPERTOS

John Unsworth Consultor Reino Unido | **Javier Fernández** Croplife | **Keith Solomon** Universidad de Guelph, Canadá | **Ana Cione** Croplife-Syngenta | **Jan Linders** ex RIVM (Instituto Holandés de Salud Pública y Ambiente) | **Allan Felsot** Universidad Estatal de Washington | **Ximena Patiño** Croplife-Bayer | **Amy Ritter** Waterbone Environmental Inc. EEUU |

PROGRAMA

9 de MAYO

9:00 – 9:15 Recepción e Introducción – John Unsworth (Consultor, UK) Resumen/formulación de problemas: objetivos de protección

9:15 – 9:45 Marco Regulatorio y Principios para una adecuada Regulación–Javier Fernández (CropLife América Latina, Costa Rica)

9:45 – 10:15 Resumen del Marco Regulatorio de la Evaluación de Riesgos – Keith Solomon (Universidad de Guelph, Canadá)

10:15 – 10:30 Break

10:30 – 11:15 Objetivos de protección y su aplicación en el proceso de evaluación de riesgos–Ana Cione, (CropLife América Latina; Syngenta, Brasil)

11:15 – 12:00 Principios para los ensayos toxicológicos –Allan Felsot (Washington State Uni., USA)

12:00 - 12:45 Descripción de Requisitos de Pruebas Internacionales - Keith Solomon (University of Guelph, Canadá)

12:45 – 13:00 Sesión de preguntas y respuestas (todos los expositores de la mañana)

13:00 – 14:00 Almuerzo

Tipificación de riesgos

14:00 – 14:45 Evaluación de la Exposición – Keith Solomon (Universidad de Guelph, Canadá)

14:45 – 15:30 Incertidumbre en la Estimación de Riesgos – Jan Linders (ex RIVM, Países Bajos)

15:30 – 15:45 Break

15:45 - 16:30 Tipificación de Riesgos -- Jan Linders (ex RIVM, Países Bajos)

16:30 – 17:15 Mitigación y corrección de Riesgos – Allan Felsot (Universidad Estatal de Washington, EE.UU)

10 de MAYO

09:00 – 09:45 Principios para desarrollar escenarios regionales de exposición.– Ximena Patiño (CropLife América Latina; Bayer CropScience, Colombia)

09:45 – 10:30 Integración de las Condiciones Locales en la Evaluación de Riesgos –Amy Ritter (Waterborne Environmental Inc., EE.UU)

10:30 – 11:00 Break

11:00 – 11:45 Aplicación y Ejecución – Allan Felsot (Universidad Estatal de Washington, EE.UU)

11:45 – 12:30 Percepción de Riesgos, Comunicación y Gestión del Riesgo -Allan Felsot (Universidad Estatal de Washington, USA)

12:30 – 13:30 Almuerzo

13:30 - 14:15 Hoja de Ruta para la conducción de la Evaluación de Riesgo -Ximena Patiño (CropLife América Latina; Bayer CropScience, Colombia)

14:00 - 14:45 Discusión y mesa redonda (Moderador Jairo Guerrero)

14:45 – 15:00 Break y fin de la sesión

Notas:

1.- Se realizará una ronda de preguntas de 5 minutos después de cada exposición oral.

2.- Los participantes contarán con una carpeta con toda la información del curso.

CONOZCA A LOS EXPERTOS

John Unsworth:

Reino Unido.

Gran experiencia en química ambiental y química analítica en las áreas diseño de estudio y monitoreo, interpretación de resultados y estudios relacionados para dar un perfil general de un producto, así como la revisión del informe. Durante más de 40 años ha estado involucrado en la industria agroquímica en las áreas medioambiental y química analítica y ha gerenciado equipos en Reino Unido, Francia y EEUU. Actualmente el Dr. Unsworth es Miembro del Comité para la Protección Química de Cultivos de IUPAC y trabaja como consultor independiente especializado en el registro de agroquímicos.

Ana Paola Cione:

Syngenta-Brasil.

Líder en Seguridad Ambiental de América Latina, función para la cartera de agroquímicos y semillas de Syngenta. La función comprende un grupo multidisciplinario científico en países latinoamericanos. Sus responsabilidades incluyen el suministro de datos de seguridad, evaluaciones de seguridad y soporte a las estrategias de regulación para la cartera de Syngenta y asegurar las licencias para venta y operación. Especialidades: Evaluación de riesgos ambientales, ciencia medioambiental, ecotoxicología, exposición medioambiental.

Amy Ritter:

Estados Unidos.

La Dra. Ritter tiene más de 20 años de experiencia especializada en evaluaciones de exposición en aguas superficiales y subterráneas para apoyar el registro global de plaguicidas. Ha realizado evaluaciones para cuantificar la exposición de plaguicidas en EEUU, Unión Europea, Asia, Australia y países latinoamericanos utilizando modelos establecidos o desarrollando modelos climáticos y agronómicos específicos.

Keith Solomon:

Canadá.

El Dr. Solomon es Profesor Emérito de la Universidad de Guelph (Canadá). Su investigación y enseñanza está enmarcada en el área de plaguicidas y ambiente. Ha publicado más de 400 artículos científicos, capítulos y libros y es Miembro de SETAC y la Academia de Ciencias Toxicológicas.

Allan Felsot:

Estados Unidos.

El Profesor Felsot ha sido miembro de la Facultad de la Universidad Estatal de Washington (WSU) por 22 años y en el periodo 1978-1993 fue miembro de Illinois Natural History Survey en la Universidad de Illinois donde dirigió el Laboratorio de Química y Toxicología de Plaguicidas. En la actualidad, el Dr. Felsot lidera el Programa de Ciencias y Matemáticas de la WSU-TC, uno de los campus urbanos de la WSU y también dirige la Coordinación de Posgrado para el Programa de Ciencias Ambientales. Sus áreas de investigación son evaluación probabilística de riesgos y sus deberes de extensión universitaria incluyen comunicación acerca de la biotecnología agrícola y tecnologías para la protección de cultivos.

Ximena Patiño:

Colombia.

Gerente de Seguridad Ambiental para Latinoamérica en Bayer CropScience con 15 años de experiencia en evaluación de riesgos de plaguicidas y procesos de registro en América Latina. Ximena Patiño es Médico Veterinario (Universidad de La Salle, Colombia), MSc. en Salud Animal Salvaje de la Royal Veterinary College de la Universidad de Londres (Reino Unido). Empezó su carrera profesional trabajando en el Centro de Rescate y Rehabilitación de la Agencia Medioambiental de Bogotá confiscado animales salvajes. En 1999 se incorporó a Bayer CropScience y empezó a trabajar en el área de evaluación de riesgos ambientales para la región andina, pasando luego a adquirir experiencia en el ámbito regulatorio y evaluación de riesgos con otros países. Fue transferida a Sao Paulo Brasil para liderar el Grupo de Evaluación de la Seguridad Medioambiental. La Dra. Patiño ha estado muy activa en los esfuerzos de evaluación de riesgos en toda América Latina.

Javier Fernández:

Costa Rica.

Javier Fernández es asesor legal y asuntos regulatorios para Croplife Latinoamérica, la investigación y desarrollo orientada a la asociación de industrias agroquímicas con responsabilidad en 18 países Latinoamericanos. Anteriormente, el Sr. Fernández gerenció los asuntos de política en propiedad intelectual mundial para CropLife Internacional, la Federación Global para la Ciencia de las Plantas ubicado en Washington y Bruselas. Durante su estancia en CropLife Internacional, el Sr. Fernández fue el embajador de la Industria para los organismos internacionales tales como WIPO, misiones a la OMC, Grupo CBD, OAS y participó activamente en las negociaciones de los Tratados de Libre Comercio. El Sr. Fernández es invitado como conferencista en foros relacionados con comercio, asuntos regulatorios para la industria de la ciencia de las plantas y políticas de propiedad intelectual en varios países de América Latina. El Sr. Fernández tiene un título en Derecho de la Universidad George Washington, es graduado y es Doctor en Jurisprudencia en Ciencias Políticas de la Universidad de Costa Rica.

Jan Linders:

Países Bajos.

Químico ambiental, ha estado trabajando como asesor de riesgos de sustancias químicas medioambientales. Esto incluye el desarrollo del sistema de apoyo para las decisiones de plaguicidas, biocidas y otras sustancias químicas. Desde 1996, el Dr. Linders es miembro activo en IUPAC en el área de evaluación de riesgos medioambientales. Es miembro del Comité Científico de los Riesgos Sanitarios y Medioambientales (SCHER) de la Comisión Europea.

ORGANIZADORES

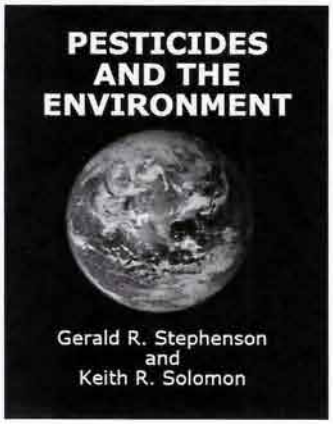
John Unsworth
Director Científico Evento
Consultor Independiente.
Reino Unido.

Nuri Gras
Coordinador Técnico Local.
CHILE

Food Intelligence Net

Pilar Lillo Lobos
Food Intelligence Net
CHILE

Punto de contacto Inscripciones y preguntas referentes al curso:



This is a unique book on the potential benefits and risks for most classes of legacy and current pesticides. It covers the underlying science involved, is both a textbook for university students, and a comprehensive reference text for professionals.

Pesticides are an increasingly important tool in providing food for all people on earth. They also protect people and their domestic animals from many diseases. Pesticides have played an important role in the history of humans but remain a controversial topic that generates considerable conflict in the public arena. This book gives important information that addresses the basic science of pesticides, their use, as well as alternatives.

Who should use this book?

This is a text-book that helps students and professionals in this field understand the scientific information on all aspects of pesticide development, use, environmental fate, as well as health and environmental effects. It also covers public controversies that have evolved as a result of pesticide accidents, misuse, or misunderstanding of the risks involved. By using the information in the chapters, study questions, and appropriate testing, this book has proven to be excellent for educators and students at the diploma, undergraduate, graduate, and professional levels. The book is a required text for a course at the University of Guelph, ON, Canada and is used in courses at the University of Copenhagen, Iowa State University, University of California, University of Nebraska.

This book has comprehensive illustrations and diagrams, an index, thorough referencing (more than 450 citations to the primary literature and government reports) as well as the IUPAC glossary of pesticide-related terms (more than 500). It is an excellent reference text for pesticide scientists at all levels of government as well as in the pest management industry.

This is a must-have book for:

Government regulators

Chemical and Agrochemical scientists in industry

Government extension personnel

University faculty

University students

University libraries

Government libraries

Book Chapters

The chapters in the book cover the following topics:

- The pesticide dilemma – the debate over pesticide risks and benefits.
- Pesticide discovery – the history and the future.
- Uses of pesticides.
- Pesticide selection, formulation and application.
- Pesticide uptake and movement in target organisms.
- Important classes of pesticides.
- Metabolism of pesticides.
- Pesticide residue analysis.
- Pesticide residues in food.
- Fate and movement of pesticides in the environment.
- The toxicology of pesticide active ingredients and formulated pesticide products.
- Ecological risk assessment of pesticides.
- Human health risk assessment of pesticides.
- Resistance to pesticides.
- Biotechnology and pest management.
- Minimizing pesticide use.
- Legislation of pesticides.

What others say about this book:

The book is unique because it includes both the use, intended and unintended effects of pesticides together with discussions on legislation and how to minimize pesticide use. I can therefore highly recommend this book to anyone working with or interested in any aspect of pesticide use, effects, or legislation. - Prof. N Cedergreen, University of Copenhagen, Denmark.

Translations

The **Portuguese translation** "Solomon KR, Stephenson GR, Correa CL, Zambrone FAD. 2010. Praguicidas e o Meio Ambiente. Sao Paulo, Brazil: ILSI Brazil. 473 p" is available from ILSI Brasil URL: publicacao@ilsi.org.br.

The **Spanish translation** "Stephenson GR, Solomon KR, Carazo E. 2012. Plaguicidas y Ambiente. San Jose, Costa Rica: University of Costa Rica. 580 p." is available from the University of Costa Rica. For information contact: María del Rosario Arguedas, Coordinadora Unidad de Distribución y Ventas Sistema Editorial de Difusión Cientifica de la Investigación, Universidad de Costa Rica, Ciudad Universitaria Rodrigo Facio, San José, Costa Rica, Apartado Postal 1150-2060, San José, Costa Rica.
Email: maria.arguedas@ucr.ac.cr

Pesticides and the Environment

Authored by Gerald R Stephenson and Keith R Solomon. xii + 425 p. Includes Table of Contents, Bibliographical References, Index, and Glossary. ISBN 978-0-9808847-0-8.

This book may be ordered from:

University of Guelph Bookstore
http://www.bookstore.uoguelph.ca/p-5940-pesticides-and-the-environment.aspx
Karen Briggs, Email, kbriggs@hrs.uoguelph.ca
Fax: 519-763-1921
Tel: 519-824-4120, ext: 54399

C.N.T.C.
R.C.C.T.
Canadian Network of Toxicology Centres Press

Price is $60.00 CDN (+ HST or GST for orders to a Canadian address). Shipping will be added to the order. Please contact the bookstore for information on bulk orders and shipping rates.

About the authors

Gerry Stephenson is a Professor Emeritus in the School of Environmental Sciences at the University of Guelph. During the early 1970s, he co-originated a University course "Pesticides and the Environment". He is an author of several books and chapters in books related to topics such as pesticide biochemistry, pesticides and human health, and pest management in agricultural, forestry and landscape environments. He is a member and current Vice Chair of the Ontario Pesticides Advisory Committee, a Fellow of the Weed Science Society of America, and Canada's representative on the International Union of Pure and Applied Chemistry Advisory Committee on Crop Protection Chemistry. He was a 1994 recipient of the Canadian Award of Excellence for Research in Weed Science and the 2003 recipient of the Weed Science Society of America, Outstanding Teacher Award.

Keith Solomon is a University Professor Emeritus in the School of Environmental Sciences and Director of the Centre for Toxicology at the University of Guelph where he taught courses in toxicology and pesticides. He conducts research into the fate and effects of pesticides and other substances in the environment, exposure of humans to pesticides and industrial chemicals, and risk assessment. He supervises graduate students at the M. Sc. and Ph. D level. He is a Fellow of the Academy of Toxicological Sciences and received the 2002 American Chemical Society International Award for Research in Agrochemicals. In 2006, he was awarded the SETAC Europe Environmental Education Award and the Society for Environmental Toxicology and Chemistry Founders Award. He has published several books, and over 400 chapters in books and peer-reviewed papers.

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ECOLOGICAL RISK ASSESSMENT WORKSHOP
HOTEL PLAZA SAN FRANCISCO
SANTIAGO, CHILE – MAY 9TH & 10TH

ERA Workshop, Santiago, Chile

J.B. Unsworth

- Chair of the IUPAC Advisory Committee on Crop Protection Chemistry

unsworjo@aol.com

ERA Workshop, Santiago, Chile

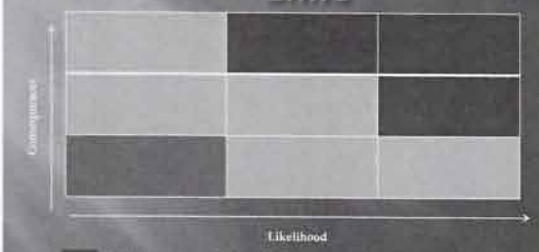
IUPAC Advisory Committee on Crop Protection Chemistry

ERA Workshop, Santiago, Chile

In the public domain risk can be thought as:

- Activities that can be a source of risk – Pesticide application
- Specific hazards that pose a threat – Accidental spillage of pesticide
- Exposure to hazards – Exposure of fish after a spill
- The harm that might result from exposure – Fish kill
- A loss of value placed on these consequences by society – Loss of an amenity

ERA Workshop, Santiago, Chile



High consequence/high probability – unacceptable risk

May require additional information to understand the risk

Low consequence/low probability – acceptable risk

UK HM Treasury

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Ecological Risk Assessment

To evaluate the likelihood that exposure to one or more pesticides may cause harmful ecological effects

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The importance of planning

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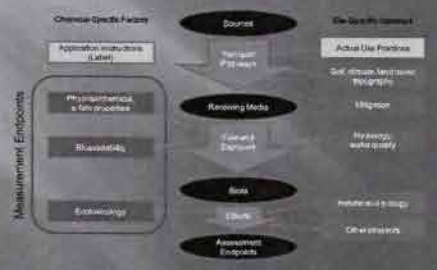
- Problem formulation
- Data collection
- Exposure estimation
- Hazard identification
- Risk characterisation
- Risk mitigation

EU Uniform System for the Evaluation of Substances (USES)

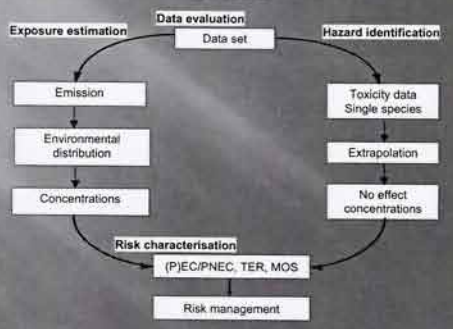
ERA Workshop, Santiago, Chile

Problem Formulation – Conceptual Model



Courtesy of the Pyrethroid Working Group

ERA Workshop, Santiago, Chile



EU Uniform System for the Evaluation of Substances (USES)

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Perception vs Reality

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Principles of Risk Communication

- Know the audience
  - What is their well-being, concerns?
- Involve the scientific experts
  - Explain the concept and process of risk assessment
- Establish expertise in communication
  - Learn skills for clear and crisp communication
- Be a credible source of information
  - Deliver speakers, some from trusted and trusted sources
- Share responsibility
  - Involve the stakeholders in decision-making especially in their concerns
- Differentiate between science and value judgement
  - Separate "facts" from "values"
- Assure transparency
  - Ensure effective communication between all interested parties
- Put the risk into perspective
  - What is the benefit compared to the risk?

ERA Workshop, Santiago, Chile

Fright Factors - Risks are generally more worrying if perceived:

- To be involuntary – rather than voluntary
- To be inequitably distributed – some benefit whilst others suffer the consequences
- As inescapable – no control over the risk
- To arise from an unfamiliar or novel source – fear of the unknown
- To result from a man-made rather than a natural source – synthetic is bad, natural is good
- To cause hidden and irreversible damage – onset after years of exposure
- To pose some particular danger to children or pregnant women – or future generations
- To threaten something of particular social value – loss of amenity
- To damage identifiable victims – rather than anonymous victim
- To be poorly understood by science – tests used are not sufficient
- As subject to contradictory statements from responsible sources – or worse the same source

From S.C. Dept. CO Health 1990

ERA Workshop, Santiago, Chile

Over The Next Two Days The Workshop Will Cover:

- The Regulatory Framework for Risk Assessment
- Protection Goals
- Ecological Testing Requirements
- Exposure Assessments
- Risk Characterisation and Uncertainties in Risk Estimation
- Risk Mitigation and Refinement
- Regional and Local Considerations in Risk Assessment
- Risk Perception, Communication and Management

CropLife INTERNATIONAL

Los Principios de Regulación

Contenido

1. El desafío global y los beneficios de la tecnología de la protección de cultivos
2. Regulación como la clave para enfrentar el desafío
3. Los principios de regulación
   - Principios regulatorios claves reconocidos
   - Mejores prácticas para el registro efectivo
   - Expectativas de la sociedad sobre regulación
4. Propuestas para la mejora continua

Nuestro planeta enfrenta enormes desafíos

La seguridad alimentaria es amenazada por:

- la población mundial llegará a exceder los 9.3 billones en 2050
- un incremento del 50% en la demanda de calorías
- solo entre 5-10% más del suelo podrá ser dispuesto para la producción agrícola mundial
- las consecuencias prácticas del cambio climático y la escasez de agua

La agricultura está en el corazón de estos desafíos

- **PRODUCIENDO ALIMENTOS**

  Incrementado rendimientos y asegurando una fuente de alimentos segura y confiable

- **CREANDO ENERGÍA RENOVABLES**

  Más allá de los alimentos, la agricultura debe proveer fuentes renovables de combustible, fibras y alimentación animal

- **SUMINISTRO SOSTENIBLE**

  Protegiendo la biodiversidad, hábitats naturales y suministros de agua a través de una producción eficiente

La Regulación es clave para enfrentar estos desafíos

La Regulación es un imperativo

Debe ser un estímulo y una salvaguarda, trabajando al servicio de la sociedad, de la agricultura y de nuevas soluciones de la ciencia de los cultivos

Regulación de plaguicidas

- Los plaguicidas juegan un papel único en la sociedad, pero sus usos, beneficios y regulación son entendidos pobremente por muchos
- Bajo el Código Internacional de Conducta, los gobiernos tienen la responsabilidad general de regular la disponibilidad, distribución y uso de los plaguicidas en sus países y asegurar la disposición de los recursos adecuados para tal mandato
- La regulación puede ser la base de buenos estándares y prácticas y por ende el fundamento para la confianza de la sociedad y el fortalecimiento de las capacidades

Una solución global para un desafío global

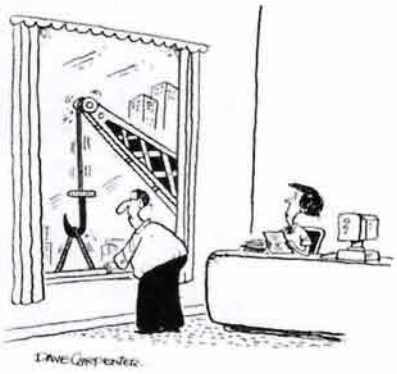
Sin embargo, las regulaciones de plaguicidas varían enormemente alrededor del mundo, reflejando la importancia relativa de la agricultura en la sociedad, en las prioridades políticas y en el desarrollo económico.

Entonces, ¿cómo podemos satisfacer las necesidades de nuestra sociedad y enfrentar los desafíos globales del futuro?

CropLife ha observado los estándares y prácticas hoy en operación y creó

'Los Principios de Regulación'

en apoyo a la buena regulación global



" IT LOOKS LIKE THEY'RE BRINGING IN THE NEW REGULATIONS MANUAL."

Los Principios de Regulación

- **Principios** regulatorios claves reconocidos
- Mejores **prácticas** identificadas para el registro efectivo
- **Expectativas** de la sociedad sobre la regulación

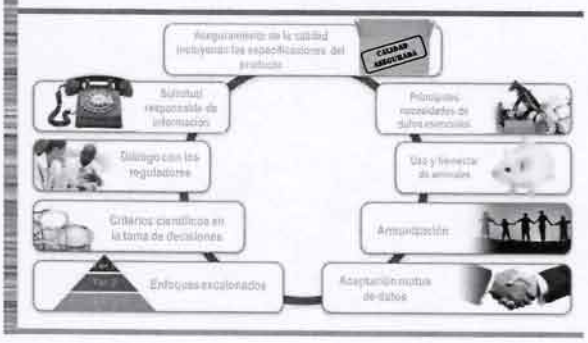
8 Principios regulatorios claves reconocidos

1. Marco político sólido que asegure altos estándares de uso y protección de la salud humana y el ambiente
2. Información de calidad y transparencia del proceso regulatorio, mientras se provee protección a los datos regulatorios, salvaguardando la información confidencial y la propiedad intelectual
3. Armonización internacional donde sea posible, pero siempre tomando en consideración necesidades y condiciones locales
4. Principios científicos y evaluación del uso (riesgo/beneficio)

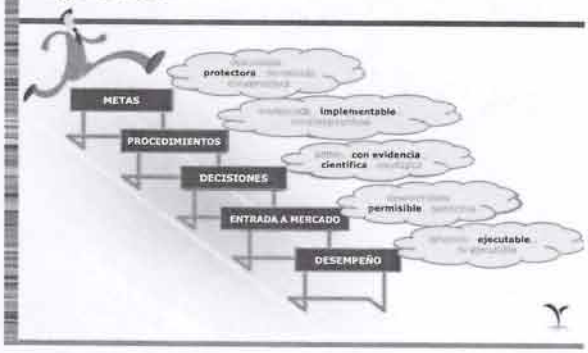
8 Principios regulatorios claves reconocidos

5. Responsabilidad de cada parte a lo largo de las cadenas de producción y distribución así como compromisos con la acción responsable
6. Sistema de monitoreo del cumplimiento y un proceso activo de respuesta para manejar incidentes adversos
7. Proceso para asegurar estándares modernos aplicado a todos los productos del mercado
8. Evaluación del impacto de cambios / revisiones significativas en las regulaciones

9 Mejores prácticas del registro efectivo



Expectativas de la sociedad sobre regulación



Expectativas de la sociedad sobre regulación

- Protectora – claras metas de protección que formen una base para decisiones balanceadas que evalúen el uso (riesgo y beneficios)
- Implementable – un proceso entendible construido alrededor de un marco común crea confianza y oportunidades para compartir trabajo y/o el fortalecimiento de las capacidades
- Informada – decisiones basadas en evidencia utilizando un marco común que extienda el entendimiento y las capacidades alrededor del mundo
- Permisible – proceso que permite el acceso a la tecnología mientras cumple con las metas de protección
- Ejecutable – responsabilidad compartida en el monitoreo y el cumplimiento post-aprobación

Análisis de la regulación existente usando los Principios de Regulación

Evaluar el proceso regulatorio contra los Principios de Regulación

Identificar las brechas y los excesos

Considerar las opciones y enfoques en un espíritu de mejora continua

Analysis de Brechas

Evaluación con métrica PoR

Brechas identificadas

Sistemas regulatorios analizados	
Argentina	Kenia
Bolivia	India
Central America	Marruecos
República Dominicana	Paraguay
Chile	Perú
Colombia	África del Sur
Ecuador	Uruguay
Egipto	USA
UE	Venezuela

Resultados análisis de brechas

Áreas de mejora:

- **Proceso de registro**
  - Aceptación mutua de prácticas
  - Propiedad intelectual
  - Transparencia
  - Tiempos
- **Proceso de evaluación**
  - Análisis de riesgo
  - Análisis riesgo/beneficio
  - Stewardship

Proposición de CropLife

- Nuestro planeta enfrenta enormes desafíos. La agricultura está en el corazón de estos desafíos y la tecnología de protección de cultivos es una parte vital de la solución.
- La regulación es un imperativo y debe ser un estímulo y una salvaguarda.
- La proposición de CropLife es un enfoque universal de los Principios de Regulación que incluye:
  - **Principios** regulatorios claves reconocidos
  - Mejores **prácticas** identificadas para el registro efectivo
  - **Expectativas** de la sociedad sobre la regulación

Overview of the Regulatory Risk Assessment Frameworks for Pesticides

Keith Solomon, May 9, 2015
Ecological Risk Assessment Workshop
Santiago Chile

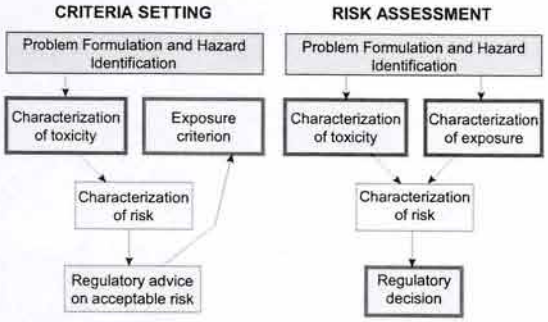
1

Regulation of pesticides

- Almost all countries regulate pesticides.
- Not all countries conduct formal risk assessments for pesticides themselves.
- Some use registration in other countries or WHO/FAO assessments as a guideline.

2

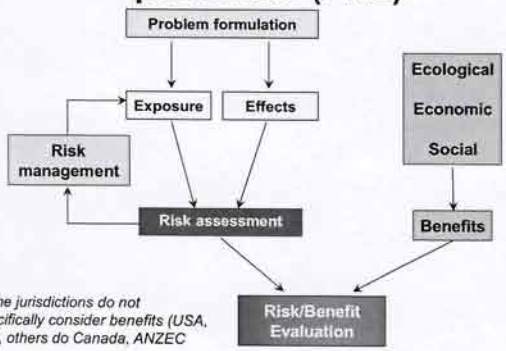
Frameworks for risk assessment



Acceptable Daily Intake, Reference Dose, Water-Quality Guidelines, etc.

3

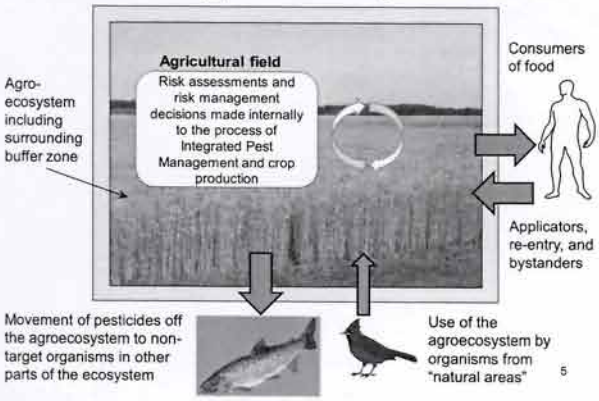
Risk-benefit assessment for pesticides (FAO)



Some jurisdictions do not specifically consider benefits (USA, EU), others do Canada, ANZEC

4

Assessing risks of pesticides



5

Assessing risks: Goals and objectives

- Protection goals
  - General
  - Political motivated
  - Regulatory
  - Unquantified and unquantifiable
- Assessment endpoints
  - Specific to the issues in hand
  - Quantifiable
  - Measurable or can be modeled
  - Can be tested with hypotheses

6

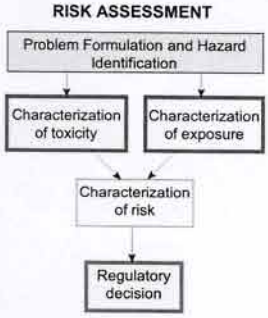
Assessment endpoints

- Ecotoxicology
- Aimed at population
  - Survival,
  - Growth,
  - Development,
  - Reproduction.
- These are apical endpoints (US EPA)

- Humans
- Aimed at the individual
  - 1 in 10,000 or less for reversible effects.
  - 1 in a million risk of irreversible harm (cancer, birth defects, etc.).

7

Frameworks for risk assessment

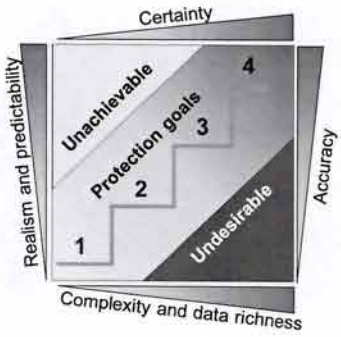


- Most regulators follow the standard format.
- Characterize
  - Exposure &
  - Toxicity
- Compare these values as a hazard ratio or as probability distribution.

8

Tiered approach

- Most regulators use a stepped or tiered approach
- Tiered process maximizes efficiency
- Achieve a desired and realistic level of protection with progressively less uncertainty



9

Risk hypotheses

- Where will the exposures be?
- Duration and frequency of exposures?
- What organisms will be exposed?
- What will the exposure concentration be?
  - Tier 1:
    - Will the exposure exceed the LC50, NOEC of a single test species?
    - What proportion of the population of a test species will be affected
  - Tier 2:
    - What proportion of species will experience an exceedence of their LC50 or NOEC?

10

Exceedence of LC50 or NOEC – quotient

$$\text{HAZARD} \approx \frac{\text{EXPOSURE CONCENTRATION}}{\text{EFFECT CONCENTRATION}}$$

(Level of Concern or LOC)

$$HQ = \frac{600}{200} = 3$$

11

Hazard quotient – humans

- Most commonly used approach
- Three issues
  - Most conservative response used
  - Point of departure
    - NOAEL (a dose from the design of the study)
    - BMD (cancer)
  - Uncertainty factors

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Uncertainty – humans

From	To	Uncertainty factor
Animal NOAEL	Human	≥ 10
Average human	Sensitive human	≥ 10
LOAEL	NOAEL	≥ 10
Subchronic	Chronic	≥ 10
Database inadequacies	NOAEL	≥ 10
Modifying factors (children, seriousness of the response, etc.)		0-10

$$\text{ADI or RfD (mg/kg bw human)} = \frac{\text{NOAEL (mg/kg bw animal)}}{(UF_1 \times UF_2 \times UF_n)}$$

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Uncertainty - ecotoxicology

Data	Canada	OECD	OECD	US EPA	EU TGD
Quantitative structure activity relationships (QSAR)	1000	1000	1000	1000	1000
Acute data (one or two species)	1000	1000	1000	1000	
Acute data (3 taxa)	100	100	100-1000	100	1000
Chronic data (1 taxon)			50-100		100
Chronic data (2 taxa)			10-100		50
Chronic data (3 taxa)	10	10	10	10	10
Chronic probabilistic					1-5
Mesocosm data				1	Case by case

14

Uncertainty in hazard quotients

- HQ assessments incorporate some form of uncertainly factor
  - Explicitly as part of the calculation itself, or
  - Criteria for acceptance of the HQ, and
  - Conservative values are used
- Common error
  - HQ itself is proportional to the "risk"
    - HQ is based on a point estimate of effect
    - Does not consider the relationship between the concentration and the effect

15

Problems with worst case

- May not be multiplicative or additive
- Inconsistent - it is always possible to conceive of a still worst case
- Do not consider the probability of occurrence
- Conservative assumptions based on premise of no societal or environmental costs resulting from regulation of false positives

16

Quotient method

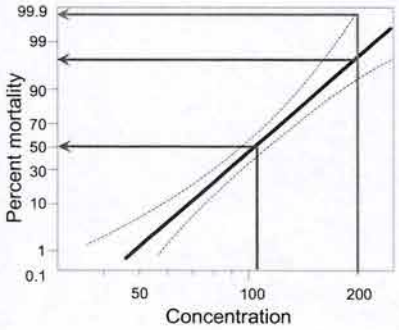
- The quotient approach is designed to be protective, not predictive.

17

"You can't say the government isn't trying."

18

Proportion of the population of a test species

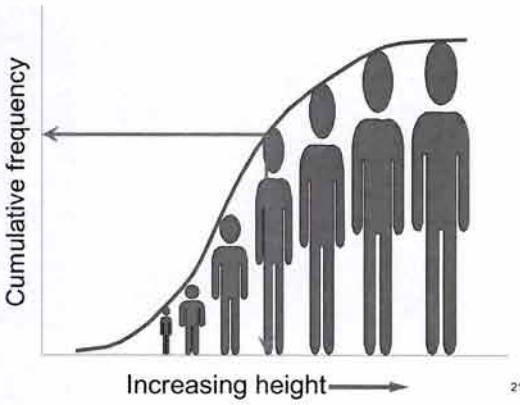


19

Probabilistic approach

CARL FRIEDRICH GAUß 30 April 1777 - 23 Feb 1855

20



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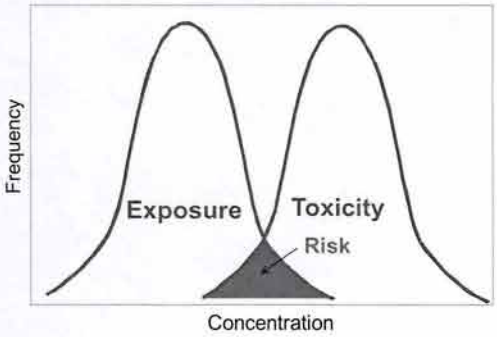
Probabilistic characterization of risk



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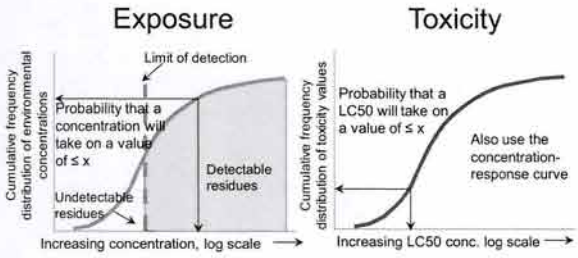
Using cumulative distributions



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Linearizing the distributions

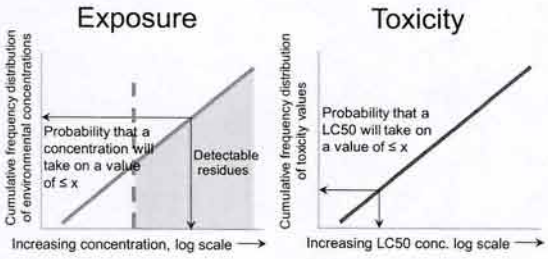

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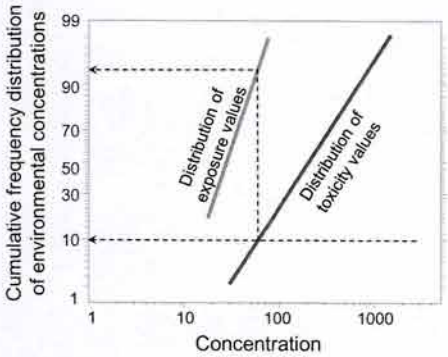
Figure 4

Combining distributions



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Other criteria for regulation

- Recent changes in pesticide registration in the EU have added **P**ersistence, **B**ioaccumulation, and **T**oxicity to criteria for registration in EC 1107/2009.
- This is not done in other regulatory frameworks for pesticides (US, Canada, etc.) but P, B, and T are assessed for chemicals used in commerce. Pesticides and pharmaceuticals are not included as they are already regulated.

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Criteria for POPs

Criteria for persistence (P)	Criteria for bioaccumulation (B)	Criteria for toxicity (T)	Potential for long-range transport (LRT)
Water: DT50 ≥60 d Sediment: DT50 ≥180 d Soil: DT50 ≥180 d	BCF ≥5,000 or Log K_{OW} ≥5 Other, e.g., very toxic or bioaccumulation in nontarget species	No specific criteria other than "significant adverse effects"	Air: DT50 ≥2 d or modeling or monitoring data which shows long-range transport

- The POPs Convention recommends that decisions be made "after rigorous scientific assessment". Classification as a POP results in global "ban".

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UNECE, 1996; UNEP, 2001, 2010

Criteria for PBT (EC1107/2009)

Persistence (P)	Bioaccumulation (B)	Toxicity (T)
Marine water: **t½ ≥60 d**; Fresh water **t½ ≥40 d** Marine sediment: **t½ ≥180 d** FW sediment: **t½ ≥120 d** Soil: **t½ ≥120 d**	**BCF ≥2,000** in aquatic species	Chronic NOEC <0.01 mg/L or is a carcinogen, mutagen, or toxic for reproduction, or other evidence of toxicity

Off J Europ Commun 52:1-50.

These criteria are more stringent than those for POPs and, triggering two of these, results in being the pesticide being placed on a list for substitution.

30

Regulating pesticides as PBTs

- Very simple measures are use for pesticides when we have much more data on environmental fate, uptake, biomagnification etc.
- Field observations not considered at all, all decisions based on data from laboratory studies.
- Inappropriate and will have serious consequences for agriculture in Europe.

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Gracias

32

Protection goals, ecosystem services and roles of risk management

Ana Cione, Ph.D.
Croplife - Syngenta

LAPRW2015

Robust and efficient environmental risk assessment procedures require clear protection goals specifying what to protect, where to protect it and over what time period.

LAPRW2015

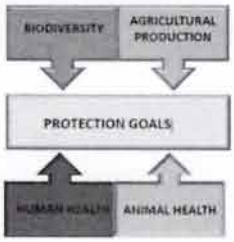
Answer to the question .....

"What do you want to protect?"

- Defined by society as part of environmental policy
- Often reflect what is valued... not always what needs protecting
- Protection goals are often formulated in legal terms using normative concepts such as "sustainability, integrity, acceptability...
- Should be balanced by other societal needs

LAPRW2015

In most countries the protection goals applicable to ERAs fall in four main categories



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Category	Species Totals
Vertebrate Animals	
Mammals	5,416
Birds	9,956
Reptiles	8,240
Amphibians	6,199
Fishes	30,000
Total Vertebrates	59,811
Invertebrate Animals	
Insects	950,000
Molluscs	81,000
Crustaceans	40,000
Corals	2,175
Others	130,200
Total Invertebrates	1,203,375

Category	Species Totals
Plants	
Flowering plants (angiosperms)	258,650
Conifers (gymnosperms)	980
Ferns and horsetails	13,025
Mosses	15,000
Red and green algae	9,671
Total Plants	297,326
Others	
Lichens	10,000
Mushrooms	16,000
Brown algae	2,849
Total Others	28,849

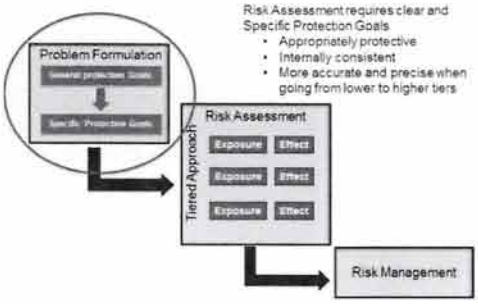
TOTAL NUMBER OF SPECIES	1,589,361

http://www.currentresults.com/Environment-Facts/Plants-Animals/number-species.php

LAPRW2015

Risk Assessment requires clear and Specific Protection Goals

- Appropriately protective
- Internally consistent
- More accurate and precise when going from lower to higher tiers



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Link to Environmental risk assessment

- The operational translation of General Protection Goals (GPGs) focuses the ERA through Specific Protection Goals (SPGs), facilitating the selection of relevant assessment endpoints, the formulation of testable hypotheses and the selection of measurement endpoints.

LAPRW2015

PROTECTION GOALS IN ENVIRONMENTAL RISK ASSESSMENT

LAPRW2015

What do you want to protect

- Typical Questions
  - Nature?
  - Habitats/Ecosystems?
    - In crop, outside crop, natural ecosystems?
    - Ecosystem structure vs Ecosystem Function
  - Non-target species?
    - all individuals,
    - all populations,
    - local populations
  - All species or e.g. 95%
    - Indicator species
    - Endangered species
    - "Beneficial" species

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What do you want to Protect

- Other questions – more detail on scale of protection
  - Do we consider short-term effects with recovery acceptable ?
  - Do we consider an effect on 10% of the individuals acceptable?
  - Are we interested in all types of effects; mortality ?, reproduction ? growth ? behaviour ?
  - Temporal aspect: Short-term vs. long-term - Should we allow for recovery?
  - Spatial aspect: Local vs. regional
  - Probability: How likely are effects (1x in 30 y)?

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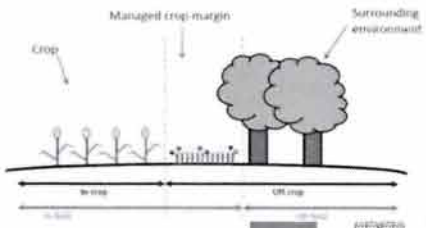
Habitat will impact protection goal

Agricultural landscapes

Agricultural landscapes contain a mixture of ecosystems that receive different levels of human management and provide different ES.



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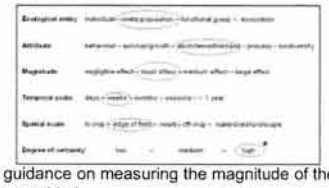
Plant Protection Products

- The approach based on the Ecosystem Services (ES) concept and describes the steps to follow to develop specific protection goals.
- A discrimination between ES in-crop and off-crop is made.
- SPGs are developed in 4 steps, applying six dimensions:
  - Ecological entity
  - Attribute
  - Magnitude
  - Temporal scale
  - Spatial scale
  - Degree of certainty



- Once SPGs are defined, guidance on measuring the magnitude of the effects and thresholds are provided.

From Nienstedt et al., 2012

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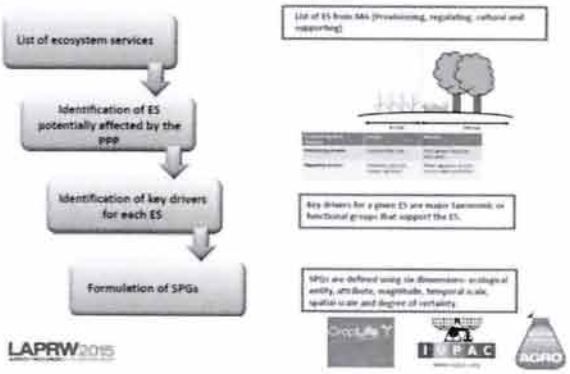
PROTECTION GOALS IN ENVIRONMENTAL RISK ASSESSMENT:

After deriving SPG for each key driver/Ecosystem Service combination, those combinations leading to similar SPG were pooled to give seven main categories :

- Microbes
- Algae
- Non-target plants
- Aquatic invertebrates
- Terrestrial non-target arthropods (including honeybees)
- Terrestrial non-target invertebrates (e.g. worms)
- Vertebrates (e.g. fish, mammals)

LAPRW2015

PROTECTION GOALS IN ENVIRONMENTAL RISK ASSESSMENT:



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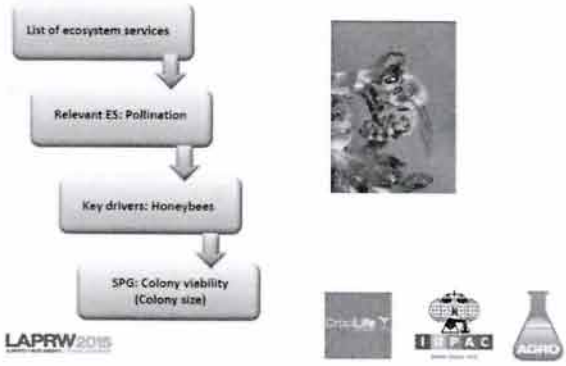
PROTECTION GOALS IN ENVIRONMENTAL RISK ASSESSMENT:



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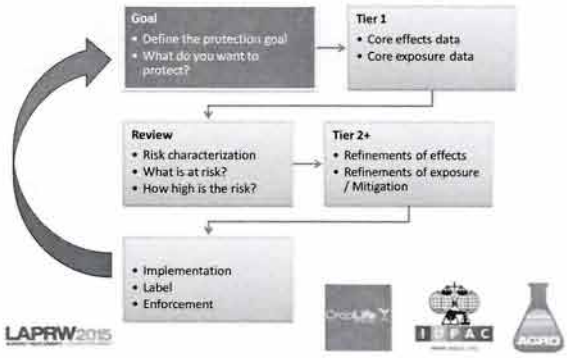
PROTECTION GOALS IN ENVIRONMENTAL RISK ASSESSMENT:

Good Regulation: The Universal Regulatory Framework for Assessing Safe Use



Ecosystems/Habitats

Habitats of concern need to reflect agricultural landscapes
Field Scale
Agricultural practice
Rivers vs ponds vs ditches etc.?
Drinking water from Ground vs surface water?
Etc.

Species Categories

- Similar protection goals can be interpreted differently

	EU	US
Birds and Mammals	✓	✓
Bees	✓	✓
Non-target arthropods	✓	x
Earthworms	✓	x
Soil micro-organisms	✓	x
Non-target plants	✓	✓
Fish	✓	✓
Aquatic Invertebrates	✓	✓
Aquatic plant growth	✓	✓

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Andean Manual ERA

- Has list of species but what are the Protection Goals?

Birds: Quail and Duck
Aquatics: Daphnia and Green Algae
For herbicides Lemna gibba
For bees: Apis mellifera
Terrestrial: Eisenia foetida

Difficult to agree any tiered assessment as not clear protection goals

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Cooperation Project for Implementation of an Environmental Risk Assessment Framework in Brazil

- Tripartite Steering Commitee: IBAMA, Academia and Industry Association reps
- Selection/election Working Gropups
  - Pollinators
  - Aquatics
- Roadmap from IBAMA
- Deliverable: Manual ERA Brazilian

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Summary:

- Protections goals: what to protect, where and for how long.
- General protection goals: biodiversity
  - "everything, everywhere."
  - No qualification of acceptable risk or effects.
- Specific protection goals: ecosystems services
  - Makes trade-offs in multifunctional landscapes transparent
  - Provides a mechanism for protecting species diversity
  - Enables socio-economic assessments
  - Makes risk assessment more relevant for risk management

LAPRW2015

WASHINGTON STATE UNIVERSITY

Ecological Risk Assessment Workshop
Santiago, Chile: May 9-10, 2015

1

Principles of Ecotoxicity Testing

Allan Felsot
Washington State University
Department of Entomology
College of Agriculture Human & Natural Resources Sciences
School of the Environment; School of Biological Sciences

AGRICULTURE | YOUTH & FAMILIES | HEALTH | ECONOMY | ENVIRONMENT | ENERGY | COMMUNITIES

The Dilemma of Ecological Risk Management

2

- Millions of species to protect
- Infinitesimal exposure scenarios
- Must accept some adverse effects (practically speaking)
  - ✓ Habitat destruction dominates any possible effect that pesticides could have (absent a spill or other intentional misuse)
- Desire to know the likelihood that communities and ecosystems will be affected
  - ✓ However, studies are largely based on examining individuals, not higher levels of hierarchy

U.S. Pesticide Law 101

3

FIFRA (1947) ← FEPCA (1972)

FFDCA (1938) ← **Miller** (1954), **Delaney** (1958)

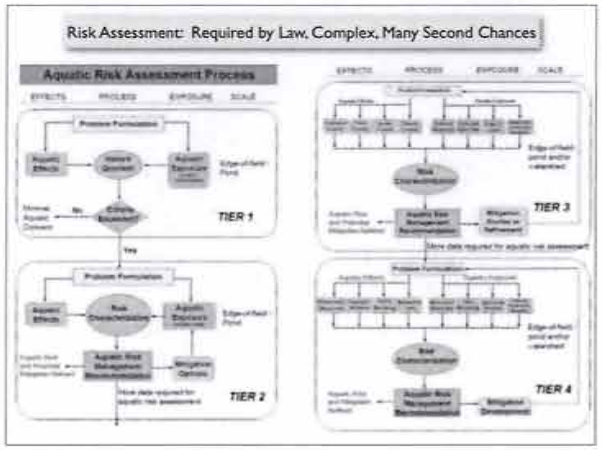
Risk Assessment → Tolerance ("MRL")

Ecological | *Human Health*

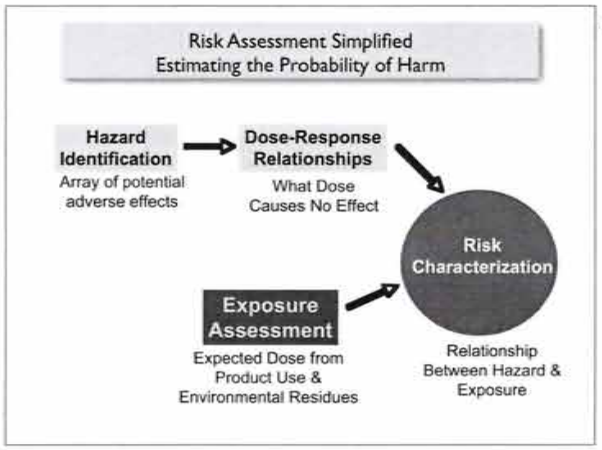
Labeling → **Registration**

FQPA (1996)

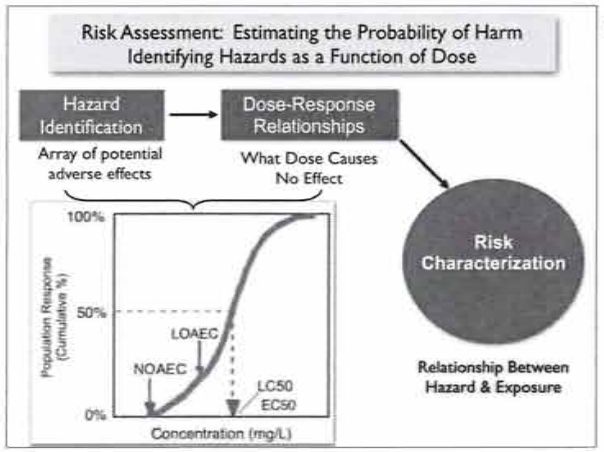
4


Risk Assessment: Required by Law, Complex, Many Second Chances
Aquatic Risk Assessment Process
TIER 1
TIER 2
TIER 3
TIER 4

5


Risk Assessment Simplified
Estimating the Probability of Harm
Hazard Identification
Array of potential adverse effects
Dose-Response Relationships
What Dose Causes No Effect
Risk Characterization
Exposure Assessment
Expected Dose from Product Use & Environmental Residues
Relationship Between Hazard & Exposure

6


Risk Assessment: Estimating the Probability of Harm
Identifying Hazards as a Function of Dose
Hazard Identification
Array of potential adverse effects
Dose-Response Relationships
What Dose Causes No Effect
100%
50%
0%
Population Response (Cumulative %)
LOAEC
NOAEC
LC50
EC50
Concentration (mg/L)
Risk Characterization
Relationship Between Hazard & Exposure

7

The Simplest Definition of Toxicity

- "The accumulation of injury over short or long periods of times that renders an organism incapable of functioning within the limits of adaptation or other forms of recovery." (Rozman et al. 2001)

- Or as Paracelsus over 500 years ago stated,
  - ✓ All things are poison, and nothing is without poison; only the dose permits something not to be poisonous
  - ✓ In other words "Dose Makes the Poison"
    - Substances considered toxic are harmless in small doses, and conversely an ordinarily harmless substance can be deadly if over-consumed

8

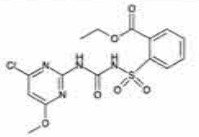
Speaking the Same Language--Toxicity Terms

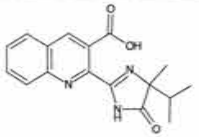
- Toxicity: innate potential of a substance to cause injury (attribute of specific 3-D chemical structure & appropriate receptor in organism)
- Hazard: potential to cause injury under specific set of circumstances
- Risk: probability (likelihood) of harm; function of the magnitude of exposure (or contamination) integrated with hazard
- Safety: subjective term and therefore not definitive, but in the context of risk management it refers to the practical certainty that injury will not result from use of a substance under specified conditions of quantity and manner of use

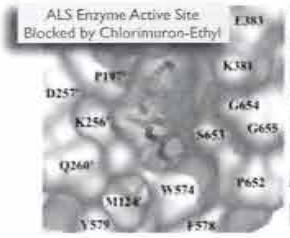
Do Not Confuse Toxicity, Hazard & Risk

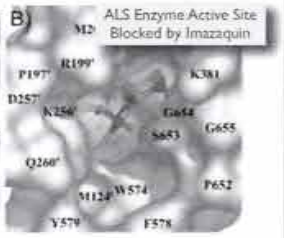
9

Seeing the World in 3D



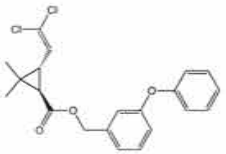






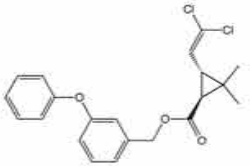
10

Pyrethroid Structural Chemistry: Only One of the Mirror Images Is Insecticidal!!



1 R trans permethrin

Bioactive Insecticide



1 S trans permethrin

Not Active

11

Hazard: Critical Variables

- Two variables are most important in determining the potential of a toxicant to cause an adverse response
  - ✓ Amount of exposure (dose)
    - Should be distinguished from dosage, the amount relative to body weight, and absorbed dose (the amount actually in the body)
  - ✓ Frequency and duration of exposure (time)
- Note that the influence of these two variables are often exposure route specific
- From an ecotoxicological perspective, environmental conditions (e.g., presence of organic matter in water) will influence the hazard

12

Toxicological Focus: Individual vs Population

- If we're concerned about pesticides affecting human health, we are focused on individual responses
  - ✓ i.e., we try to protect the individual from any type of toxic response
- If we're concerned about pest control, we are focused on populations of pests
  - ✓ i.e., we're focused on lowering the population and the only toxic response we're interested in is death
- If we're concerned about non-target plants & wildlife, we are focused on stability of populations

Toxicological Endpoints

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- Must have endpoints if we are to measure toxicity at either the individual or population level
  - ✓ An endpoint is the direct or indirect biochemical, cellular, physiological, or behavioral response following an exposure to a toxicant
- Death (often equated with acute toxicity, although severe injury rather than death may result)
  - ✓ In the context of non-occupational exposures to pesticides, this endpoint is only relevant to the pests we're trying to control
    - However, mortality will still be measured to understand potency among chemicals and also to determine whether non-target organisms are likely to be harmed
  - ✓ Lethality can be expressed quantitatively as the median response in a population, i.e.,...
    - LD_{50}: dose lethal to 50% of the test population
    - LC_{50}: concentration lethal to 50% of the test population

Toxicological Endpoints

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- Sublethal Effects
  - ✓ Biochemical
  - ✓ Genetic
  - ✓ Cellular
  - ✓ Physiological
  - ✓ Morphological
  - ✓ Functional
  - ✓ Behavioral

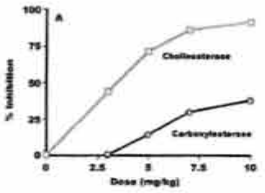
Although these endpoint can be caused by a single dose exposure, often these endpoints are studied in association with repeated exposures

Sublethal effects following repeated "small dose" exposures are often called chronic toxicity, which includes cancer, developmental effects, and immunological & neurological deficits

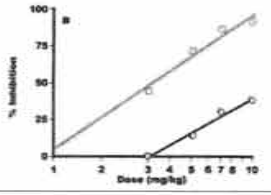
Individual Organism Response Is Graded

15

- If a single organism was treated with any toxicant (e.g., a pesticide), and a single endpoint was followed (e.g., enzyme inhibition activity), then a graded response would be seen as this individual was exposed to ever larger doses



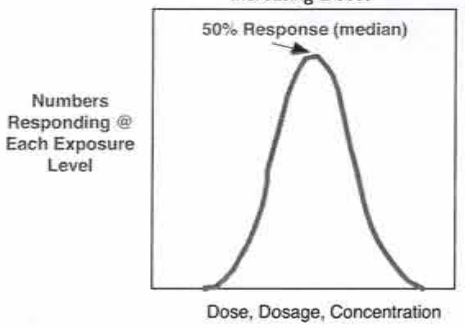
- The graded response of the individual assumes a straight line when the dose is changed to log form



16

Basis for Quantitatively Expressing Toxicity

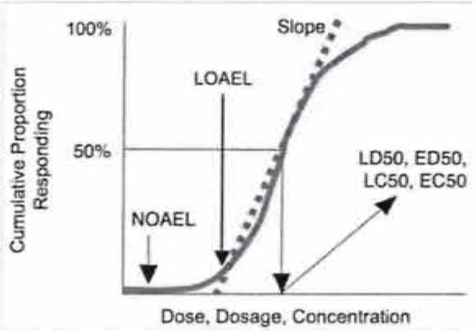
Distribution of Individual Responses to Increasing Doses



17

Basis for Quantitatively Expressing Toxicity

Cumulative Proportion Responding

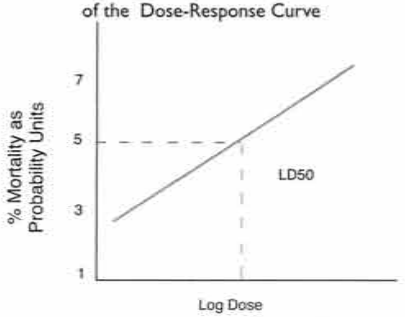


18

Basis for Quantitatively Expressing Toxicity

Probit Transformation-Linearization of the Dose-Response Curve

% Mortality	Probit
10	3.72
20	4.16
30	4.48
40	4.75
50	5.00
60	5.25
70	5.52
80	5.84
90	6.28



Probit values can be calculated in EXCEL using the "normal inverse" function: '=NORMINV(proportion responding, 5, 1)'

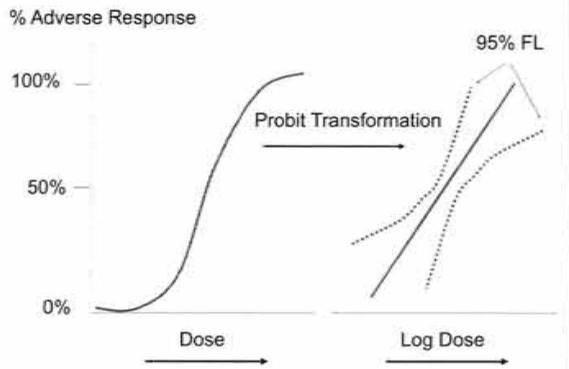
19

How do you know when two populations response estimates are different or seem different as a result of random chance?

Use of 95% Fiducial Limits

- Analogous to the 95% confidence interval (or limits) calculated for univariate statistics
  - ✓ If an experiment was conducted 100 times, then the CL or FL represents the distribution of the data (or interval of data) that is predicted to capture the mean (CL) or median (FL) response (or any measured variable) 95 times
  - ✓ Thus, there is a 5% chance that the mean or median response was not captured by the estimated interval
  - ✓ For any two measured populations, if the estimated 95% FL for the response overlap, then we cannot conclude there is a difference between them with less than 5% probability of Type I error

20

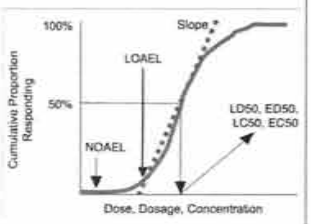


Note that the FL are narrower about the median response

21

Threshold

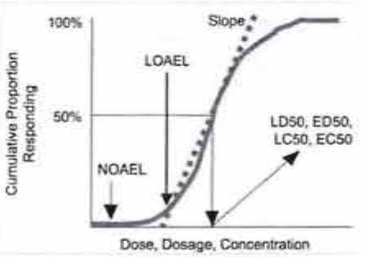
- For protecting humans & other non-target organisms, we are interested in the dose not causing a toxic response (any kind of toxicity)
- Expressed as the NOAEL or NOAEC
  - ✓ No Observable Adverse Effect Level
  - ✓ No Observable Adverse Effect Concentration
- In EPA risk assessments, empirically derived, although can be modeled based on a curve fit function
- In rodent tests, based on chronic and subchronic exposure tests
- In ecotox tests, based on chronic exposure; i.e., life cycle tests



22

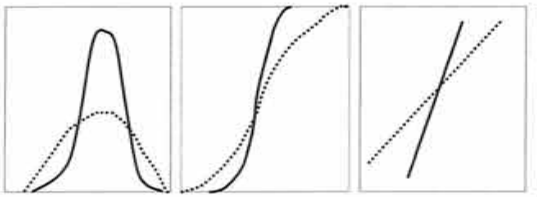
Lowest Measurable Effect

- LOAEL or LOAEC
  - ✓ The lowest adverse response is determined by examining for statistically significant differences between the no-dose control and the lowest dose causing an effect



23

Important Information Contained in the Slope of the Dose-Response Curve

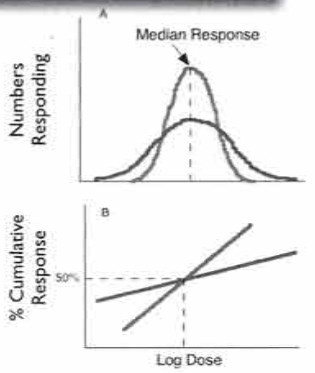


The slope is the key to understanding the variation in population response, and it can be used to compare two or more populations, or alternatively, how different factors affect the response of one population.

24

Importance of Slope

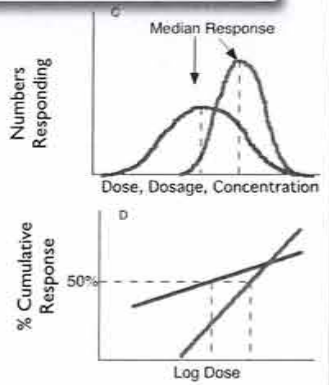
- Represents variability in population response
- Characterizes margin of safety
- Response of different species exhibiting same median response to same chemical



Importance of Slope

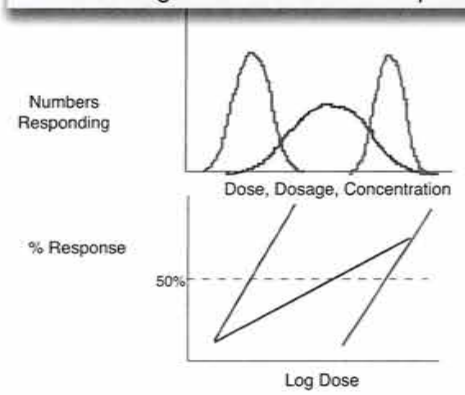
25

- Variation in response of two different species reacting to the same chemical
- Variation in response of single species reacting to two different chemicals



Monitoring of Resistance Development

26



Measuring Herbicide Toxicity: Animals vs Plants

27

- Animal toxicity measurements involve observations of the cumulative proportion of the population exhibiting a specific toxicological endpoint over the range of doses tested
  - ✓ Effects are expressed as a percentage responding relative to the log dose or log concentration; probit analysis is commonly used to estimate slope of the response and calculate the percentage response at any dose (i.e., LD_{10}, LD_{50}, LD_{90})
  - ✓ The objective is to ultimately find the lowest dose causing an effect and the lowest dose not causing an effect (experiments are limited by feasible numbers that can be tested)
- In contrast, plant responses are measured as a graded reduction in normal plant vitality over a range of herbicide concentrations or application rates
  - ✓ The objective is to quantify plant sensitivity to a herbicide, but mostly comparisons in herbicide activity are being made between the weed and the crop
    - * Thus, trying to observe selectivity by examining whether a dose-response curve differs between two species or a single species under different conditions
      - – Ultimately a "good" herbicide is one in which the weed shows injury at a lower dose than the crop
  - ✓ Furthermore, any evaluation of the effect of herbicide chemistry, plant genotype, environment, or adjuvants on plant responses to herbicides is in essence comparison of two or more dose-response curves ("differential dose-response relationships")

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Measuring Herbicide Toxicity to Plants: Responses Observed

- Plant Part Response
  - ✓ Seed germination
  - ✓ Root or shoot elongation
  - ✓ Cell multiplication or deformity
  - ✓ Chlorosis or necrosis of leaves
  - ✓ Any other morphological changes
- Whole Plant Response
  - ✓ Suppression or inhibition of growth
  - ✓ Flowering & seed production
  - ✓ Physiological activity (O_2 or CO_2 evolution)
  - ✓ Metabolic properties
  - ✓ Death

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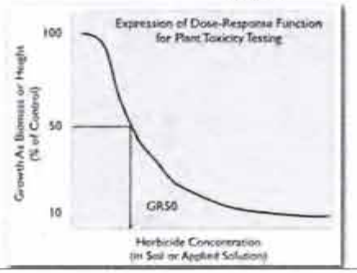
Measuring Herbicide Toxicity to Plants: Estimation of the Dose-Response Function

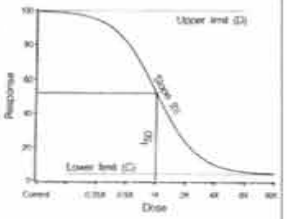
- The concept of an LD_{50} or LC_{50} is replaced by a GR_{50} (a concentration or spray application rate causing 50% reduction in growth parameters compared to an untreated plant);
- In some cases an I_{50} (inhibition of growth or physiological/biochemical process) is used; or, an EC_{50} may be used (concentration effectively causing 50% reduction in some parameter compared to the normal response)



30

Measuring Herbicide Toxicity to Plants: Mathematics of Dose-Response Function

- The graded (or continuous) response of plants (i.e., a population of plants) relative to dose applied to soil or concentration sprayed on the foliage can be characterized by a log-logistic function
  - ✓ This function is preferred over the linearization technique using probit because one is interested in doses not causing any crop toxicity in comparison to the weed response or the dose causing the maximum response; therefore, the response curve nonlinearity should be estimated
- Parameter Definitions:
  - ✓ C = lower response limit (response at the highest doses tested)
  - ✓ D = upper response limit (mean response of untreated control)
  - ✓ b = slope
  - ✓ I_{50} (or GR_{50}) = dose giving 50% response



$$y = f(x) = C + \frac{D - C}{1 + (x/I_{50})^b}$$

$$= C + \frac{D - C}{1 + \exp[b(\log(x) - \log(I_{50}))]}$$

Testing Organisms ("The Guinea Pigs")

- Mammalian toxicology for regulatory risk assessment (RA)
  - ✓ Rodents
  - ✓ Dogs
- Ecological toxicity testing for regulatory RA
  - ✓ Invertebrates, vertebrates, microbes, plants
  - ✓ Aquatic, terrestrial

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Ecotox Testing: Aquatic Invertebrates

- *Daphnia magna* and other species
- Amphipod (scuds)
- Insects
  - ✓ Stoneflies
  - ✓ Mayflies
  - ✓ Midges

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Ecotox Testing: Aquatic Vertebrates

Coho salmon

Fathead minnow

Atlantic salmon

Bluegill sunfish

Rainbow trout

33

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Ecotox Testing: Aquatic Plants

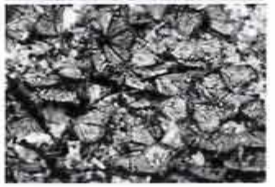
Green algae

Duckweed

Parrotfeather

35

Ecotox Testing: Terrestrial Invertebrates



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Ecotox Testing: Terrestrial Vertebrates

Mallard Duck

Northern Bobwhite Quail

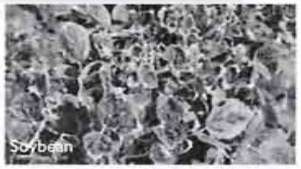
37

Ecotox Testing: Terrestrial Vertebrates

Rat

38

Ecotox Testing: Terrestrial Plants



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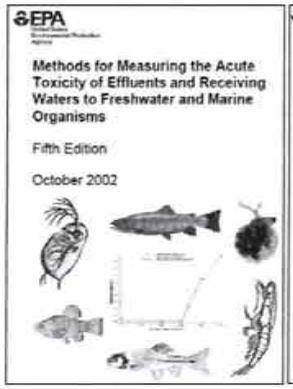
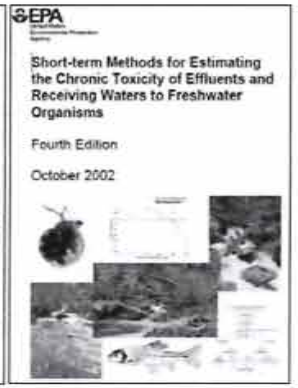
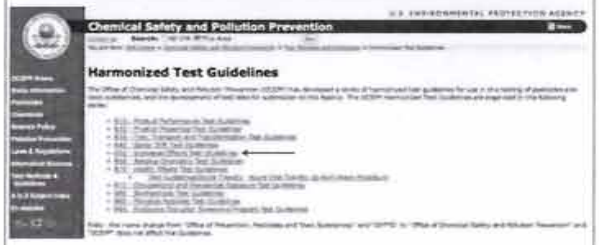




OPPTS Harmonized Test Guidelines



http://epa.gov/ocspp/pubs/frs/home/guidelin.htm

40

http://epa.gov/ocspp/pubs/frs/home/draftguidelines.htm

41

"Enquiring" Minds Want to Know

- How can modern pesticides be toxic to pests but when used as prescribed by the label, be pretty safe for everything else?

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The Secrets of Pesticide Selectivity

- Selectivity refers to the pesticidal activity of a chemical against pests with minimal biological activity against non-target organisms
  - ✓ For example, herbicides are toxic to plants at legal rates of application but lack effects on animals
  - ✓ For example, 2,4-D products are toxic to most broadleaf plants but lack effects on grasses when applied according to label instructions
- Selectivity is what allows you to take therapeutic doses of pharmaceutical drugs that are known poisons at higher doses
- Selectivity is what allows us to eat many plant products, even though those plants produce biochemical toxins against herbivorous pests

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Selectivity Is Due to Two Major Physiological Phenomena

- Pharmacokinetic (toxicokinetics)
  - ✓ Processes controlling absorption, distribution, metabolism, and excretion (ADME) of pharmaceutical drugs and toxicants by an organism
  - ✓ The differential toxicity of a compound between a pest organism and a nontarget organism may be due to...
    - Differences in penetration through integument
    - Conferred by extent (reactivity) and/or rate of metabolism (toxicokinetics)
      - The nontarget organism very quickly detoxifies the chemical (but in the pest it is more persistent)

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Selectivity Is Due to Two Major Physiological Phenomena

- Pharmacodynamics (toxicodynamics)
  - ✓ Interactions of pharmaceutical drugs and toxicants with specific biochemical receptors or enzymes in an organism
  - ✓ Selectivity occurs when...
    - Nontarget organisms lack the appropriate biochemical receptor or enzyme target
    - The pesticide poorly binds (or interacts) with the biochemical target

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Exposure ≠ Hazard

- Must consider pharmacokinetics (toxicokinetics) & pharmacodynamics (toxicodynamics)
- Basic processes (ADME)
  - ✓ Absorption
  - ✓ Distribution
  - ✓ Metabolism
  - ✓ Elimination (Excretion)
- Measure
  - ✓ Extent of process
  - ✓ Rate of process

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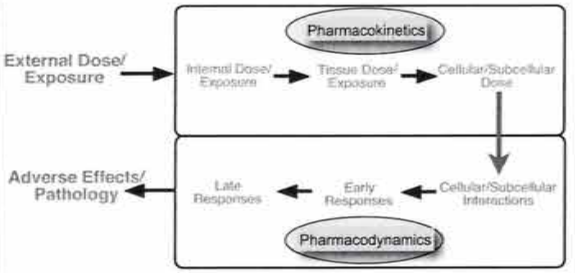
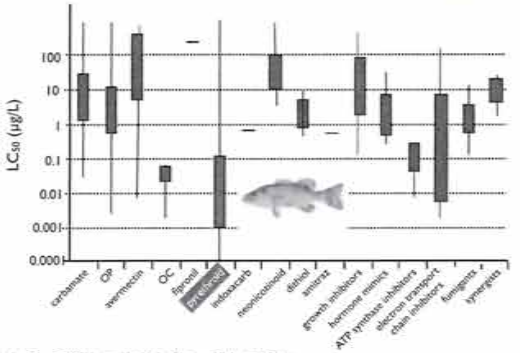
Conceptual Model of Role of Pharmacokinetics (Toxicokinetics) & Pharmacodynamics (Toxicodynamics) in Generation of Toxicity (or Not)



- For any one species, pharmacokinetics is used to predict body dose distribution
  - ✓ Relies on viewing body as series of compartments with interfaces
  - ✓ Toxicant travels from compartment to compartment until it is eliminated from the body, typically through extensive metabolism and excretion

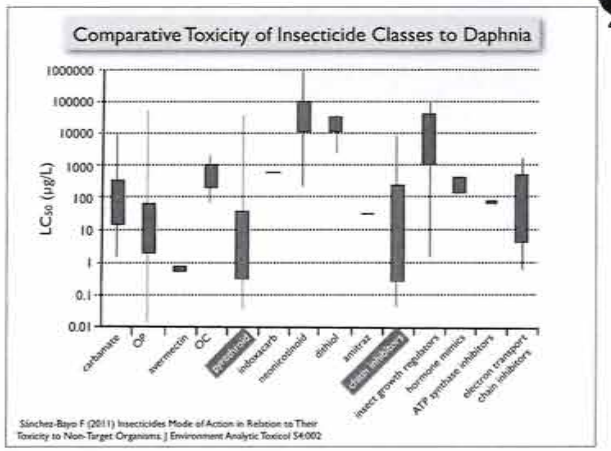
48

Comparative Toxicity of Insecticide Classes to Fish

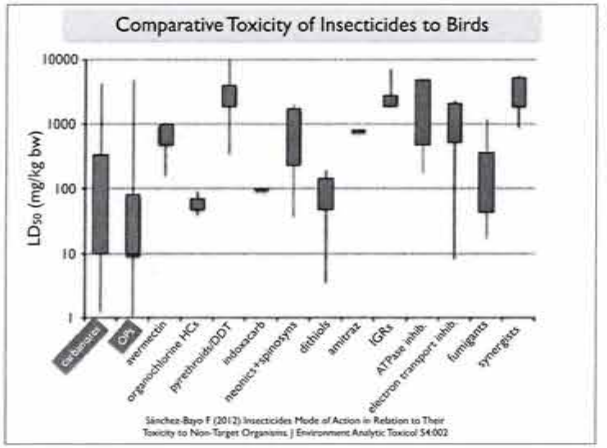


Sánchez-Bayo F (2011) Insecticides Mode of Action in Relation to Their Toxicity to Non-Target Organisms. J Environment Analytic Toxicol 5:4:002

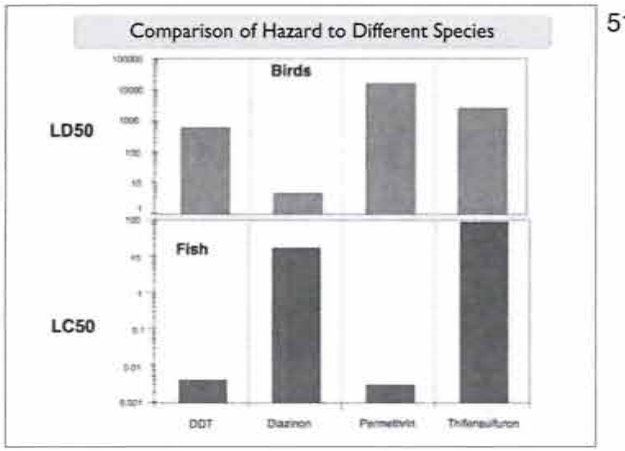
49


Comparative Toxicity of Insecticide Classes to Daphnia
LC50 (µg/L)
1000000
100000
10000
1000
100
10
1
0.1
0.01
carbamate
OP
avermectin
OC
pyrethroid
indoxacarb
neonicotinoid
dithiol
amitraz
chitin inhibitor
insect growth regulators
hormone mimics
ATP synthase inhibitors
electron transport chain inhibitors
Sánchez-Bayo F (2011) Insecticides Mode of Action in Relation to Their Toxicity to Non-Target Organisms. J Environment Analytic Toxicol 54:002

50

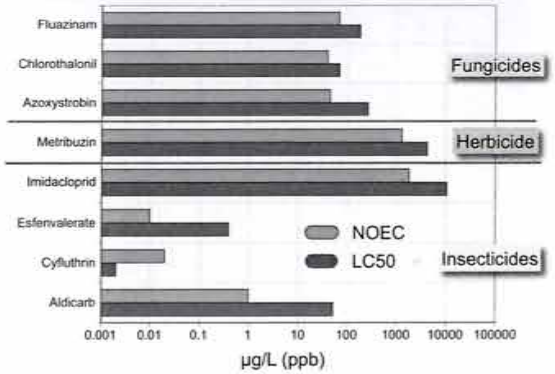

Comparative Toxicity of Insecticides to Birds
LD50 (mg/kg bw)
10000
1000
100
10
1
carbamate
OPs
avermectin
organochlorine HCs
pyrethroids/DDT
indoxacarb
neonics+spinosyns
dithiols
amitraz
IGRs
ATPase inhib.
electron transport inhib.
fumigants
synergists
Sánchez-Bayo F (2012) Insecticides Mode of Action in Relation to Their Toxicity to Non-Target Organisms. J Environment Analytic Toxicol 54:002

51


Comparison of Hazard to Different Species
Birds
LD50
Fish
LC50
DDT
Diazinon
Permethrin
Thifensulfuron

52

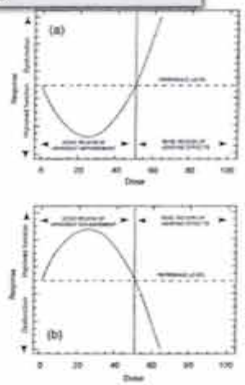
Comparison of Acute (LC50) & Chronic Toxicity (NOEC) of Potato Pesticides to Aquatic Invertebrates



53

Hormesis

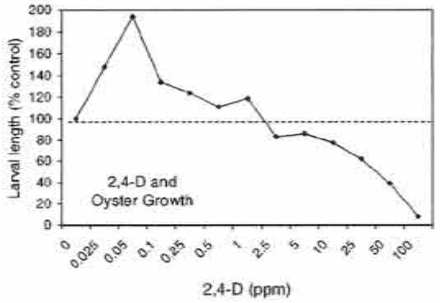
- "Low dose stimulation, high dose inhibition"
- Recent analysis of many studies shows it is a common phenomenon across species and compounds
- Hypothesized to be a widely generalizable phenomenon that results from overcompensation by homeostatic mechanisms following a small chemical insult (Crump 2001, Crit. Rev. Toxicol. 31:669)
- Insects (esp. aphids and mites) have been observed to have a hormetic response to low concentrations of insecticides
  - ✓ Increases in fecundity



Calabrese & Baldwin (2003) Ann Rev Pharmacol Toxicol 43:175

54

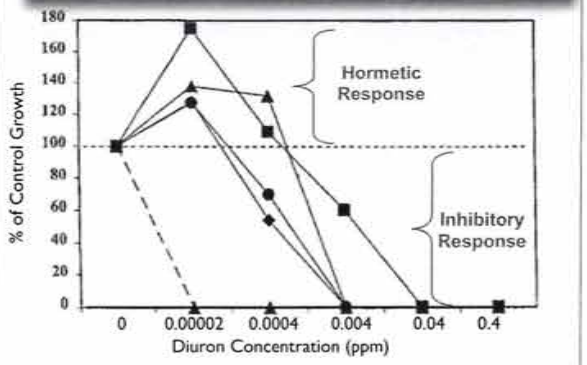
Stimulation of Oyster Larval Growth by the Herbicide 2,4-D



Davis HC, Hidu H. 1969. Effects of pesticides on embryonic development of clams and oysters and on survival and growth of the larvae. Fish. Bull. 67:393–404

Response of Five Algal Species to the Herbicide Diuron

55



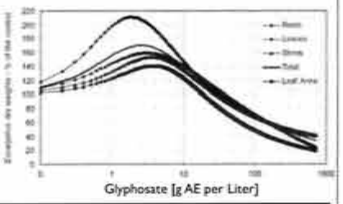
(originally published by Ukeles 1962; reprinted in Calabrese & Baldwin 2002)

Hormetic Response to Glyphosate

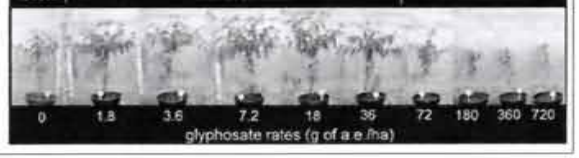
56

- Eucalyptus grandis was sprayed with glyphosate at 0, 1.8, 3.6, 7.2, 18, 36, 72, 180, 360 or 720 g AE (acid equivalents) ha^{-1}
- Plants were collected 60 DAT to measure leaf area and root, leaf, stem and total dry weights

Velini et al. (2008) Pest Management Sci 64:489-496



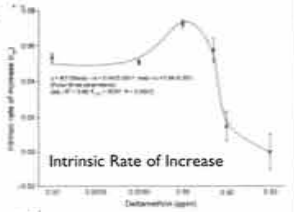
Eucalyptus grandis plants 60 days after glyphosate application at different doses

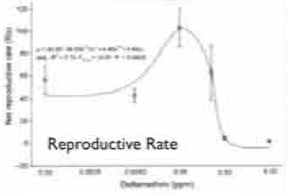


Maize Weevil Hormesis

57

Guedes et al. (2010) J. Appl. Entomol. 134:142–148





- Hormetic response of maize weevils to low doses of deltamethrin is not through survival
- Rather, response is increase in intrinsic rate of increase through enhancement of net reproduction rate

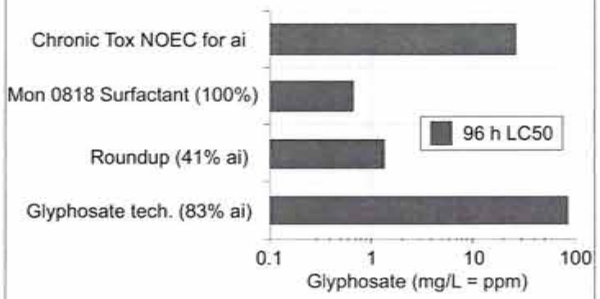
58

Factors Influencing Hazard

- Factors related to toxic agent
  - ✓ Material is crystalline or liquid at room temp.
  - ✓ Exposure to formulated material as opposed to isolated residues
- Factors related to exposure situation
  - ✓ Dermal contact (exposure via integument)
  - ✓ Oral contact (dietary exposure)
  - ✓ Inhalational (via respiratory ventilation)
- Factors related to dose frequency and timing
  - ✓ Single dose; pulsed dose; chronic dose
- Factors related to the exposed organism
  - ✓ e.g., age, health, nutritional status previous exposures
- Environmental factors related to the subject
  - ✓ e.g., Temperature (for insects & other non-target)
  - ✓ For aquatic organisms, pH; dissolved organic matter

59

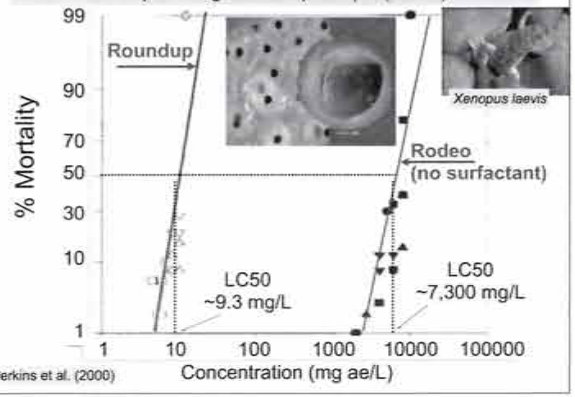
POEA Surfactant Is More Toxic than the Active Ingredient



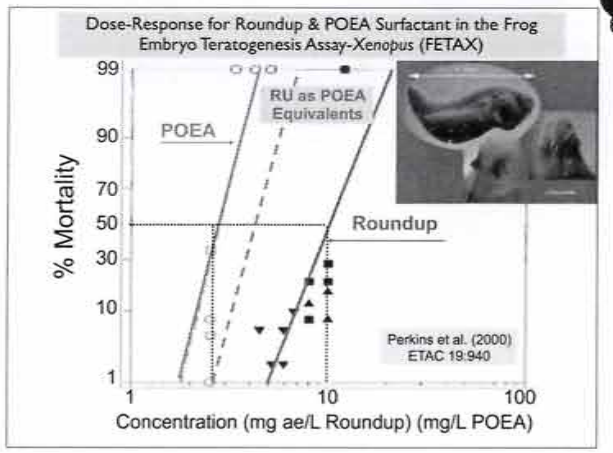
Rainbow Trout: Most Sensitive Species to Glyphosate Products
(Patterson 2004, EPA ESA Consultation Report)

60

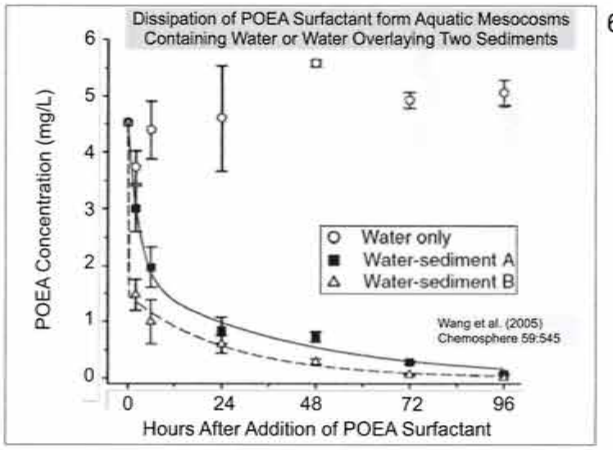
Dose-Response for Roundup & Rodeo Formulations in the Frog Embryo Teratogenesis Assay-*Xenopus* (FETAX)



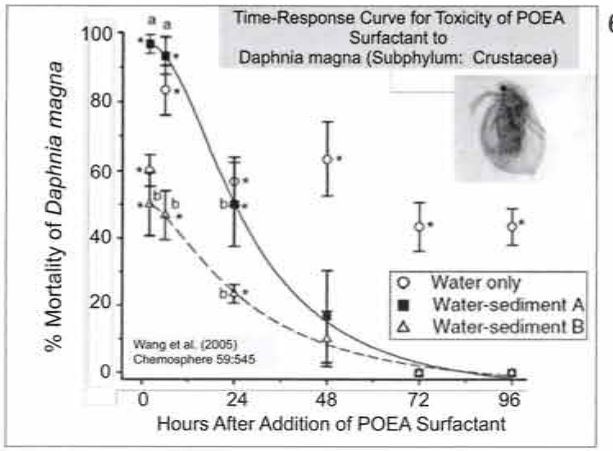
Perkins et al. (2000)


Dose-Response for Roundup & POEA Surfactant in the Frog Embryo Teratogenesis Assay-Xenopus (FETAX)
RU as POEA Equivalents
POEA
Roundup
% Mortality
99
90
70
50
30
10
1
1
10
100
Concentration (mg ae/L Roundup) (mg/L POEA)
Perkins et al. (2000) ETAC 19:940

61

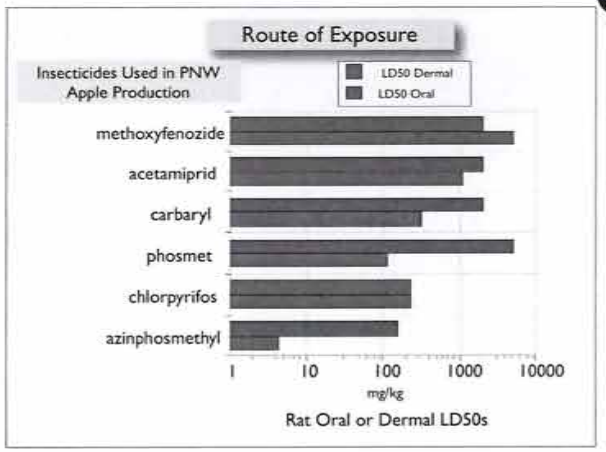

Dissipation of POEA Surfactant form Aquatic Mesocosms Containing Water or Water Overlaying Two Sediments
POEA Concentration (mg/L)
6
5
4
3
2
1
0
Water only
Water-sediment A
Water-sediment B
Wang et al. (2005) Chemosphere 59:545
0
24
48
72
96
Hours After Addition of POEA Surfactant

62

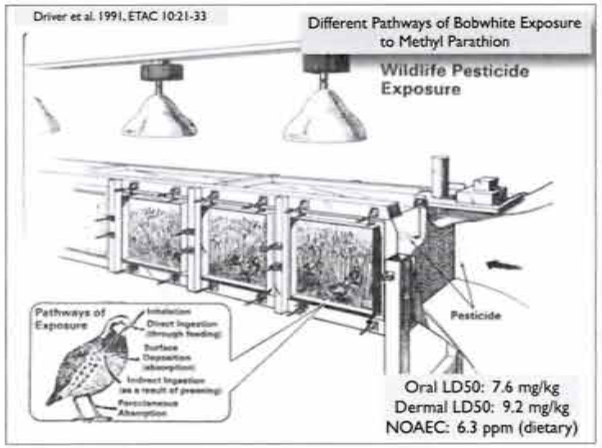

Time-Response Curve for Toxicity of POEA Surfactant to Daphnia magna (Subphylum: Crustacea)
% Mortality of Daphnia magna
100
80
60
40
20
0
Water only
Water-sediment A
Water-sediment B
Wang et al. (2005) Chemosphere 59:545
0
24
48
72
96
Hours After Addition of POEA Surfactant

63

64



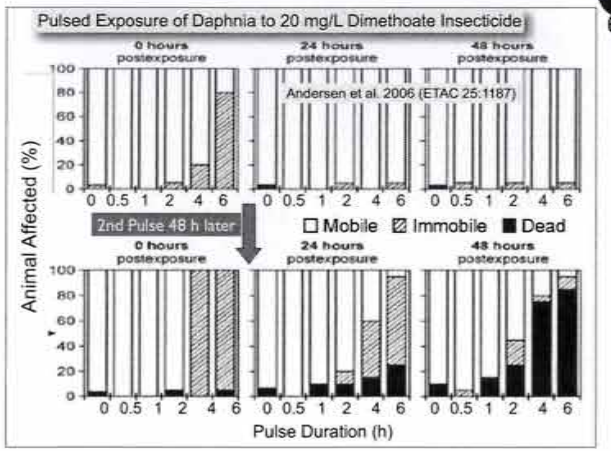
65



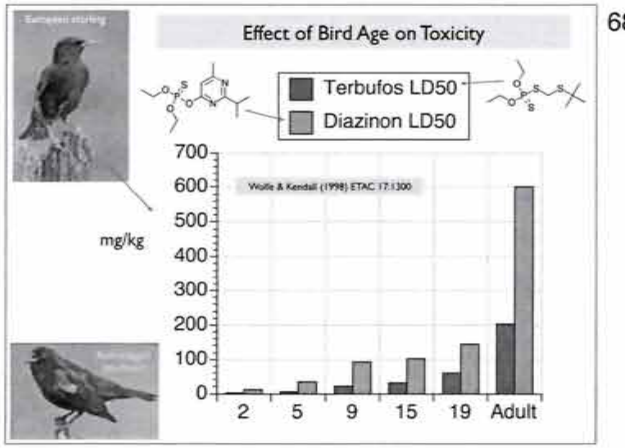
66

Influence of Exposure Situation on Response

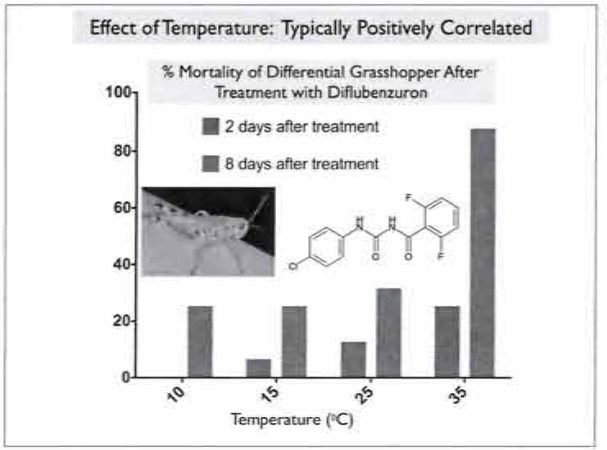
- Effect of pulse exposure duration and repeat exposure on time course of effects
  - ✓ When examining response in a cohort of test organisms, must ensure that a long enough observation time has been allowed to observe the chosen endpoint
  - ✓ Longer pulse duration can result in greater toxicity
  - ✓ Shorter duration between pulses can result in greater toxicity


Pulsed Exposure of Daphnia to 20 mg/L Dimethoate Insecticide
0 hours postexposure
24 hours postexposure
48 hours postexposure
Andersen et al. 2006 (ETAC 25:1187)
Animal Affected (%)
2nd Pulse 48 h later
Mobile
Immobile
Dead
Pulse Duration (h)

67


Effect of Bird Age on Toxicity
Terbufos LD50
Diazinon LD50
mg/kg
Wolfe & Kendall (1998) ETAC 17:1300
2
5
9
15
19
Adult

68

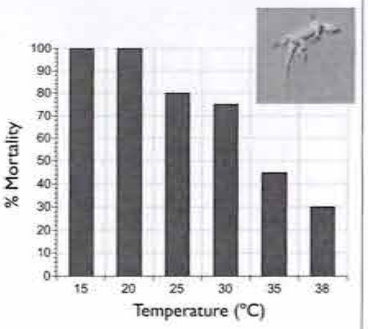

Effect of Temperature: Typically Positively Correlated
% Mortality of Differential Grasshopper After Treatment with Diflubenzuron
2 days after treatment
8 days after treatment
Temperature (°C)

69

70

Inverse Temperature Effect on Toxicity

- Green anole lizards exposed to 300 mg/L dip of natural pyrethrins insecticide product
- % mortality recorded at each temperature
- Phenomenon is relevant to pyrethrins, pyrethroids, and DDT
  - ✓ All are inhibitors of sodium channel closing on nerve axon

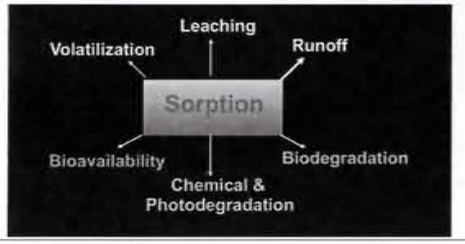


Talent (2005) ETAC 24:3113

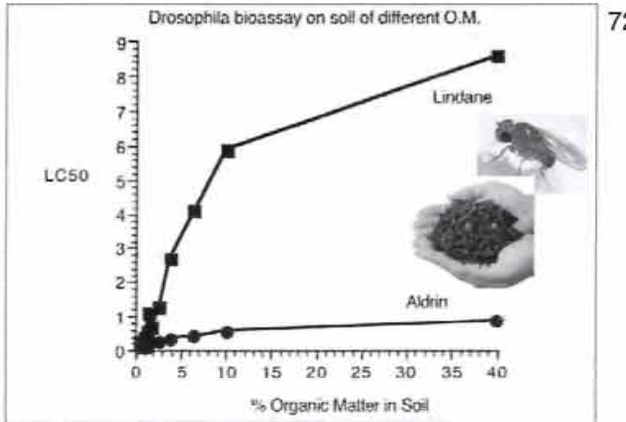
71

Sorption: Key Process Affecting Fate of Chemicals in the Environment

- Rate limiting
  - ✓ Limiting mass transfer
  - ✓ Limiting bioavailability
  - ✓ Limiting degradation



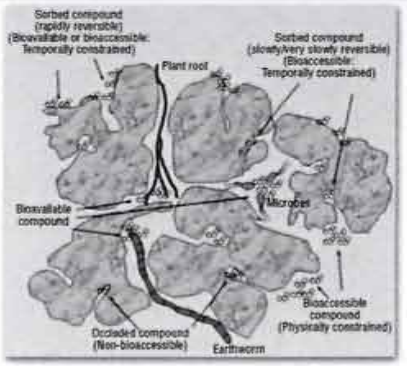
72



Drawn from data in Edwards et al. (J. Econ. Entomol. 1957)

Sorption & Aging Control Bioavailability & Bioaccessibility

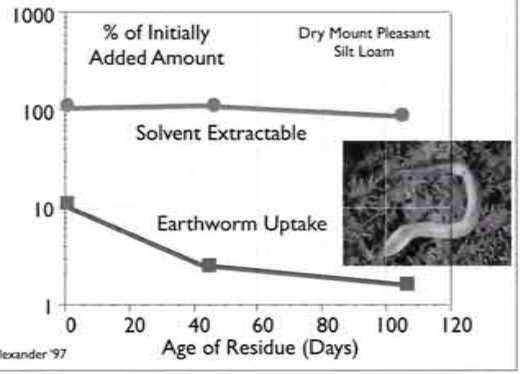
73



Graphic from Semple et al. ES&T 2004

Effect of Residue Aging on Bioavailability & Extractability of Atrazine

74



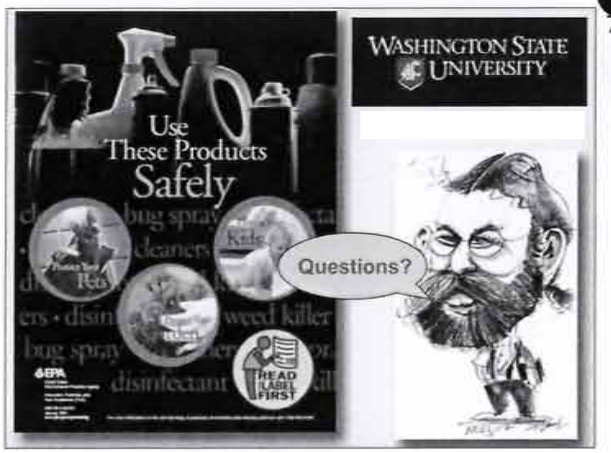
Kelsey & Alexander '97

Hazard Identification-Sublethal Effects in Fish

75

Pesticide	Effect	Fish spp. (age)	Effective Dose (ppb)	LC50 (ppb)	95th%tile EEC (ppb)
Chlorpyrifos	Impaired swimming	Rainbow trout (juvenile)	5	8	0.026
Permethrin	Impaired swimming	" "	7	7	<0.010
2,4-DBE	Increased predation	Sockeye salmon (fry & smolts)	700	<1000	<0.15
Chlorpyrifos	Schooling behavior	Fathead minnow (juvenile)	47	203	0.026
Trifluralin	Skeletal deformities	Atlantic salmon (fry/adult)	250	210	0.011

Caveat: When evaluating sublethal effects, especially on behavior, critical view the doses used. In the above table assembled from older literature studied, the effective dose causing the measured effect was a substantial percentage of the LC_{50}. Thus, sublethal effects in these cases are associated with acute toxicity.



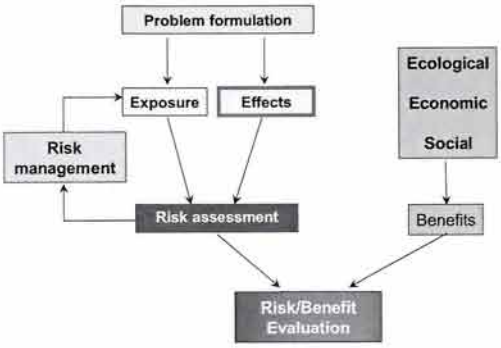
WASHINGTON STATE UNIVERSITY

Overview of International Testing Requirements for Pesticides

Keith Solomon, May 9, 2015
Ecological Risk Assessment Workshop
Santiago Chile

1

Risk-benefit (FAO)



2

Was ist das nit gifft ist? alle ding sind gifft vnd nichts ohne gifft/ Allein die dosis macht das ein ding kein gift ist.*

The dose makes the poison

3

Use of data from tests on pesticides

Risks that result from the use of a pesticide.

Risks that result from not using the pesticide or from using an alternative method for pest control.

4

Testing requirements

- No single global standard.
- US EPA's harmonized tests are close to a global standard and are equivalent to those required in other countries (OECD members).
- Testing is usually done using standardized protocols with Good Laboratory Practice and Quality Assurance and Quality Control so data are accepted in most countries.
  - Test data are thus widely accepted.

5

Use of the test data may be different

- In practice, registrants will register a pesticide in one country first.
- Other locations will follow, especially if they have slightly different requirements for registration.
  - Some regulatory agencies do not test for efficacy.
  - Some regulators regulatory agencies only consider risks.
- All characterize toxicity and exposure (risk).

6

Testing protocols

US EPA Harmonized Test Guidelines	
Series	**Series Name**
810	Product Performance Test Guidelines
830	Product Properties Test Guidelines
835	Fate, Transport and Transformation Test Guidelines
840	Spray Drift Test Guidelines
850	Ecological Effects Test Guidelines
860	Residue Chemistry Test Guidelines
870	Health Effects Test Guidelines
875	Occupational and Residential Exposure Test Guidelines
880	Biochemicals Test Guidelines
885	Microbial Pesticide Test Guidelines
890	Endocrine Disruptors Screening Program Test Guidelines

US EPA Office of Chemical Safety and Pollution Prevention, March 2015, provided in the handout

7

Common issues in testing

- Exposure routes.
- Endpoints (responses) for the tests (what is measured).
- Handling the data (statistics).
- Other issues (costs, animal welfare, disposal and treatment of waste).

See supplied notes for more details

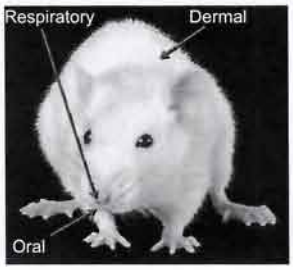
8

Health Effects Test Guidelines

- **Acute tests** for toxicity and other responses (eye, skin, lungs) – protection of human in occupational exposures.
- **Subchronic tests** – to identify NOELs, maximum tolerated dose (MTD) and also for developmental toxicity (fetal development).
- **Chronic tests** – oral feeding for the normal lifespan, three doses (MTD) – cancer as an endpoint.
  - Two or three-generation reproduction studies – trangenerational effects.
- Explanatory studies – metabolism, genotoxicity, etc.

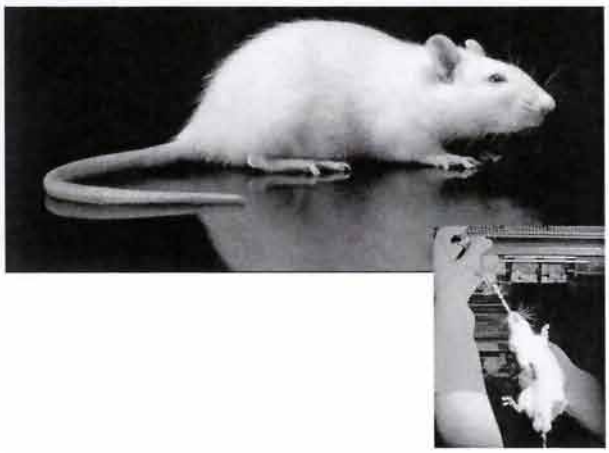
9

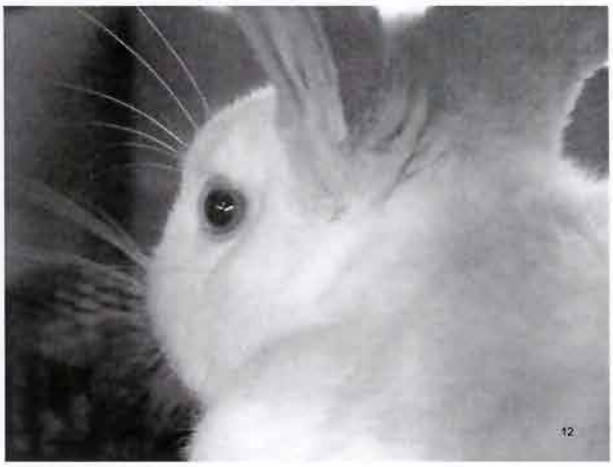
Mammals



- Routes of exposure
  - Oral, dietary, inhalation
- Endpoints
  - Death (acute) many for chronic
- Statistical treatment
  - Quantal and non- quantal
- Assay methods

10





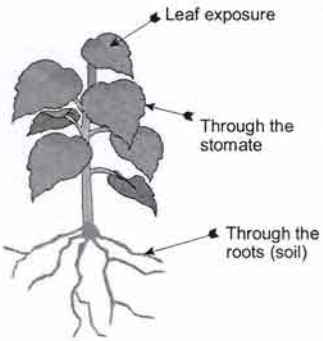
12

Maximum tolerated dose (MTD

- **Studies on chronic responses and reproduction.**
  - The highest dose used must cause some effects in the test organisms – weight loss, slight reductions in functions such as reduced number of young, etc – MTD.
  - Small number of animals used and the need to demonstrate that effects can be observed
  - Other two doses hopefully include the LOAEL and the NOAEL
  - In studies on reproduction, effects on the developing fetus may be caused by effects on the mother at the MTD – must be considered when these studies are interpreted.

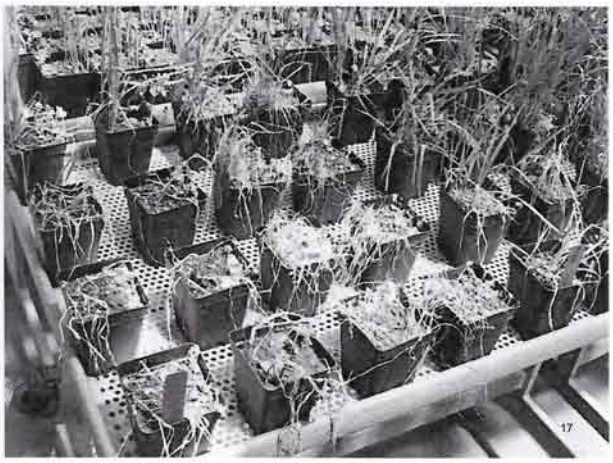
14

Ecological Effects Test Guidelines: Terrestrial plants



- Routes of exposure
  - Soil
  - Soil water
- Endpoints
  - Growth (size, numbers, yield)
- Statistical treatment
  - Mostly non-quantal
- Assay methods

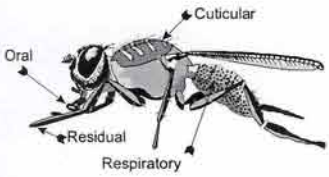
15



Soil microorganisms

- Routes of exposure
  - Soil
- Endpoints
  - Function (nitrification, denitrification, mineralization)
- Statistical treatment
  - Mostly non-quantal
- Assay methods

Ecological Effects Test Guidelines: Terrestrial invertebrates



- Routes of exposure
- Endpoints
  - Acute
    - Death
    - Morbidity
  - Chronic
    - Growth
    - Numbers
- Statistical treatment
  - Acute - quantal
  - Chronic - non quantal
- Assay methods

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Ecological Effects Test Guidelines: Terrestrial wildlife

- Routes of exposure
  - Oral gavage or in diet
- Endpoints
  - Death
  - Growth (size)
  - Numbers of eggs
- Statistical treatment
  - Quantal and non-quantal
- Assay methods

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Birds

- Routes of exposure
  - Oral gavage or in diet
- Endpoints
  - Death
  - Growth (size)
  - Numbers of eggs
- Statistical treatment
  - Quantal and non- quantal
- Assay methods

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Table 19

Ecological Effects Test Guidelines: Aquatic plants

- Routes of exposure
  - Matrix
  - Water
  - Sediment
- Endpoints
  - Growth (size, numbers)
- Statistical treatment
  - Mostly non-quantal
- Assay methods

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Table 20

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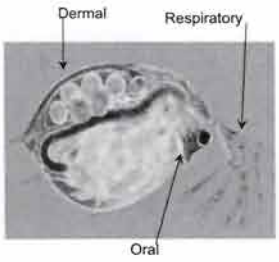
Ecological Effects Test Guidelines: Aquatic fauna test guidelines



- Routes of exposure
  - Matrix
- Endpoints
  - Acute
    - Death and morbidity
  - Chronic
    - Growth
    - Reproduction
- Statistical treatment
  - Quantal and non-quantal
- Assay methods

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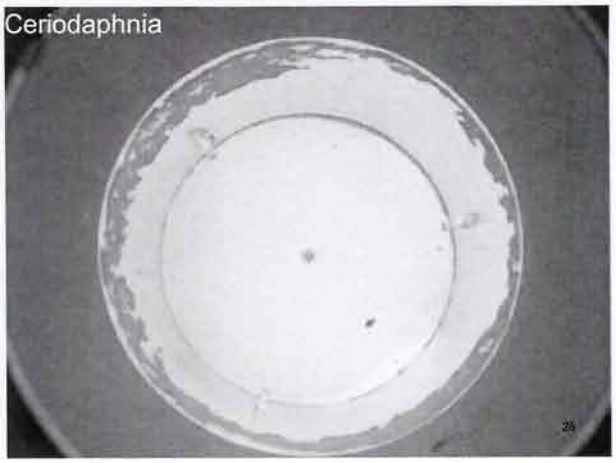
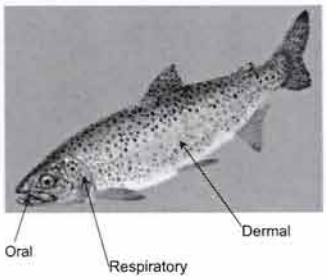


Ecological Effects Test Guidelines: Aquatic fauna



- Routes of exposure
  - Matrix
- Endpoints
  - Survival,
  - Growth
  - Reproduction
- Statistical treatment
  - Quantal and non-quantal
- Assay methods

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Endocrine: Endocrine Disruptor Screening Program

- Group A—EDSP Tier 1 Test Guidelines

890.1100	Amphibian metamorphosis (frog)
890.1150	Androgen receptor binding (rat prostate cytosol)
890.1200	Aromatase (human recombinant)
890.1250	Estrogen receptor binding (rat uterine cytosol)
890.1300	Estrogen receptor transcriptional activation (human cell line (HeLa-9903))
890.1350	Fish short-term reproduction
890.1400	Hershberger (rat)
890.1450	Female pubertal (rat)
890.1500	Male pubertal (rat)
890.1550	Steroidogenesis (human cell line – H295R)
890.1600	Uterotrophic (rat)

- Group B—EDSP Tier 2 Test Guidelines (under development)
  - Two-generation tests for mammals, birds, and invertebrates
  - Fish chronic, fish partial life-cycle
  - Amphibian partial life-cycle

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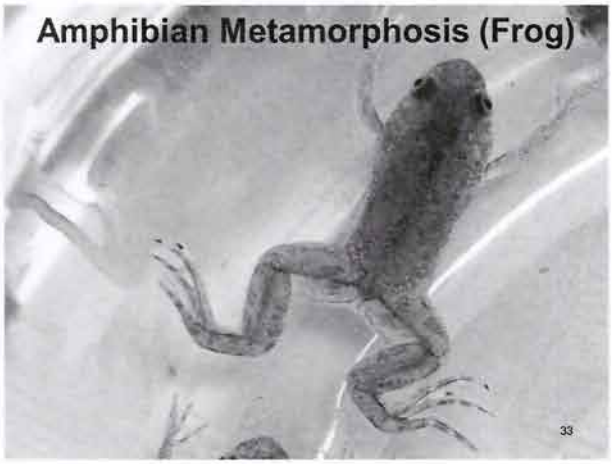
Amphibian Metamorphosis (Frog)



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THE QUALITY OF THE TEST

- Use of guidelines and proper designs
- Measured concentrations
- Healthy controls
- Good Laboratory Practice, Quality Control, and Quality Assurance
- Good science is also important (ask the right question)

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Gracias

See additional information in the handout

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1 STANDARDIZED METHODS FOR MEASURING ECOTOXICITY

Standardized test methods are routinely used and required by a number of regulatory agencies. In Canada, several standardized test methods have been suggested by Environment Canada at the federal level. In the US, a number of test methods have been developed by the US EPA for various regulatory purposes. These guidelines include protocols for testing efficacy, physical/chemical properties, environmental fate, and for the registration of pesticides under FIFIRA (USEPA 2015). The US EPA's harmonized guidelines are similar to those used in other jurisdictions such as the Organization for Economic Cooperation and Development (OECD), which has published a number of methods (OECD 2011). The American Society for Testing and Materials (ASTM) has a long history of methods development, testing and validation. In addition, a number of statistical programs to analyze these types of data are available (Norberg-King 1993, USEPA 1992b, a). The following listings are a sample of the types of tests that can be used to assess toxicity. See the listing by US EPA (USEPA 2015) for listings of other tests.

1.1 MAMMALS AND TERRESTRIAL WILDLIFE

Laboratory mammals are most commonly used as surrogates for humans and terrestrial wildlife and additional tests are not normally conducted (Lynch 1995). In most cases, oral toxicity is measured, either as a dose or as a concentration in the diet. Most of the data for terrestrial vertebrates is generated in response to the regulatory requirements for pesticides, pharmaceuticals, and food additives.

Tests on mammals are of three types; acute, to provide data for assessing risks in highly exposed individuals, such as those handling the pure substance; subchronic, to provide data on longer term exposures such as those related to therapeutic use of the substance; and chronic, to provide data on exposures over a lifetime, such as would occur with food additives and pesticides. Additional tests may be conducted to provide explanatory information on absorption, distribution, metabolism, and excretion (ADME) and mechanism of action. However, the primary focus is to provide the data to determine "safe" exposures for acute and lifetime scenarios. For a more detailed discussion of these methods and their uses see the section on Mammalian Toxicology and Risk Assessment.

1.1.1 Routes of exposure

Exposure is largely through the diet or by direct gavage.

1.1.2 Endpoints

Death, reproduction, carcinogenicity, teratogenicity, neurotoxicity and physiological responses are considered.

1.1.3 Statistical treatments

As the responses are usually quantal, probit analysis can be used for statistical analysis. Non quantal analysis may be applied to some endpoints.

1.1.4 Summary of assay methods

Table 1. Methods for assessing toxicological responses in terrestrial vertebrates.

Test	Exposure route	Endpoint	Statistical treatment
Acute oral toxicity. US EPA guideline 870.1100. OECD Guidelines 401, 420, 423,	Rats: Weighing from 200 to 300 g, 6-20 animals per replicate (4-6 doses) are starved for 16-18 h and the toxicant then administered in food, by gavage or injection. Such studies are wasteful of animals and there is a general move away from these to threshold studies that make more use of symptomology and clinical observations to derive	Mortality is the main objective with symptoms a secondary objective.	Probit analysis

Test	Exposure route	Endpoint	Statistical treatment
425.	more useful data from fewer animals. Other organisms such as birds may also be used.		
Dermal toxicity tests. US EPA guideline 870.1200. OECD Guideline 402	The test animal is usually the rabbit. The trunk is clipped, fitted with a rubber sleeve and the substance injected between the sleeve and the skin. After 24 h, the sleeve is removed, unabsorbed substance removed and the skin wiped dry. The rabbit is then held under observation for 14 d. In the test for irritation, the skin is abraded lightly, a gauze patch containing toxicant is placed on it and the area covered with a rubberized cloth. This patch is removed after 24 h and skin reaction observed after 24, 48, and 72 h.	The objectives are to evaluate the toxicity of the substance and its potential to cause irritation.	Probit or non-quantal analysis
Acute eye irritation. US EPA guideline 870.2400. OECD Guideline 405	The material is instilled into the one eye of a rabbit. The other eye is used as a control	The effects of the toxicant on the conjunctiva of the eye are also tested using the	A scoring system is used for evaluation
Inhalation tests. US EPA guideline 870.1300. OECD Guideline 403	The substance is atomized into the test chamber and the animals are usually exposed for 4-6 hours. Normally, particles <10 µm can be inhaled into the alveoli whereas those >10 µm are trapped in the nose and other parts of the respiratory tract.	Toxicity due to dermal contact or oral ingestion is avoided by using chambers that permit exposure only to the head.	Probit analysis
Subchronic oral toxicity. US EPA guidelines. 870.3050 870.3100 870.3150 870.3200 870.3250 870.3465 870.3550 870.3650 870.3800	Normally, the dosages used are 50% of LC50 values plus 5 smaller dosages. Twenty rats (10 males and 10 females) are used for each dosage. Exposure is during most of the developmental period of the animal, i.e. in the rat, 3-6 months of age. Birds may also be used in these studies. These include: Repeated Dose 28-day Oral Toxicity Study in Rodents 90-Day Oral Toxicity in Rodents 90-Day Oral Toxicity in Nonrodents 21/28-Day Dermal Toxicity 90-Day Dermal Toxicity 90-Day Inhalation Toxicity Reproduction/Development Toxicity Screening Test Combined Repeated Dose Toxicity with the Reproduction/Development Toxicity Screening Test Reproduction and Fertility Effects	Observations are: Daily: behavior, general appearance: Weekly: food consumption and growth. Frequent analyses of blood and urine are conducted. At the conclusion of the test, the animals are sacrificed and organs (bladder, brain, gonads, heart, kidney, liver, muscles, spinal cord etc.) examined, both visually and microscopically.	The objective of these tests is to find the maximum daily dosage that the animal can survive, i.e. the daily dosage that can be consumed by the animal without any demonstrable effect, i.e. the "no observed effect level"; NOEL and to find the nature of the effects of the substance when administered above the NOEL. Probit analysis in not used.
Chronic oral toxicity. US EPA guideline 870.4100, 870.4200 870.4300	Treatments are at 3 doses, based on results of subchronic tests, and similar protocols to subchronic tests are applied. The greatest dose is chosen to cause some signs of toxicity such as reduced weight gain or some non-specific physiological response and is called the Maximum Tolerated Dose (MTD). Larger numbers of animals are used than in subchronic studies (50 of each sex) and, in reproduction studies, animals and offspring may be observed for two generations.	Observations are similar to subchronic tests plus reproductive, teratogenic and carcinogenic effects.	

Test	Exposure route	Endpoint	Statistical treatment
Terato-genicity. US EPA guideline 870.3700.	Usually conducted in two species, rabbits and rat. Dosed on a daily basis during pregnancy.	Deformities in the pups.	
Reproduction and fertility effects. US EPA guideline 870.3800.	Usually conducted in mice	Number of pups etc.	

1.2 TERRESTRIAL SYSTEMS, PLANTS

Plant toxicity tests are legion and largely non-standardized, although the development of a standardized testing scheme for pesticides was begun (Boutin et al. 1993) but is not yet in place. US EPA has published a method for use in soils (USEPA 1996a) and there is a standardized method for testing toxicity of contaminated soils to plants (Environment Canada 2007). A testing protocol for soil microorganisms is used in Europe (Lynch 1995, EPPO 1994).

1.2.1 Routes of exposure

Routes of exposure in terrestrial plants include air, soil, and water. Aerial exposure includes volatiles that enter through stomata as well as particulates and liquids that enter through the leaf surface. Caution must be exercised when using laboratory tests to assess possible environmental impacts of volatile substances in plants. Plants under water stress in the field will close their stomata, thus reducing exposure. Under laboratory test conditions, they will likely have plentifully water and their stomata will be wide open, thus allowing greater exposures to the substance. For the soil organism test (EPPO 1994), the chemical is added to a single soil, usually a sandy soil and the test is conducted under field conditions. For pesticides applied to soil, the rate of application is twice the greatest recommended rate of use. A reference substance is used and the soil is amended with an organic substrate such as alfalfa meal to ensure microbiological activity.

1.2.2 Endpoints

Endpoints for plant test include growth of shoots, roots and the entire plant as well as reproductive potential as in seed production. For the soil microbiological activity test, nitrogen transformation, carbon mineralization (Gerber et al. 1991, Malkomes 1986) and legume-rhizobium symbiosis are measured (Gerber et al. 1991, Horemans et al. 1987).

1.2.3 Statistical treatments

More often than not, scoring systems are used or the effect measure is compared to that in control untreated plants. Endpoints are usually not quantal but may be subjected to any suitable transform for the purposes of interpolation. Extrapolation beyond the data range is not recommended for non-quantal data. Means tests such as ANOVA are recommended for the soil microbiological activity assay.

1.2.4 Summary of assay methods

Table 2. Methods for assessing toxicological responses in terrestrial plants.

Test	Exposure route	Endpoint	Statistical treatment
Seedling emergence and growth (Environment Canada 2007). US EPA test guideline 850.4100, 850.4230	Chemically amended soils or contaminated soils diluted with control soils.	Germination and growth	Non-quantal, EC50 and other measures estimated by interpolation.

Test	Exposure route	Endpoint	Statistical treatment
Seedling germination or emergence (battery of species) US EPA test guideline 850.4100, 850.4230	Chemically amended soils or contaminated soils diluted with control soils or through solution in water	Number of seeds germinated to seedlings emerged	
Early seedling growth test (battery of species) (OECD 2006d)		Biomass measurements (e.g., root, shoot or whole-plant (wet or dry biomass), amount of chlorophyll, etc.	
Plant vigor (beyond seeding stage battery of species) US EPA guideline 850.4150 (OECD 2006c)		Growth or biomass	ANOVA Non-quantal, EC50 and other measures estimated by interpolation.
Partial life-cycle test using *Arabidopsis* (Ratsch et al. 1986)		Length, weight and morphological features.	
Wisconsin fast plant assay (*Brassica napus*)		Plants will complete their life cycle in 12 weeks allowing yield of seeds to be used in a relatively short life cycle bioassay. Length, weight, morphological features, seed production, seed viability etc.	
Root elongation (battery of species)	Extracted soil solution or nutrient solution to which a test substance has been added	Root growth and/or biomass	
Phytotoxicity of air pollutants	Specialized tests for a particular route of exposure	Many endpoints including biomarker enzymes.	Percent of control response, scores.

1.3 TERRESTRIAL SYSTEMS, BENEFICIAL INSECTS, INVERTEBRATES, AND SOIL AND WASTEWATER MICROORGANISMS

The only bioassay on a terrestrial invertebrate that is required for regulatory risk assessment in the US and Canada is the bioassay of the honey bee and its sensitivity to pesticides (Urban and Cook 1986, EPPO 1992, OECD 1998a). A wide range of insects are routinely tested for sensitivity to pesticides in regard to integrated pest management (IPM) and resistance monitoring programs (Barrett et al. 1995). A protocol for earthworm acute toxicity has been developed (OECD 1984) and a test for sublethal effects is under development (Lynch 1995).

1.3.1 Routes of exposure

Various routes of exposure include oral, dermal and respiratory. The dermal route is often exploited in the use of treated surfaces.

1.3.2 Endpoints

Death is relatively easily assessed in insects but reproductive endpoints may also be measured.

1.3.3 Statistical treatments

As the responses are usually quantal, probit analysis can be used for statistical analysis.

1.3.4 Summary of assay methods

Table 3. Methods for assessing toxicological responses in terrestrial invertebrates.

Test	Exposure route	Endpoint	Statistical treatment
Earthworms (*Eisenia andrei, Eisenia fetida*, or *Lumbricus terrestris, Enchytraeus albidus*) US EPA guideline 850.3100 (Environment Canada 2004).	Chemically amended soils or contaminated soils diluted with control soils.	Avoidance, mortality and growth.	Probit analysis Non-quantal procedures
Microorganisms (bacteria and fungi) US EPA guideline 850.3200, 850.3300. (OECD 2007a).	Soils amended with test substance or contaminated soils diluted with control soils. Modified Activated Sludge, Respiration Inhibition Test	Nitrification (aerobic) (EPPO 1994), denitrification (anaerobic), heterotrophic nitrification, mineralization of glutamic acid (EPPO 1994)	Non-quantal, EC50 and other measures estimated by interpolation, ANOVA
Honey bee *Apis mellifera* US EPA guidelines 850.3020, 850.3030, 850.3040, (OECD 1998b, a, 2013)	Topical application of substance to the dorsal thorax of the bee, either through a spray or as droplets directly applied to the exocuticle. Oral exposure in sucrose solution. Other tests are for toxicity of residues on foliage, subchronic feeding study and field testing for pollinators.	Acute: Death Failure to fly.	Probit analysis Non-quantal procedures
Parasitic wasps *Aphidius rophalosiphi* *Encarsia formosa*	Topical application of substance to the dorsal thorax.	Acute: Death Chronic: Percent parasitism	Probit anaysis Non-quantal procedures
Mites *Phytoseiulus persimilis* *Hypoaspis (Geolaelaps) aculeifer (OECD 2008b)*	Contact with treated paper substrate or contaminated soil	Acute: Death Chronic: Production of eggs and number of juveniles	Probit analysis Non-quantal procedures
Beetles *Aleochara bilineata* (rove beetle) *Bembidion lampros* (carabid beetle)	Contact or Whole soils amended with test substance	Acute: Death Chronic: Egg production	Probit analysis Non-quantal procedures
Dung flies(*Scathophaga stercoraria,* Musca autumnalis)(OECD 2008c)	Contaminated dung from cattle treated with pharmaceuticals and parasiticides	Emergence (number, time to, sex ratio) morphological change	Probit analysis Non-quantal procedures
Colembola (springtails)(OECD 2009a) *Folsomia candida*	Through contaminated soils, either as found or specifically prepared. May be diluted with control soils to obtain a dose-response. Artificial media may also be used.	Acute: Death, or avoidance. Chronic: Growth/biomass, and reproduction Chronic: Adult survival, fecundity, otal number of juveniles	Probit analysis or non-quantal responses such as percent of control. Non-quantal responses such as percent of control.
Nematode *Plectus acuminatus* *Steinemema spp*		Acute: Percent mortality Chronic: total biomass production.	Non-quantal responses such as percent of control.
Isopod *Porcellio scaber*		Chronic: C/N mineralization, survival, growth of individuals	ANOVA

1.4 TERRESTRIAL SYSTEMS, BIRDS AND MAMMALS

At present there are several guidelines available for testing the acute oral toxicity to birds. Some of the guidelines are for the LD50 dose (USEPA 1996c) whereas others (in OECD 2002) favor determination of only lethal threshold and no-observed-effect doses, with a view to reducing the number of animals

needed per test. While testing in accordance with any of these guidelines is acceptable, testing in accordance with the proposed OECD guideline is preferred. Bird species other than, or in addition to, Japanese quail can be used in the test. There are EPA and OECD guidelines for avian dietary toxicity and avian reproduction tests available (USEPA 1996b, c, OECD 2003).

1.4.1 Routes of exposure

Exposure is largely through the diet or by direct gavage where the material is dissolved in a carrier or placed in a gelatin capsule and directly inserted stomach. Exposure through preening in birds has been considered but is not routinely applied.

1.4.2 Endpoints

Death and symptoms, reproduction (number of eggs laid, cracked eggs, viable eggs, number of live embryos, egg hatch, survival of young, growth of young, etc.) are considered.

1.4.3 Statistical treatments

As the responses are usually quantal, probit analysis can be used for statistical analysis. Non quantal analysis may be applied to some endpoints.

1.4.4 Summary of assay methods

Table 4. Methods for assessing toxicological responses in birds.

Test	Exposure route	Endpoint	Statistical treatment
Acute oral toxicity. US EPA guideline 850.2100 (OECD 2010a)..	Species used in these tests include bobwhite quail, *Colinus virginianus*; coturnix quail, *Coturnix coturnix*; Japanese quail, *Coturnix coturnix japonica*; leghorn cockerel, *Gallus gallus*; mallard duck, *Anas platyrhynchos*; and ring-necked pheasant, *Phasianus colchicus*. Birds, healthy and acclimatized for at least seven d are treated with at least three doses to at least three animals of each sex. If a dose of 2,000 mg/kg does not cause death, further testing is not required. The material is administered by gavage in a carrier or in a gelatin capsule. The birds are observed for at least 14 d after exposure. In the dietary toxicity test, similar procedures are used but the birds are fed a diet amended with the stressor (US EPA 712-C-12-024. Exposures are for 7-14 days.	Mortality is the main objective with symptoms a secondary objective. Gross pathology may be assessed in birds at the end of the study.	Probit analysis
Avian dietary toxicity test. US EPA guideline 850.2200	Species used in these tests include bobwhite quail, *(C. virginianus)*, mallard *(A. platyrhynchos)* , pigeon *(Columba livia);* Japanese quail *(C. c. japonica);* ring-necked pheasant *(Phasianus colchicus);* and red-legged partridge *(Alectoris rufa)*. Birds are fed with amended diet to 5 d and observed for 3 additional days	Mortality is the main objective with symptoms and body weight as secondary objectives.	
Avian repro-duction bioassay. US EPA guideline 850.2300	Species normally include bobwhite quail, *Colinus virginianus*; Japanese quail, *Coturnix coturnix japonica*; and mallard duck, *Anas platyrhynchos*. Birds are fed food amended with the pesticide for a period of 18 or more weeks.	Number of eggs laid, cracked eggs, viable eggs, number of live embryos, egg hatch, survival of young, growth of young	ANOVA and similar hypothesis techniques to determine LOAEC and NOAEC

Test	Exposure route	Endpoint	Statistical treatment
Wild mammal acute toxicity US EPA guideline 850.2400. Also, Field testing for terrestrial wildlife US EPA guideline 850.2500	Testing is on mammals representative of those found in the area likely to be affected.	Mortality as LD50 or LC50 (dietary) with 95% CI. Various endpoints used for field testing	Probit analysis

1.5 AQUATIC SYSTEMS, ALGAE AND MACROPHYTES

Tests on aquatic algae and aquatic macrophytes are commonly required for the registration of pesticides, particularly herbicides. Several reviews have been published on general methods and interpretation of results (Parrish 1984, Lewis 1990) and OECD has a standard method (OECD 2011). Suter et al. have questioned the use of tests where nutrients are not limited; nutrients are usually limited in the environment (Suter et al. 2007). Grazing pressure by herbivores in the environment also needs to be taken into consideration. The use of *Lemna spp.* as a representative aquatic macrophyte has been criticized as it is not rooted and does not produce seeds. It is, however, relatively easy to grow.

1.5.1 Routes of exposure

Through the aquatic matrix.

1.5.2 Endpoints

For algae, number of cells, chlorophyll content, and carbon assimilation (photosynthesis) has been used. For macrophytes, number of fronds, internodal growth, chlorophyll content, and weight has been used.

1.5.3 Statistical treatments

Usually, percent of control response.

1.5.4 Summary of assay methods

Table 5. Methods for assessing toxicological responses in aquatic algae and macrophytes.

Test	Exposure route	Endpoint	Statistical treatment
Freshwater species of algae, US EPA guideline 850.4500, (OECD 2006a) *Pseudokirchneriella subcapitata* (formerly *Selanastrum capricornutum*) *Anabaena flos-aquae* *Microcystis aeriginosa* *Navicula peliculosa* **Saltwater species of algae**, *Chlorella spp* *Chlorococcum spp* *Dunaliella tertiolecta* *Isochrysis galbana* *Nitzchia closterium* *Skeletonema costatum* *Porphyridium cruentus*	Matrix, as a solution or suspension.	Weight, Number of cells, Chlorophyll content, Carbon assimilation These are assessed on the basis of final cell numbers by EPA (USEPA 1992c) and on the basis of maximum growth rate by OECD (OECD 2006a).	Non-quantal methods are used.
Macrophytes (duckweed, *Lemna spp.*) US EPA guideline 850.4400 and (Environment Canada 1999), (OECD 2006b).	Through the matrix or by spray application (for pesticides)	Number of fronds produced.	Non-quantal methods.

Test	Exposure route	Endpoint	Statistical treatment
Myriophyllum spp.	Through the water matrix or the sediment (ASTM 1998).	Internodal growth, frond length, weight.	Non-quantal methods.

1.6 AQUATIC SYSTEMS, INVERTEBRATES

Aquatic invertebrates are quite widely used because of the ease of production and because of their small size. These methods have been extensively described in the literature (Parrish 1984, Environment Canada 1990c, a, 1992a, OECD 2011).

1.6.1 Routes of exposure

These are usually through the matrix.

1.6.2 Endpoints

Mortality (usually assessed as morbidity or lack of movement after a stimulus)

1.6.3 Statistical treatments

Probit analysis and non-quantal methods are used.

1.6.4 Summary of assay methods

Table 6. Methods for assessing toxicological responses in aquatic invertebrates.

Test	Exposure route	Endpoint	Statistical treatment
Fresh-water species: *Daphnia magna* 48-96-h LC50 or EC50 acute assay. US EPA guideline 96–114. Lifecycle 21 day chronic assay for reproduction. US EPA guideline 850.1300 and (Environment Canada 1990a, OECD 2008a, 2004a). *Ceriodaphnia* 48-h acute assay (US EPA guideline 72-2) and 7-d assay for mortality and reproduction. US EPA guideline 850.1300 and (Environment Canada 1992a). *Hyelella azteca* acute assay (Environment Canada 1997b).	Through the matrix.	Mortality or morbidity, growth and reproduction.	Probit analysis and non-quantal approaches.
Salt-water species: *Americamysis bahia* and *Penaeus duorarum* are used for 96-h acute assays. US EPA guideline 850.1035 and 850.1045. Lifecycle 21 and 28-d assays for reproduction, mortality and growth. US EPA guideline 850.1350. The oyster embryo-larval test *Crassostrea spp.* is also used in a 48-h acute assay. US EPA guideline 850.1025. There is a two-generation test protocol for *Americamysis bahia* (ASTM 1997).	Through the matrix.	Mortality or morbidity, growth and reproduction.	Probit analysis and non-quantal approaches.
Benthic organisms *Chironomus spp* assays for 48 and 96-h lethality. US EPA guideline 850.1790 and (Environment Canada 1997a), (OECD 2004b, c). *Lumbriculus spp.* for 28 d (OECD 2007b).	Through the matrix.	Mortality or morbidity, growth and reproduction.	Probit analysis and non-quantal approaches.

1.7 AQUATIC SYSTEMS, VERTEBRATES

Bioassay methods for fish are well standardized (USEPA 2015, OECD 2011, ASTM 1991, Parrish 1984, Environment Canada 1992c, 1990b, d, e). These standardized tests include acute, life cycle tests and early life stage tests. Some assays have been reported with amphibians (mostly larval) and none with marine mammals. Both freshwater and saltwater species are used in these assays.

1.7.1 Routes of exposure

Through the matrix in most cases but through food in some.

1.7.2 Endpoints

Acute lethality, growth and development are measured.

1.7.3 Statistical treatments

These include probit analysis and non-quantal approaches.

1.7.4 Summary of assay methods

Table 7. Methods for assessing toxicological responses in aquatic vertebrates.

Test	Exposure route	Endpoint	Statistical treatment
Acute assays in freshwater species.			
Rainbow trout (*Onchorynchus mykiss*) (Environment Canada 1990b).	Through the matrix for 48-h to 96-h.	Survival and mortality	Probit analysis.
Brook trout (*Salvelinus fontinalis*)			
Channel catfish (*Ictalurus punctatus*)			
Fathead minnow (*Pimephales promelas*)			
Bluegill (*Lepomis macrochirus*), and others. US EPA guideline *850.1075.*			
Acute assays in saltwater species.			
Sheepshead minnow *(Cyprinodon variegatus*)			
Mummichog (*Fundulus heteroclitus*)			
Longnose killifish (*Fundulus similis*)			
Silverside (*Menidia spp.*)			
Threespine stickleback (*Gasterosteus aculeatus*), and others. US EPA guideline 850.1075 and (Environment Canada 1990d)			
Early life stage tests			
Fathead minnow *(Pimephales promelas*) (Environment Canada 1992c).	Exposure via the matrix for 30 to 90 days. Usually in a continuous flow apparatus	These range from effects on sperm motility to development of gonadal tissue in the adult. For a more comprehensive review see McKim (McKim 1984)	Mostly non-quantal.
Rainbow trout, Coho salmon, or Atlantic salmon) (Environment Canada 1992b, 1998).			
Bluegill (*Lepomis macrochirus*)			
Brook trout (*Salvelinus fontinalis*)			
Flagfish (*Jordanella floridae*)			
Sheepshead minnow (*Cyprinodon variegatus*). US EPA guideline 850.1400			
Short term tests			
Fish short term reproduction. US EPA guideline 890.1350.	Matrix	Production of vitellogenin.	Non-quantal
Fathead minnow (*Pimephales promelas*), Japanese medaka, or zebra fish (OECD 2010b).		Estrogenic and androgenic activity, and aromatase inhibition	Non-quantal
21-day fish assay 230 (OECD 2009b).			
Tadpole/Sediment Subchronic Toxicity Test. US EPA guideline 890.1800	Water and sediment, exposures for 30 d.	Mortality and growth (weight)	Probit analysis and non-quantal.

Test	Exposure route	Endpoint	Statistical treatment
Full life cycle tests			
Fathead minnow *(Pimephales promelas)* Bluegill (*Lepomis macrochirus*) Brook trout (*Salvelinus fontinalis*) Flagfish (*Jordanella floridae*) Sheepshead minnow (*Cyprinodon variegatus*). US EPA guideline 850.1500.	Exposure via the matrix for the entire life cycle. Usually in a continuous flow apparatus	Percentage hatching, percentage survival, length and wet weight and physical and behavioral characteristics through 30, 60, 160 d and termination, Time to egg production, Number of spawns, eggs per spawn, eggs per female, 30-d survival of F_1 fish. See review in (Petrocelli 1984).	Probit analysis and non-quantal
Amphibian metamorphosis			
African clawed frog (*Xenopus laevis).* US EPA guideline 890.1100, (OECD 2009c)	Exposure via the matrix for 21d from Stage 51 on the NF scale. Usually in a continuous flow apparatus	Developmental stage, snout-to-vent, hind limb length, and histopathology of the thyroid gland.	Non-quantal
Fish short-term reproduction assay.			
Fathead minnow *(Pimephales promelas)* US EPA guideline 890.1350, (OECD 2010b)	Exposure via the matrix for 21 d. Usually in a continuous flow apparatus	Egg production, vitellogenin and secondary sexual characteristics.	Non-quantal

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Environment Canada. 1992c. Biological Test Method: Test of Larval Growth and Survival Using Fathead Minnows. Ottawa, ON: Environment Canada. Reference Method. Report EPS 1/RM/22.

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OCSPP[1] Harmonized Test Guidelines - Master List

Last Updated March 2015

The OCSPP harmonized guidelines are organized in the following series:

Series No.	Series Name	Docket ID No.	Last Changed
810	Product Performance Test Guidelines	EPA-HQ-OPPT-2009-0150	Dec-2012
830	Product Properties Test Guidelines	EPA-HQ-OPPT-2009-0151	Nov-2008
835	Fate, Transport and Transformation Test Guidelines	EPA-HQ-OPPT-2009-0152	Nov-2008
840	Spray Drift Test Guidelines	EPA-HQ-OPPT-2009-0153	Mar-1998
850	Ecological Effects Test Guidelines	EPA-HQ-OPPT-2009-0154	Jan-2012
860	Residue Chemistry Test Guidelines	EPA-HQ-OPPT-2009-0155	Nov-2008
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875	Occupational and Residential Exposure Test Guidelines	EPA-HQ-OPPT-2009-0157	Feb-1996
880	Biochemicals Test Guidelines	EPA-HQ-OPPT-2009-0158	Feb-1996
885	Microbial Pesticide Test Guidelines	EPA-HQ-OPPT-2009-0159	Feb-1996
890	Endocrine Distruptor Screening Program Test Guidelines	EPA-HQ-OPPT-2009-0576	Aug-2009

FINAL Guidelines

The Final guidelines can be be accessed through http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm, as well as through www.Regulations.gov using the Docket ID Number provided in the table.

DRAFT Guidelines

Please note, those guidelines labeled as "Public Draft" are listed because they were issued in draft for public review and comment, but are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.

What does "[Reserved]" mean?

We use the phrase "[Reserved]" in the title column as a placeholder whenever the number has been assigned, but the FINAL Guideline has not yet been issued.

[1] Note - Guidelines issued before April 22, 2010, refer to "OPPTS" because the office name changed from "Office of Prevention, Pesticides and Toxic Substances" and "OPPTS" to "Office of Chemical Safety and Pollution Prevention" and "OCSPP." This name change does not otherwise affect the Guidelines.

:/OCSPP-TestGuidelines_MasterList-2013-02-20.xlsx

Series 810—Product Performance Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0150 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub Number	Date Issued
		OPPT	OPP	OECD		
Final 810 Test Guidelines						
Group A—General.						
810.1000	Overview, Definitions, and General Considerations	none	90–1, 90–3, 90–30	none	712-C-98–001	Mar-98
Group B—Antimicrobial Efficacy Test Guidelines.						
810.2000	General Considerations for Public Health Uses of Antimicrobial Agents	none	91-1	none	712-C-07-005	Mar-12
810.2100	Sterilants--Efficacy Data Recommendations	none	91-2	none	712-C-07-056	Mar-12
810.2200	Disinfectants for Use on Hard Surfaces--Efficacy Data Recommendations	none	91-2, 91-30	none	712-C-07-074	Mar-12
810.2300	Sanitizers for Use on Hard Surfaces--Efficacy Data Recommendations	none	91-2, 91-30	none	712-C-07-091	Mar-12
810.2400	Disinfectants and Sanitizers for Use on Fabrics and Textiles	none	91-4, 91-30	none	730-C-11-003	Jun-12
810.2500	Air Sanitizers	none	91-5, 91-30	none	730-C-11-003	Jun-12
810.2600	Disinfectants for Use in Water	none	91-8, 91-30	none	730-C-11-003	Jun-12
810.2700	Products with Prion-Related Claims	none	none	none	712-C-13-001	Dec-12
Group C—Invertebrate Control Agent Product Performance Test Guidelines.						
810.3000	General Considerations for Efficacy of Invertebrate Control Agents	none	95–1	none	712-C-98–409	Mar-98
810.3100	Soil Treatments for Imported Fire Ants	none	95–3	none	712-C-98–410	Mar-98
810.3200	Livestock, Poultry, Fur- and Wool-bearing Animal Treatments	none	95–8	none	712-C-98–414	Mar-98
810.3300	Treatments to Control Pests of Humans and Pets	none	95-9, 95-30,	none	712-C-98-411	Mar-98
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments	none	95-10	none	712-C-98-419	Mar-98
810.3500	Premises Treatments	none	95-11, 95-30	none	712-C-98-413	Mar-98
810.3600	Structural Treatments	none	95-12	none	712-C-98-424	Mar-98

Series 810—Product Performance Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0150 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub Number	Date Issued
		OPPT	OPP	OECD		
810.3700	Insect Repellents for Human Skin and Outdoor Premises	none	95-9, 95-10	none	712-C-10-001	Jul-10
810.3800	Methods for Efficacy Testing of Termite Baits	none		none	712-C-04-371	Aug-04
DRAFT 810 Test Guidelines						
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	None.					

[1] Note - Guidelines issued before April 22, 2010, refer to "OPPTS" because the office name changed from "Office of Prevention, Pesticides and Toxic Substances" and "OPPTS" to "Office of Chemical Safety and Pollution Prevention" and "OCSPP." This name change does not otherwise affect the Guidelines.

Series 830—Product Properties Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0151 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 830 Test Guidelines						
830.1000	Background for Product Properties Test Guidelines	none	60-1, 60-2, 60-3	none	712-C-96–310	Mar-98
Group A—Product Identity, Composition, and Analysis Test Guidelines.						
830.1550	Product Identity and Composition	none	158.155	none	712-C-96–006	Aug-96
830.1600	Description of Materials Used to Produce the Product	none	158.160	none	712-C-96–007	Aug-96
830.1620	Description of Production Process	none	158.162	104	712-C-96–008	Aug-96
830.1650	Description of Formulation Process	none	158.165	104	712-C-96–009	Aug-96
830.1670	Discussion of Formation of Impurities	none	158.167	104	712-C-96–010	Aug-96
830.1700	Preliminary Analysis	none	158.170	104	712-C-96–011	Aug-96
830.1750	Certified Limits	none	158.175	104	712-C-96–012	Aug-96
830.1800	Enforcement Analytical Method	none	158.180	104	712-C-96–013	Aug-96
830.1900	Submittal of Samples	none	64-1	104	712-F-08-002	Nov-08
Group B—Physical/Chemical Properties Test Guidelines.						
830.6302	Color	none	63-2	none	712-C-96–019	Aug-96
830.6303	Physical State	none	63-3	none	712-C-96–020	Aug-96
830.6304	Odor	none	63-4	none	712-C-96–021	Aug-96
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	none	63-13	none	712-C-96–022	Aug-96
830.6314	Oxidation/Reduction: Chemical Incompatabiity	none	63-14	none	712-C-96–023	Aug-96
830.6315	Flammability	none	63-15	none	712-C-96–024	Aug-96
830.6316	Explodability	none	63-16	none	712-C-96–025	Aug-96
830.6317	Storage Stability	none	63-17	113	712-C-96–026	Jun-02
830.6319	Miscibility	none	63-19	none	712-C-96–027	Aug-96
830.6320	Corrosion Characteristics	none	63-20	none	712-C-96–028	Aug-96
830.6321	Dielectric Breakdown Voltage	none	63-21	none	712-C-96–029	Aug-96
830.7000	pH	796.1450	63-12	none	712-C-96–030	Aug-96
830.7050	UV/Visible Absorption	796.1050	none	101	712-C-96–031	Aug-96
830.7100	Viscosity	none	63-18	114	712-C-96–032	Aug-96
830.7200	Melting Point/Melting Range	796.1300	63-5	102	712-C-96–033	Mar-98
830.7220	Boiling Point/Boiling Range	796.1220	63-6	103	712-C-96–034	Aug-96

Series 830—Product Properties Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0151 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
830.7300	Density/Relative Density/Bulk Density	796.1150	63-7	109	712-C-96–035	Jun-02
830.7370	Dissociation Constants in Water	796.1370	63-10	112	712-C-96–036	Aug-96
830.7520	Particle Size, Fiber Length, and Diameter Distribution	796.1520	none	110	712-C-96–037	Aug-96
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	796.1550	63-11	107	712-C-96–038	Aug-96
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method	796.1720	63-11	none	712-C-96–039	Aug-96
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	796.1570	63-11	117	712-C-96–040	Aug-96
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	796.1840	63-8	105	712-C-96–041	Mar-98
830.7860	Water Solubility, Generator Column Method	796.1860	63-8	none	712-C-96–042	Mar-98
830.7950	Vapor Pressure	796.1950	63-9	104	712-C-96–043	Aug-96
DRAFT 830 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
	None.					

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Series 835—Fate, Transport and Transformation Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0152 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 835 Test Guidelines						
835.0001	Principles and Strategies Related to Biodegradation Testing of Organic Chemicals under the Toxic Substances Control Act (TSCA)	none	none	none	712-C-08-008	Nov-08
Group A—Laboratory Transport Test Guidelines.						
835.1110	Activated Sludge Sorption Isotherm	none	none	none	712-C-98–298	Jan-98
835.1210	Soil Thin Layer Chromatography	796.2700	none	none	712-C-98–047	Jan-98
835.1220	Sediment and Soil Adsorption/Desorption Isotherm	796.2750	none	106	712-C-98–048	Jan-98
835.1230	Adsorption/Desorption (Batch Equilibrium)	none	163-1	106	712-C-08-009	Nov-08
835.1240	Leaching Studies	none	163-1	312	712-C-08-010	Nov-08
835.1410	Laboratory Volatility	none	163-2	none	712-C-08-011	Nov-08
Group B—Laboratory Abiotic Transformation Test Guidelines.						
835.2110	Hydrolysis as a Function of pH [SUPERSEDED BY 835.2120]	796.3500	none	111	712-C-98–057	Jan-98
835.2120	Hydrolysis [SUPERSEDES 835.2110]	none	161-1	111	712-C-08-012	Nov-08
835.2130	Hydrolysis as a Function of pH and Temperature	796.3510	none	none	712-C-98–059	Jan-98
835.2210	Direct Photolysis Rate in Water by Sunlight	796.3700	none	none	712-C-98–060	Jan-98
835.2240	Photodegradation in Water	none	161-2	none	712-C-08-013	Nov-08
835.2310	Maximum Direct Photolysis Rate in Air from UV/Visible Spectroscopy	796.3800	none	none	712-C-98–066	Jan-98
835.2370	Photodegradation in Air	none	161-4	none	712-C-08-014	Nov-08
835.2410	Photodegradation in Soil	none	161-3	none	712-C-08-015	Nov-08
Group C—Laboratory Biological Transformation Test Guidelines.						
835.3100	Aerobic Aquatic Biodegradation	796.3100	none	none	712-C-98–075	Jan-98
835.3110	Ready Biodegradability	796.3180, 796.3200, 796.3220, 796.3240, 796.3260.	none	301	712-C-98–076	Jan-98
835.3120	Sealed-Vessel Carbon Dioxide Production Test [SUPERSEDED BY 3140]	none	none	none	712-C-98–311	Jan-98

Series 835—Fate, Transport and Transformation Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0152 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
835.3140	Ready Biodegradability – CO2 in Sealed Vessels (Headspace Test) [SUPERSEDES 3120]	none	none	310	712-C-08-001	Nov-08
835.3160	Biodegradability in Sea Water	none	none	306	712-C-98-351	Jan-98
835.3170	Shake Flask Die-Away Test	none	none	none	712-C-98–297	Jan-98
835.3180	Sediment/Water Microcosm Biogradation Test	none	none	none	712-C-98–083	Jan-98
835.3190	Aerobic Mineralization in Surface Water – Simulation Biodegradation Test	none	none	309	712-C-08-002	Oct-08
835.3200	Zahn-Wellens/EMPA Test	796.3360	none	302B	712-C-98–084	Jan-98
835.3210	Modified SCAS Test	796.3340	none	302A	712-C-98–085	Jan-98
835.3215	Inherent Biodegradability - Concawe Test	none	none	none	712-C-08-003	Oct-08
835.3220	Porous Pot Test	none	none	none	712-C-98–301	Jan-98
835.3240	Simulation Test—Aerobic Sewage Treatment: A. Activated Sludge Units	none	none	303	712-C-08-004	Oct-08
835.3260	Simulation Test—Aerobic Sewage Treatment: B. Biofilms	none	none	303	712-C-08-005	Oct-08
835.3280	Simulation Tests to Assess the Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater	none	none	314	712-C-08-006	Oct-08
835.3300	Soil Biodegradation	796.3400	none	304A	712-C-98–088	Jan-98
835.3400	Anaerobic Biodegradability of Organic Chemicals	796.3140	none	none	712-C-98–090	Jan-98
835.3420	Anaerobic Biodegradability of Organic Compounds in Digested Sludge: By Measurement of Gas Production	none	none	311	712-C-08-007	Oct-08
Group D—Transformation in Water and Soil Test Guidelines.						
835.4100	Aerobic Soil Metabolism	none	162-1	307	712-C-08-016	Oct-08
835.4200	Anaerobic Soil Metabolism	none	162-2	307	712-C-08-017	Oct-08
835.4300	Aerobic Aquatic Metabolism	none	162-3	308	712-C-08-018	Oct-08
835.4400	Anaerobic Aquatic Metabolism	none	162-4	308	712-C-08-019	Oct-08
Group E—Transformation Chemical-Specific Test Guidelines.						
835.5045	Modified SCAS Test for Insoluble and Volatile Chemicals	795.4500	none	none	712-C-98–097	Jan-98
835.5154	Anaerobic Biodegradation in the Subsurface	795.5400	none	none	712-C-98–098	Jan-98
835.5270	Indirect Photolysis Screening Test: Sunlight Photolysis in Waters Containing Dissolved Humic Substances	795.7000	none	none	712-C-98–099	Jan-98

Series 835—Fate, Transport and Transformation Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0152 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Group F—Field Dissipation Test Guidelines.						
835.6100	Terrestrial Field Dissipation	none	164-1	none	712-C-08-20	Oct-08
835.6200	Aquatic (Sediment) Field Dissipation	none	164-2	none	712-C-08-21	Oct-08
835.6300	Forestry Dissipation	none	164-3	none	712-C-08-22	Oct-08
835.6400	Combination and Tank Mixes Field Dissipation	none	164-4	none	712-C-08-23	Oct-08
Group G—Ground Water Monitoring Test Guidelines.						
835.7100	Guidance for Prospective Ground-Water Monitoring Studies	none	166-1	none	712-B-10-001	Aug-08
Group H—Volatility from Soil Test Guidelines.						
835-8100	Field Volatility	none	163-3	none	712-C-08-024	Nov-08
DRAFT 835 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
	None.					

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Series 840—Spray Drift Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0153 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 840 Test Guidelines						
840.1000	Background for Pesticide Aerial Drift Evaluation	none	201-1, 201-4	none	712-C-98-319	Mar-98
840.1100	Spray Droplet Size Spectrum	none	201-1	none	712-C-98-055	Mar-98
840.1200	Spray Drift Field Deposition	none	201-1	none	712-C-98-112	Mar-98
DRAFT 840 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
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Series 850—Ecological Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0154 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 850 Test Guidelines						
850.1000	[Reserved]					
Group A—Aquatic and Sediment-Dwelling Fauna, Aquatic Microcosm and Field Testing Test Guidelines.						
850.1010	[Reserved]					
850.1020	[Reserved]					
850.1025	[Reserved]					
850.1035	[Reserved]					
850.1045	[Reserved]					
850.1055	[Reserved]					
850.1075	[Reserved]					
850.1085	[Reserved]					
850.1300	[Reserved]					
850.1350	[Reserved]					
850.1400	[Reserved]					
850.1500	[Reserved]					
850.1710	[Reserved]					
850.1730	[Reserved]					
850.1735	[Reserved]					
850.1740	[Reserved]					
850.1790	[Reserved]					
850.1800	[Reserved]					
850.1850	[Reserved]					
850.1900	[Reserved]					
850.1925	[Reserved]					
850.1950	[Reserved]					
Group B—Terrestrial Wildlife Test Guidelines.						
850.2000	Background and Special Considerations- Tests with Terrestrial Wildlife	none	none	none	712-C-12-026	Jan-12
850.2100	Avian Acute Oral Toxicity Test	797.2175	71-1	none	712-C-12-025	Jan-12
850.2200	Avian Dietary Toxicity Test	797.2050	71-2	205	712-C-12-024	Jan-12
850.2300	Avian Reproduction Test	797.2130 797.2150	71-4	206	712-C-12-023	Jan-12

Series 850—Ecological Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0154 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
850.2400	Wild Mammal Toxicity Testing	none	71-3	none	712-C-12-022	Jan-12
850.2500	Field Testing for Terrestrial Wildlife	none	71-5	none	712-C-12-021	Jan-12
Group C—Terrestrial Beneficial Insects, Invertebrates, and Soil and Wastewater Microorganisms Test Guidelines.						
850.3000	Background and Special Considerations- Tests with Terrestrial Beneficial Insects, Invertebrates and Microorganisms	none	none	none	712-C-12-020	Jan-12
850.3020	Honey Bee Acute Contact Toxicity Test	none	141-1	none	712-C-12-019	Jan-12
850.3030	Honey Bee Toxicity of Residues on Foliage	none	141-2	none	712-C-12-018	Jan-12
850.3040	Field Testing for Pollinators	none	141-5	none	712-C-12-017	Jan-12
850.3100	Earthworm Subchronic Toxicity Test	795.1500	none	none	712-C-12-016	Jan-12
850.3200	Soil Microbial Community Toxicity Test	797.3700	none	none	712-C-12-015	Jan-12
850.3300	Modified Acticvated Sludge, Respiration Inhibition Test	795.1700	none	none	712-C-12-014	Jan-12
Group D—Terrestrial and Aquatic Plants, Cyanobacteria, and Terrestrial Soil Core Microcosm Test Guidelines.						
850.4000	Background and Special Considerations- Tests with Terrestrial and Aquatic Plants, Cyanobacteria, and Terrestrial Soil-Core Microcosms	none	120-1	none	712-C-12-013	Jan-12
850.4100	Seedling Emergence and Seedling Growth	none	122-1	none	712-C-12-012	Jan-12
850.4150	Vegetative Vigor	none	122-1	none	712-C-12-011	Jan-12
850.4230	Early Seedling Growth Toxicity Test	797.2800	123-1	none	712-C-12-010	Jan-12
850.4300	Terrestrial Plants Field Study	none	124-1	none	712-C-12-009	Jan-12
850.4400	Aquatic Plant Toxicity Test Using *Lemna* spp.	797.1160	122-2, 123-2	none	712-C-12-008	Jan-12
850.4450	Aquatic Plants Field Study	none	124-2	none	712-C-12-007	Jan-12
850.4500	Algal Toxicity	797.1050	122-2, 123-2	201	712-C-12-006	Jan-12
850.4550	Cyanobacteria *(Anabaena flos-aquae)* Toxicity	797.1050	122-2, 123-2	201	712-C-12-005	Jan-12
850.4600	Rhizobium-Legume Toxicity	797.2900	none	none	712-C-12-004	Jan-12
850.4800	Plant Uptake and Translocation Test	797.2850	none	none	712-C-12-002	Jan-12
850.4900	Terrestrial Soil-Core Microcosm Test	797.3775	none	none	712-C-12-003	Jan-12
Group E—Reserved.						

Series 850—Ecological Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0154 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Group F—Field Test Data Reporting Guidelines.						
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation (Renumbered OPPTS 850.7100)	none	none	none	712-C-12-001	Jan-12

DRAFT 850 Test Guidelines

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850.1000	*Special Consideration for Conducting Aquatic Laboratory Studies*	*none*	*none*	*none*	*712-C-96-113*	*Apr-96*
Group A—Aquatic Fauna Test Guidelines.						
850.1010	*Aquatic Invetebrate Acute Toxicity, Test, Freshhwater Daphnids*	*797.1300*	*72–2*	*none*	*712-C-96–114*	*Apr-96*
850.1020	*Gammarid Acute Toxicity Test*	*795.120*	*none*	*none*	*712-C-96–130*	*Apr-96*
850.1025	*Oyster Acute Toxicity Test (Shell Deposition)*	*797.1800*	*72–3*	*none*	*712-C-96–115*	*Apr-96*
850.1035	*Mysid Acute Toxicity Test*	*797.1930*	*72–3*	*none*	*712-C-96-136*	*Apr-96*
850.1045	*Penaeid Acute Toxicity Test*	*797.1970*	*72-3*	*none*	*712-C-96-137*	*Apr-96*
850.1055	*Bivalve Acute Toxicity Test (Embryo Larval)*	*none*	*72-3*	*none*	*712-C-96-100*	*Apr-96*
850.1075	*Fish Acute Toxicity Test, Freshwater and Marine*	*797.1400*	*72–1, 72-3*	*203*	*712-C-96-118*	*Apr-96*
850.1085	*Fish Acute Toxicity Mitigated by Humic Acid*	*797.1460*	*none*	*none*	*712-C-96-117*	*Apr-96*
850.1300	*Daphnid Chronic Toxicity Test*	*797.1330*	*72–4*	*202*	*712-C-96-120*	*Apr-96*
850.1350	*Mysid Chronic Toxicity Test*	*797.1950*	*72–4*	*none*	*712-C-96-166*	*Apr-96*
		Document incorrectly says publication Number ends in "-120".				
850.1400	*Fish Early-Life Stage Toxicity Test*	*797.1000*	*72–4*	*210*	*712-C-96-121*	*Apr-96*
850.1500	*Fish Life Cycle Toxicity*	*none*	*72-5*	*none*	*712-C-96-122*	*Apr-96*
850.1710	*Oyster BCF*	*797.1830*	*72–6*	*none*	*712-C-96-127*	*Apr-96*
850.1730	*Fish BCF*	*797.1520*	*72–6, 165-4*	*305*	*712-C-96-129*	*Apr-96*
850.1735	*Whole Sediment Acute Toxicity Invertebrates, Freshwater*	*none*	*none*	*none*	*712-C-96-354*	*Apr-96*
850.1740	*Whole Sediment Acute Toxicity Invertebrates, Marine*	*none*	*none*	*none*	*712-C-96-355*	*Apr-96*

Series 850—Ecological Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0154 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
850.1790	*Chironomid Sediment Toxicity Test*	*795.135*	*none*	*none*	*712-C-96-313*	*Apr-96*
850.1800	*Tadpole/Sediment Subchronic Toxicity Test*	*797.1995*	*none*	*none*	*712-C-96-132*	*Apr-96*
850.1850	*Aquatic Food Chain Transfer*	*none*	*72-6*	*none*	*712-C-96-133*	*Apr-96*
850.1900	*Generic Freshwater Microcosm Test, Laboratory*	*797.3050, 797.3100*	*none*	*none*	*712-C-96-134*	*Apr-96*
850.1925	*Site-Specific Aquatic Microcosm Test, Laboratory*	*797.3100*	*none*	*none*	*712-C-96-173*	*Apr-96*
850.1950	*Field Testing for Aquatic Organisms*	*none*	*72–7,*	*none*	*712-C-96-135*	*Apr-96*
850.6100	*Data Reporting or Environmental Chemistry Method*	*none*	*none*	*none*	*712-C-96-348*	*Apr-96*

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Series 860—Residue Chemistry Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0155 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 860 Test Guidelines						
860.1000	Background	none	170-1	none	712-C-96-169	Aug-96
860.1000 Supplement	Guidance on Constructing Maximum Reasonably Balanced Diets (MRBD)				n/a	Jun-08
860.1100	Chemical Identity	none	171-2	none	712-C-96-170	Aug-96
860.1200	Directions for Use	none	171-3	none	712-C-96-171	Aug-96
860.1300	Nature of the Residue—Plants, Livestock	none	171–4a,b	none	712-C-96-172	Aug-96
860.1340	Residue Analytical Method	none	171–4c,d	none	712-C-96-174	Aug-96
860.1360	Multiresidue method	none	171–4m	none	712-C-96-176	Aug-96
860.1380	Storage Stability Data	none	171–4e	none	712-C-96-177	Aug-96
	Document incorrectly says publication number ends in "-95-177".					
860.1400	Water, Fish, and Irrigated Crops	none	171–4f,g,h, 165-5	none	712-C-96-178	Aug-96
860.1460	Food Handling	none	171–4i	none	712-C-96-181	Aug-96
860.1480	Meat/Milk/Poultry/Eggs	none	171-4j	none	712-C-96-182	Aug-96
860.1500	Crop Field Trials	none	171-4k	none	712-C-96-183	Aug-96
860.1520	Processed Food/Feed	none	171-4l	none	712-C-96-184	Aug-96
860.1550	Proposed Tolerances	none	171-6	none	712-C-96-186	Aug-96
860.1560	Reasonable Grounds in Support of the Petition	none	171-7	none	712-C-96-187	Aug-96
860.1650	Submittal of Analytical Reference Standards	none	171-13	none	712-F-08-001	Nov-08
860.1850	Confined Accumulation in Rotational Crops	none	165-1	none	712-C-96-188	Aug-96
860.1900	Field Accumulation in Rotational Crops	none	165-2	none	712-C-96-189	Aug-96
DRAFT 860 Test Guidelines						
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	None.					

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Series 860—Residue Chemistry Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0155 @ http://www.regulations.gov)

As of March 2015

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Series 870—Health Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0156 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
	Final 870 Test Guidelines					
Group A—Acute Toxicity Test Guidelines.						
870.1000	Acute Toxicity Testing-Background	none	none	none	712-C-02-189	Dec-02
870.1100	Acute Oral Toxicity (AOT)	798.1175	81-1	401, 420, 423, 425	712-C-02-190	Dec-02
	- AOT Up-And-Down Procedure (Additional Guidance & Tools at http://www.epa.gov/oppfead1/harmonization/.)					
870.1200	Acute Dermal Toxicity	798.1100	81-2	402	712-C-98-192	Aug-98
870.1300	Acute Inhalation Toxicity	798.1150	81-3	403	712-C-98-193	Aug-98
870.1350	[Reserved]					
870.2400	Acute Eye Irritation	798.4500	81-4	405	712-C-98-195	Aug-98
870.2500	Acute Dermal Irritation	798.4470	81-5	404	712-C-98-196	Aug-98
870.2600	Skin Sensitization	798.4100	81-6	406	712-C-03-197	Mar-03
Group B—Subchronic Toxicity Test Guidelines.						
870.3050	Repeated Dose 28-day Oral Toxicity Study in Rodents	none	none	407	712-C-00-366	Jul-00
870.3100	90-Day Oral Toxicity in Rodents	798.2650	82-1	408	712-C-98-199	Aug-98
870.3150	90-Day Oral Toxicity in Nonrodents	none	82-1	409	712-C-98-200	Aug-98
870.3200	21/28-Day Dermal Toxicity	none	82-2	410	712-C-98-201	Aug-98
870.3250	90-Day Dermal Toxicity	798.2250	82-3	411	712-C-98-202	Aug-98
870.3465	90-Day Inhalation Toxicity	798.2450	82-4	413	712-C-98-204	Aug-98
870.3500	[Reserved]					
870.3550	Reproduction/Development Toxicity Screening Test	none	none	421	712-C-00-367	Jul-00
870.3600	[Reserved]					
870.3650	Combined Repeated Dose Toxicity with the Reproduction/Development Toxicity Screening Test	none	none	422	712-C-00-368	Jul-00
870.3700	Prenatal Developmental Toxicity Study	798.4900	83-3	414	712-C-98-207	Aug-98
870.3800	Reproduction and Fertility Effects	798.4700	83-4	416	712-C-98-208	Aug-98
Group C—Chronic Toxicity Test Guidelines.						
870.4100	Chronic Toxicity	798.3260	83-1	452	712-C-98-210	Aug-98
870.4200	Carcinogenicity	798.3300	83-2	451	712-C-98-211	Aug-98
870.4300	Combined Chronic Toxicity/Carcinogenicity	798.3320	83-5	453	712-C-98-212	Aug-98

Series 870—Health Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0156 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Group D—Genetic Toxicity Test Guidelines.						
870.5100	Bacterial Reverse Mutation Test	798.5100, 798.5265	84-2	471	712-C-98-247	Aug-98
870.5140	Gene Mutation in *Aspergillus nidulans*	798.5140	84-2	none	712-C-98-215	Aug-98
870.5195	Mouse Biochemical Specific Locus Test	798.5195	84-2	none	712-C-98-216	Aug-98
870.5200	Mouse Visible Specific Locus Test	798.5200	84-2	none	712-C-98-217	Aug-98
870.5250	Gene Mutation in *Neurospora crassa*	798.5250	84-2	none	712-C-98-218	Aug-98
870.5265	[Reserved]					
870.5275	Sex-linked Recessive Lethal Test in *Drosophila melanogaster*	798.5275	84-2	477	712-C-98-220	Aug-98
870.5300	In vitro Mammalian Cell Gene Mutation Test	798.5300	84-2	476	712-C-98-221	Aug-98
870.5375	In Vitro Mammalian Chromosome Aberration Test	798.5375	84-2	473	712-C-98-223	Aug-98
870.5380	Mammalian Spermatogonial Chromosomal Aberration Test	798.5380	84-2	483	712-C-98-224	Aug-98
870.5385	Mammalian Bone Marrow Chromosomal Aberration Test	798.5385	84-2	475	712-C-98-225	Aug-98
870.5395	Mammalian Erythrocyte Micronucleus Test	798.5395	84-2	474	712-C-98-226	Aug-98
870.5450	Rodent Dominant Lethal Assay	798.5450	84-2	478	712-C-98-227	Aug-98
870.5460	Rodent Heritable Translocation Assays	798.5460	84-2	485	712-C-98-228	Aug-98
870.5500	Bacterial DNA Damage or Repair Tests	798.5500	84-2	none	712-C-98-229	Aug-98
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	798.5550	84-2	482	712-C-98-230	Aug-98
870.5575	Mitotic Gene Conversion in *Saccharomyces cerevisiae*	798.5575	84-2	481	712-C-98-232	Aug-98
870.5900	In Vitro Sister Chromatid Exchange Assay	798.5900	84-2	479	712-C-98-234	Aug-98
870.5915	In Vitro Sister Chromatid Exchange Assay	798.5195	84-2	none	712-C-98-235	Aug-98
Group E—Neurotoxicity Test Guidelines.						
870.6100	Acute and 28-day Delayed Neurotoxicity of Organophosphorus Substances	798.6450, 798.6540, 798.6560	81-7, 82-5, 82-6	418, 419	712-C-98-237	Aug-98
870.6200	Neurotoxicity Screening Battery	798.6050, 798.6200, 798.6400	81-8, 82-7, 83-1	424	712-C-98-238	Aug-98
870.6300	Developmental Neurotoxicity Study	none	83-6	none	712-C-98-239	Aug-98
870.6500	Schedule-Controlled Operant Behavior	798.6500	85-5	none	712-C-98-240	Aug-98
870.6850	Peripheral Nerve Function	798.6850	85-6	none	712-C-98-241	Aug-98
870.6855	Neurophysiology: Sensory Evoked Potentials	798.6855	none	none	712-C-98-242	Aug-98

Series 870—Health Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0156 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Group F—Special Studies Test Guidelines.						
870.7200	Companion Animal Safety	none	none	none	712-C-98-349	Aug-98
870.7485	Metabolism and Pharmacokinetics	798.7485	85-1	417	712-C-95-244	Aug-98
870.7600	Dermal Penetration	none	85-3	none	712-C-98-350	Aug-98
870.7800	Immunotoxicity	none	85-7	none	712-C-98-351	Aug-98
Group G—Health Effects Chemical-Specific Test Guidelines.						
870.8223	[Reserved]					
870.8245	[Reserved]					
870.8300	[Reserved]					
870.8320	[Reserved]					
870.8340	[Reserved]					
870.8355	Combined Chronic Toxicity/Carcinogenicity Testing of Respirable Fibrous Particles	798.3320	none	none	712-C-01-352	Jul-01
870.8360	[Reserved]					
870.8380	[Reserved]					
870.8500	[Reserved]					
870.8600	[Reserved]					
870.8700	[Reserved]					
870.8800	[Reserved]					
DRAFT 870 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
870.1350	*Acute Inhalation Toxicity with Histopathology*	*none*	*none*	*none*	*712-C-96-291*	*Jun-96*
870.3500	*Preliminary Developmental Toxicity Screen*	*none*	*none*	*none*	*712-C-96-205*	*Jun-96*
870.3600	*Inhalation Developmental Toxicity Study*	*none*	*none*	*none*	*712-C-96-206*	*Jun-96*
870.5265	*The Salmonella typhimurium Reverse Mutation Assay*	*none*	*none*	*none*	*712-C-96-219*	*Jun-96*
870.8223	*Pharmacokinetic Test*	*none*	*none*	*none*	*712-C-96-250*	*Jun-96*
870.8245	*Dermal Pharmacokinetics of DGBE and DGBA*	*none*	*none*	*none*	*712-C-96-251*	*Jun-96*
870.8300	*Dermal Absorption for Compounds that are Volatile and Metabolized to Carbon Dioxide*	*none*	*none*	*none*	*712-C-96-252*	*Jun-96*
870.8320	*Oral/Dermal Pharmacokinetics*	*none*	*none*	*none*	*712-C-96-253*	*Jun-96*

Series 870—Health Effects Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0156 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
870.8340	*Oral and Inhalation Pharmacokinetic Test*	*none*	*none*	*none*	*712-C-96-254*	*Jun-96*
870.8360	*Pharmacokinetics of Isopropanal*	*none*	*none*	*none*	*712-C-96-255*	*Jun-96*
870.8380	*Inhalation and Dermal Pharmacokinetics of Commercial Hexane*	*none*	*none*	*none*	*712-C-96-256*	*Jun-96*
870.8500	*Toxicokinetic Test*	*none*	*none*	*none*	*712-C-96-257*	*Jun-96*
870.8600	*Developmental Neurotoxicity Screen*	*none*	*none*	*none*	*712-C-96-258*	*Jun-96*
870.8700	*Subchronic Oral Toxicity Test*	*none*	*none*	*none*	*712-C-96-259*	*Jun-96*
870.8800	*Morphologic Transformation of Cells in Culture*	*none*	*none*	*none*	*712-C-96-260*	*Jun-96*

What does "[Reserved]" mean?

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Series 875—Occupational and Residential Exposure Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0157 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 875 Test Guidelines						
Group A—Applicator Exposure Monitoring Test Guidelines.						
875.1000	Background for Application Exposure Monitoring Test Guidelines	none	230	none	712-C-96-261	Feb-96
875.1100	Dermal Exposure—Outdoor	none	231	none	712-C-96-262	Feb-96
875.1200	Dermal Exposure—Indoor	none	233	none	712-C-96-209	Feb-96
875.1300	Inhalation Exposure—Outdoor	none	232	none	712-C-96-263	Feb-96
875.1400	Inhalation Exposure—Indoor	none	234	none	712-C-96-213	Feb-96
875.1500	Biological Monitoring	none	235	none	712-C-96-264	Feb-96
875.1600	Application Exposure Monitoring Data Reporting	none	236	none	712-C-96-265	Feb-96
Group B—Postapplication Exposure Monitoring Test Guidelines.						
875.2000	Background for Postapplication Exposure Monitoring Test Guidelines	none	130, 131	none	712-C-96-266	Feb-96
875.2100	Foliar Dislodgeable Residue Dissipation	none	132-1	none	712-C-96-267	Feb-96
875.2200	Soil Residue Dissipation	none	132-1	none	712-C-96-243	Feb-96
875.2400	Dermal Exposure	none	133-3	none	712-C-96-269	Feb-96
875.2500	Inhalation Exposure	none	133-4	none	712-C-96-270	Feb-96
875.2600	Biological Monitoring	none	235	none	712-C-96-271	Feb-96
875.2800	Descriptions of Human Activity	none	133-1	none	712-C-96-283	Feb-96
875.2900	Data Reporting and Calculations	none	134	none	712-C-96-272	Feb-96
DRAFT 875 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
	None.					

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Series 880—Biochemicals Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0158 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 880 Test Guidelines						
Group A—Product Analysis Test Guidelines.						
880.1100	Product Identity and Composition	none	151-10	none	712-C-96-273	Feb-96
880.1200	Description of Starting Materials, Production and Formulation Process	none	151-11	none	712-C-96-274	Feb-96
880.1400	Discussion of Formation of Impurities	none	151-12	none	712-C-96-275	Feb-96
Group B—Toxicology Test Guidelines.						
880.3550	Immunotoxicity	none	152-18	none	712-C-96-280	Feb-96
880.3800	Immune Response	none	152-24	none	712-C-96-281	Feb-96
Group C—Nontarget Organisms and Environmental Testing Test Guidelines.						
880.4350	Nontarget Insect Testing	none	154-11	none	712-C-96-285	Feb-96
880.4425	Dispenser Water Leaching	none	155-5	none	712-C-96-286	Feb-96
DRAFT 880 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
	None.					

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Series 885—Microbial Pesticide Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0159 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 885 Test Guidelines						
885.0001	Overview for Microbial Pest Control Agents	none	150A	none	712-C-96-280	Feb-96
Group A—Product Analysis Test Guidelines.						
885.1100	Product Identity	none	151A-10	none	712-C-96–273	Feb-96
885.1200	Manufacturing Process	none	151A-11	none	712-C-96–293	Feb-96
885.1250	Deposition of Sample - Nationally Recognized Culture Collection	none	151A-11	none	712-C-12-027	Apr-12
885.1300	Discussion of Formation of Unintentional Ingredients	none	151A-01	none	712-C-96–294	Feb-96
885.1400	Analysis of Samples	none	151A-13	none	712-C-96-295	Feb-96
885.1500	Certification of Limits	none	151A-15	none	712-C-96-296	Feb-96
Group B—Residues Test Guidelines.						
885.2000	Background for Residue Analysis of Microbial Pest Control Agents	none	153A-1	none	712-C-96-299	Feb-96
885.2100	Chemical Identity	none	153A-4	none	712-C-96-300	Feb-96
885.2200	Nature of the Residue in Plants	none	153A-6	none	712-C-96–302	Feb-96
885.2250	Nature of the Residue in Animals	none	153A-7	none	712-C-96–303	Feb-96
885.2300	Analytical Methods—Plants	none	153A-8a	none	712-C-96-304	Feb-96
885.2350	Analytical Methods—Animals	none	153A-8b	none	712-C-96-305	Feb-96
		Document incorrectly says publication Number ends in "-304".				
885.2400	Storage Stability	none	153A-9	none	712-C-96-306	Feb-96
885.2500	Magnitude of Residues in Plants	none	153A-10	none	712-C-96-307	Feb-96
885.2550	Magnitude of Residues in Meat, Milk, Poultry, Eggs	none	153A-11	none	712-C-96-308	Feb-96
885.2600	Magnitude of Residues in Potable Water, Fish, and Irrigated Crops	none	153A-01	none	712-C-96–309	Feb-96
Group C—Toxicology Test Guidelines.						
885.3000	Background–Mammalian Toxicity/Pathogenicity/Infectivity	none	152A-1	none	712-C-96–314	Feb-96
885.3050	Acute Oral Toxicity/Pathogenicity	none	152A-10	none	712-C-96–315	Feb-96
885.3100	Acute Dermal Toxicity/Pathology	none	152A-11	none	712-C-96-316	Feb-96
885.3150	Acute Pulmonary Toxicity/Pathogenicity	none	152A-12	none	712-C-96-317	Feb-96
		Document incorrectly says publication Number ends in "-318".				
885.3200	Acute Injection Toxicity/Pathogenicity	none	152A-13	none	712-C-96-318	Feb-96
885.3400	Hypersensitivity Incidents	none	152A-15	none	712-C-96-320	Feb-96
885.3500	Cell Culture	none	152A-16	none	712-C-96-321	Feb-96
885.3550	Acute Toxicology, Tier II	none	152A-20	none	712-C-96-322	Feb-96

Series 885—Microbial Pesticide Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0159 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
885.3600	Subchronic Toxicity/Pathogenicity	none	152A-21	none	712-C-96-323	Feb-96
		Document incorrectly says publication Number ends in "-232".				
885.3650	Reproductive/Fertility Effects	none	152A-30	none	712-C-96-324	Feb-96
Group D—Nontarget Organism and Environmental Expression Test Guidelines.						
885.4000	Background for Nontarget Organism Testing of Microbial Pest Control Agents	none	154A-1, 154A-2, 154A-3, 154A-4, 154A-5	none	712-C-96-328	Feb-96
885.4050	Avian Oral, Tier I	none	154A-16	none	712-C-96-329	Feb-96
885.4100	Avian Inhalation Test, Tier I	none	154A-17	none	712-C-96-330	Feb-96
885.4150	Wild Mammal Testing, Tier I	none	154A-18	none	712-C-96-331	Feb-96
885.4200	Freshwater Fish Testing, Tier I	none	154A-19	none	712-C-96-332	Feb-96
885.4240	Freshwater Aquatic Invertebrate Testing, Tier I	none	154A-20	none	712-C-96-333	Feb-96
885.4280	Estuarine and Marine Animal Testing, Tier I	none	154A-21	none	712-C-96-334	Feb-96
885.4300	Nontarget Plant Studies, Tier I	none	154A-22	none	712-C-96-335	Feb-96
885.4340	Nontarget Insect Testing, Tier I	none	154A-23	none	712-C-96-336	Feb-96
885.4380	Honey Bee Testing, Tier I	none	154A-24	none	712-C-96-337	Feb-96
885.4600	Avian Chronic Pathogenicity and Reproduction Test, Tier III	none	154A-26	none	712-C-96-342	Feb-96
885.4650	Aquatic Invertebrate Range Testing, Tier III	none	154A-27	none	712-C-96-343	Feb-96
885.4700	Fish Life Cycle Studies, Tier III	none	154A-28	none	712-C-96-344	Feb-96
885.4750	Aquatic Ecosystem Test	none	154A-29	none	712-C-96-345	Feb-96
Group E—Environmental Expression Test Guidelines.						
885.5000	Background for Microbial Pesticides Testing	none	155A-1,2	none	712-C-96–056	Feb-96
885.5200	Expression in a Terrestrial Environment	none	155A-10	none	712-C-96–338	Feb-96
885.5300	Expression in a Freshwater Environment	none	155A-11	none	712-C-96-339	Feb-96
885.5400	Expression in a Marine or Estuarine Environment	none	155A-12	none	712-C-96-312	Feb-96

DRAFT 885 Test Guidelines

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Series 885—Microbial Pesticide Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0159 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
	None.					

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Series 890—Endocrine Distruptor Screening Program Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0576 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		
Final 890 Test Guidelines						
890.0001	[Reserved]	none	none	none	740-C-09-001	
Group A—EDSP Tier 1 Test Guidelines.						
890.1100	Amphibian Metamorphosis (Frog)	none	none	231	740-C-09-002	Oct-09
890.1150	Androgen Receptor Binding (Rat Prostate Cytosol)	none	none		740-C-09-003	Oct-09
890.1200	Aromatase (Human Recombinant)	none	none		740-C-09-004	Oct-09
890.1250	Estrogen Receptor Binding (Rat Uterine Cytosol)	none	none		740-C-09-005	Oct-09
890.1300	Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903))	none	none	455	740-C-09-006	Oct-09
890.1350	Fish Short-term Reproduction	none	none	299	740-C-09-007	Oct-09
890.1400	Hershberger (Rat)	none	none	441	740-C-09-008	Oct-09
890.1450	Female Pubertal (Rat)	none	none		740-C-09-009	Oct-09
890.1500	Male Pubertal (Rat)	none	none		740-C-09-012	Oct-09
890.1550	Steroidogenesis (Human Cell Line – H295R)	none	none		740-C-09-011	Oct-09
890.1600	Uterotrophic (Rat)	none	none	440	740-C-09-010	Oct-09
Group B—EDSP Tier 2 Test Guidelines.						
890.2100	[Reserved]	none	none			
890.2200	[Reserved]	none	none			
890.2300	[Reserved]	none	none			
DRAFT 890 Test Guidelines						
Please note, those guidelines labeled as "Public Draft" are are not yet available in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.						
The following Tier 2 assays are being developed for EDSP and information on the assay or their status under the EDSP validation process is posted at http://www.epa.gov/scipoly/oscpendo/index.htm.						
890.2100	*Avian Two-Generation Toxicity Test in the Japanese Quail*	*none*	*none*			Jan-15
890.2200	*Medaka Extended One-Generation Reproduction Test (MEOGRT)*	*none*	*none*			Jan-15
890.2300	*Larval Amphibian Growth and Development Assay (LAGDA)*	*none*	*none*			Jan-15

Series 890—Endocrine Distruptor Screening Program Test Guidelines

(Docket ID No. EPA-HQ-OPPT-2009-0576 @ http://www.regulations.gov)

As of March 2015

OCSPP[1] Guideline No.	Guideline Names	Other Reference Numbers			EPA Pub No.	Date Issued
		OPPT	OPP	OECD		

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OCSPP[1] Harmonized Test Guidelines - Public DRAFTs (Not Yet Final)

As of March 2015

This is a compilation of the guidelines that have been issued in draft, but have not yet been issued in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.

	OCSPP[1] Guideline Number	Guideline	Other Reference Numbers			EPA Pub	Docket ID No.	Comment Period Status
		OPPT	OPP	OECD				
850.1000	Special Considerations for Conducting Aquatic Laboratory Studies	none	none	none	712-C-96-113	Apr-96	n/a	Closed
850.1010	Aquatic Invetebrate Acute toxicity, Test, Freshhwater Daphnids	797.1300	72–2	none	712-C-96–114	Apr-96	n/a	Closed
850.1020	Gammarid Acute Toxicity Test	795.120	none	none	712-C-96–130	Apr-96	n/a	Closed
850.1025	Oyster Acute Toxicity Test (Shell	797.1800	72–3	none	712-C-96–115	Apr-96	n/a	Closed
850.1035	Mysid Acute Toxicity Test	797.1930	72–3	none	712-C-96-136	Apr-96	n/a	Closed
850.1045	Penaeid Acute Toxicity Test	797.1970	72-3	none	712-C-96-137	Apr-96	n/a	Closed
850.1575	Bivalve Acute Toxicity Test (Embryo Larval)	none	72-3	none	712-C-96-100	Apr-96	n/a	Closed
850.1075	Fish Acute Toxicity Test, Freshwater and Marine	797.1400	72–1, 72-3	203	712-C-96-118	Apr-96	n/a	Closed
850.1085	Fish Acute Toxicity Mitigated by Humic Acid	797.1460	none	none	712-C-96-117	Apr-96	n/a	Closed
850.1300	Daphnid Chronic Toxicity Test	797.1330	72–4	202	712-C-96-120	Apr-96	n/a	Closed
850.1350	Mysid Chronic Toxicity Test	797.1950	72–4	none	712-C-96-166	Apr-96	n/a	Closed
		Document incorrectly says publication Number ends in "-120".						
850.1400	Fish Early-Life Stage Toxicity Test	797.1000	72–4	210	712-C-96-121	Apr-96	n/a	Closed
850.1500	Fish Life Cycle Toxicity	none	72-5	none	712-C-96-122	Apr-96	n/a	Closed
850.1710	Oyster BCF	797.1830	72–6	none	712-C-96-127	Apr-96	n/a	Closed
850.1730	Fish BCF	797.1520	72–6, 165-4	305	712-C-96-129	Apr-96	n/a	Closed
850.1735	Whole Sediment Acute Toxicity Invertebrates, Freshwater	none	none	none	712-C-96-354	Apr-96	n/a	Closed
850.1740	Whole Sediment Acute Toxicity Invertebrates, Marine	none	none	none	712-C-96-355	Apr-96	n/a	Closed
850.1790	Chironomid Sediment Toxicity Test	795.135	none	none	712-C-96-313	Apr-96	n/a	Closed
850.1800	Tadpole/Sediment Subchronic Toxicity Test	797.1995	none	none	712-C-96-132	Apr-96	n/a	Closed
850.1850	Aquatic Food Chain Transfer	none	72-6	none	712-C-96-133	Apr-96	n/a	Closed
850.1900	Generic Freshwater Microcosm Test, Laboratory	797.3050, 797.3100	none	none	712-C-96-134	Apr-96	n/a	Closed
850.1925	Site-Specific Aquatic Microcosm Test, Laboratory	797.3100	none	none	712-C-96-173	Apr-96	n/a	Closed

OCSPP[1] Harmonized Test Guidelines - Public DRAFTs (Not Yet Final)

As of March 2015

This is a compilation of the guidelines that have been issued in draft, but have not yet been issued in final form. Although you may consult these guidelines, please check with the appropriate office before you use a draft guideline to generate data for submission to EPA under FIFRA, FFDCA or TSCA.

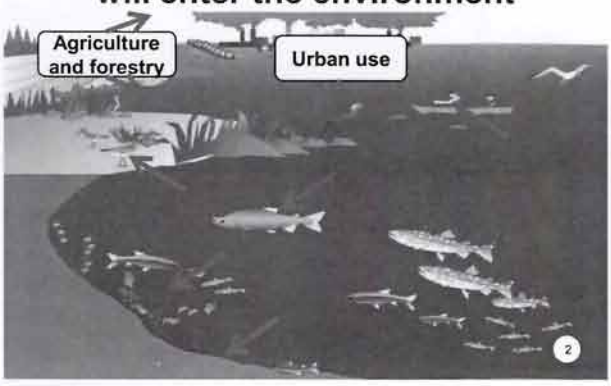
850.1950	*Field Testing for Aquatic Organisms*	*none*	*72–7, 165-5*	*none*	*72-C-96-135*	*Apr-96*	n/a	Closed
870.7100	*Data Reporting for Environmental Chemistry Methods*	*none*	*none*	*none*	*712-C-96-348*	*Apr-96*	n/a	Closed
870.1350	*Acute Inhalation Toxicity with Histopathology*	*none*	*none*	*none*	*712-C-96-291*	*Jun-96*	n/a	Closed
870.3500	*Preliminary Developmental Toxicity Screen*	*none*	*none*	*none*	*712-C-96-205*	*Jun-96*	n/a	Closed
870.3600	*Inhalation Developmental Toxicity Study*	*none*	*none*	*none*	*712-C-96-206*	*Jun-96*	n/a	Closed
870.5265	*The salmonella typhimurium Reverse Mutation Assay*	*none*	*none*	*none*	*712-C-96-219*	*Jun-96*	n/a	Closed
870.8223	*Pharmacokinetic Test*	*none*	*none*	*none*	*712-C-96-250*	*Jun-96*	n/a	Closed
870.8245	*Dermal Pharmacokinetics of DGBE and DGBA*	*none*	*none*	*none*	*712-C-96-251*	*Jun-96*	n/a	Closed
870.8300	*Dermal Absorption for Compounds that are Volatile and Metabolized to Carbon Dioxide*	*none*	*none*	*none*	*712-C-96-252*	*Jun-96*	n/a	Closed
870.8320	*Oral/Dermal Pharmacokinetics*	*none*	*none*	*none*	*712-C-96-253*	*Jun-96*	n/a	Closed
870.8340	*Oral and Inhalation Pharmacokinetic Test*	*none*	*none*	*none*	*712-C-96-254*	*Jun-96*	n/a	Closed
870.8360	*Pharmacokinetics of Isopropanal*	*none*	*none*	*none*	*712-C-96-255*	*Jun-96*	n/a	Closed
870.8380	*Inhalation and Dermal Pharmacokinetics of Commercial Hexane*	*none*	*none*	*none*	*712-C-96-256*	*Jun-96*	n/a	Closed
870.8500	*Toxicokinetic Test*	*none*	*none*	*none*	*712-C-96-257*	*Jun-96*	n/a	Closed
870.8600	*Developmental Neurotoxicity Screen*	*none*	*none*	*none*	*712-C-96-258*	*Jun-96*	n/a	Closed
870.8700	*Subchronic Oral Toxicity Test*	*none*	*none*	*none*	*712-C-96-259*	*Jun-96*	n/a	Closed
890.8800	*Morphologic Transformation of Cells in Culture*	*none*	*none*	*none*	*712-C-96-260*	*Jun-96*	n/a	Closed
890.2100	*Avian Two-generation Toxicity Test in the Japanese Quail*	*none*	*none*	*none*		*Jan-15*	*EPA-HQ-OPPT-2009-0576-0013*	Mar-15
890.2200	*Medaka Extended One-Generation Reproduction Test (MEOGRT)*	*none*	*none*	*none*		*Jan-15*	*EPA-HQ-OPPT-2009-0576-0014*	Mar-15
890.2300	*Larval Amphibian Growth and Development Assay (LAGDA)*	*none*	*none*	*none*		*Jan-15*	*EPA-HQ-OPPT-2009-0576-0015*	Mar-15

[1] Note - Guidelines issued before April 22, 2010, refer to "OPPTS" because the office name changed from "Office of Prevention, Pesticides and Toxic Substances" and "OPPTS" to "Office of Chemical Safety and Pollution Prevention" and "OCSPP." This name change does not otherwise affect the Guidelines.

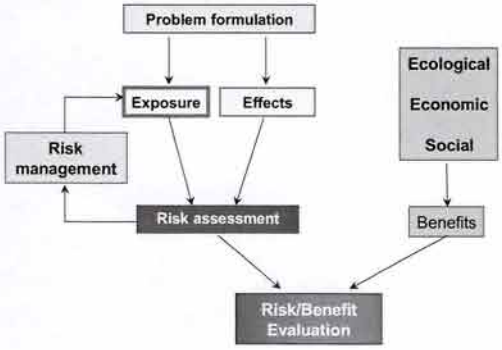
Exposure Assessment

Keith Solomon, May 9, 2015
Ecological Risk Assessment Workshop
Santiago Chile

As result of use, some pesticides will enter the environment



Risk-benefit (FAO)



3

Exposure

Was ist das nit gift ist? alle ding sind gift vnd nichts ohn gift/ Allein die dosis macht das ein ding kein gift ist.*

The dose makes the poison

4

Environmental processes
Degradation or change

- Photolysis
  - Light intensity (water and atmosphere)
- Oxidation
  - Oxidant concentration (water, air and soil)
- Reduction
  - Reductant concentrations (water, air and soil)
- Hydrolysis
  - Temperature, pH (water)
- Biotransformation
  - Organism populations, nutrient concentrations, temperature, pH

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Environmental processes
Movement

- Rain-out
  - Precipitation rate, sticking coefficient (atmosphere)
- Volatilization
  - Henry's constant, surface texture (water and soil)
- Sorption
  - Organic matter, lipid, clay content (soil, sediment)
- Transport with the matrix
  - Wind velocity (atmosphere): Current velocity (water): Percolation (ground water): Particle transport (soil runoff)
- Bioconcentration
  - Lipid content of organisms (biota)
- Biomagnification
  - Bioconcentration, resistance to metabolism, and K_{OA}

6

Transformations

- One (or two) process(es) usually dominate(s)
- Relative importance may change over time or space
- Because concentrations are usually small and intensity of environmental factors is usually low, transformation reactions are:
  - Zero or
  - First order

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Measuring exposure concentrations

- Critical component of risk assessment
- Errors
  - Improper sampling techniques
  - Incorrect analyses
  - Loss or contamination of sample:
    - Transport - Field blank (containing no residue) and field spike sample
    - Storage - Storage spike and blank

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Measurement

- Environmental sampling
  - Soil and sediments
  - Water
  - Air
  - Biota

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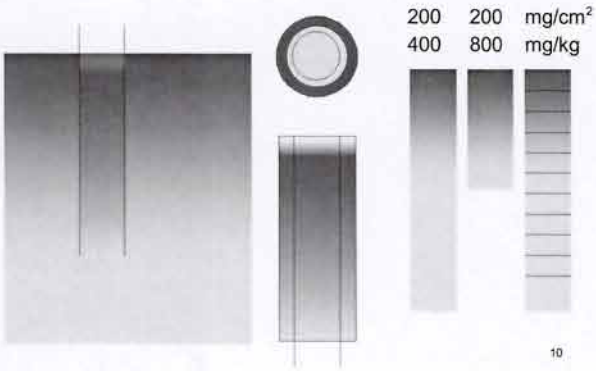
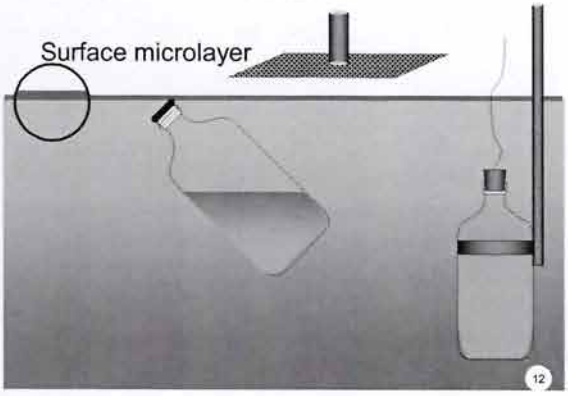
Soil and sediment



Environmental fate in soil

Water



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Sampling of air

- Pump
  - Draws a measured amount of air through an
- Absorption device
  - Very low temperatures (to condense out volatiles)
  - Special absorbents designed to selectively remove organic substances from the air.
    - Silica gel,
    - C_{18} resins
    - Polyurethane foam
- Particulates are separated from air prior to adsorption

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Biota

- Organisms present difficulties
  - Not always easy to locate
  - Rare and susceptible to sampling pressure.
- Because of differences in age or lipid content, concentrations of hydrophobic organic compounds in biota may be highly variable
  - Concentrations are often normalized for lipid content (µg/g lipid)

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Audit trail

- GLP is now necessary in many jurisdictions for analyses done for regulatory purposes
- For legal purposes an even more complex and complete audit trail may be necessary

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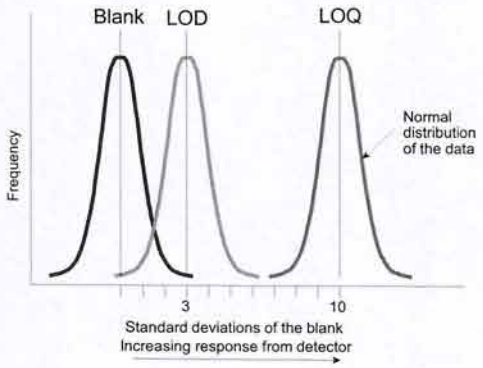
Handling the data



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Values below the MDL/LOD

- Should not be ignored or forgotten
- An important part of the data set
- Need to be considered when probabilistic distributions of environmental concentrations are determined

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Estimating the environmental concentration

- Cannot be measured:
  - Too difficult to measure
  - Too expensive
  - Too many samples needed
  - Not used in the environment yet (new pesticide or industrial substance)

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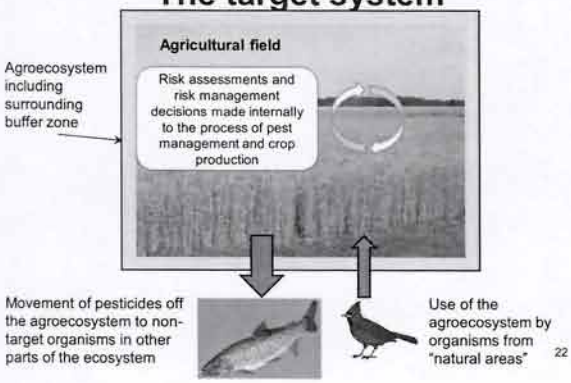
Estimating exposure to pesticides: The target system



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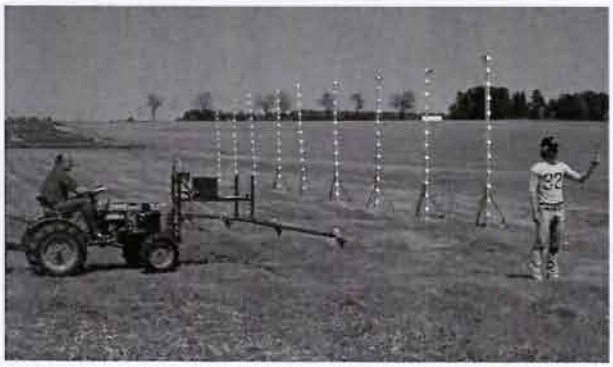

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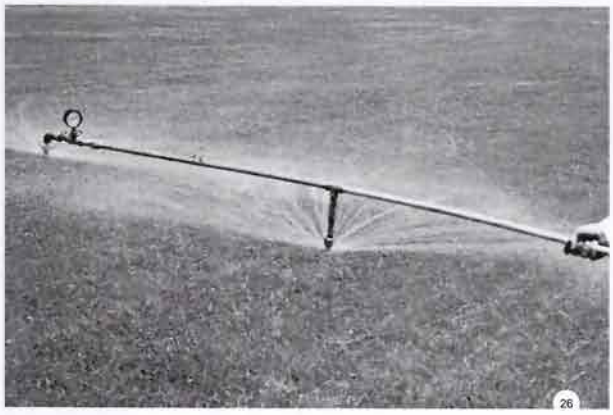

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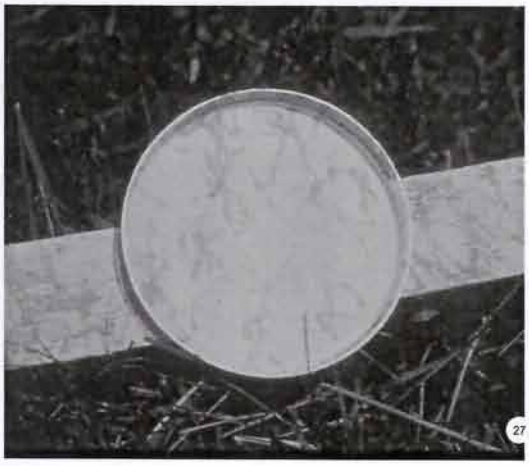

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BBA drift tables

Distance from crop (m)	Field crops, boom sprayer, early and late growth	Grape vines, air blast sprayer		Fruit trees, air blast sprayer		Hops, air blast sprayer	Vegetable, ornamental, small fruit, pedestrian sprayer	
		Early growth	Late growth	Early growth	Late growth	Early and late growth	< 50 cm high	>50 cm high
	Deposition as percent of rate applied to field (upper 95th CI of the 95th centile)							
1	4	-	-	-	-	-	4	-
3	1	4.9	7.5	29.6	15.5	-	-	7.5
5	0.6	1.6	5	20	10	12.5	0.6	5
10	0.4	0.4	1.5	11	4.5	9	0.4	1.5
15	0.2	0.2	0.8	6	2.5	5	0.2	0.8
20	0.1	0.1	0.4	4	1.5	4	0.1	0.4
30	0.1	0.1	0.2	2	0.6	2	0.1	0.2
40	-	0.1	0.2	0.4	0.4	-	-	0.2
50	-	0.1	0.2	0.2	0.2	0.3	-	0.2

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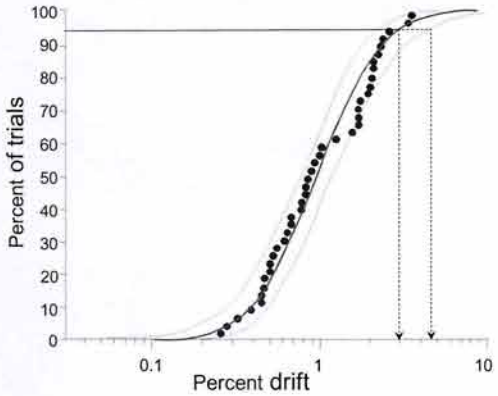
BBA DRIFT TABLES



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Concentrations in water

Method	Application rate (kg/ha)	Depth of pond (m)	Maximum concentration in water	
			(mg/L)	(µg/L)
US EPA farm pond	1	2	0.05	50
Europe, farm pond (FOCUS 2001)	1	1	0.10	100
Europe, ditch (FOCUS 2001)	1	0.3	0.33	333
Canada (forest pool) and US EPA (wetland)	1	0.15	0.67	670

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Concentrations in soil

Application rate	Depth of soil (cm)	Density of soil (kg/L)	Maximum concentration if soil (mg/kg)
1	2.5	1.5	2.67
1	5.0	1.5	1.34
1	20.0	1.5	0.34

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Birds and mammals

Food source	Application rate (kg/ha)	Residue on food (mg/kg)	Amount of pesticide eaten in a day (mg/kg)	
			Small bird or mammal (100 g)	Large bird or mammal (500 g)
Foliage	1	20	60	20
Seeds	1	10	3	1
Insects (large)	1	10	3	1
Insects (small)	1	100	30	10

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GENEEC

- **GEN**eric **E**stimated **E**nvironmental **C**oncentration model.
- Available at:
  http://www.epa.gov/oppefed1/models/water/geneec2_users_manual.htm
- Download the model and run a chemical through it to get a Tier-1a exposure estimate.

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Gracias

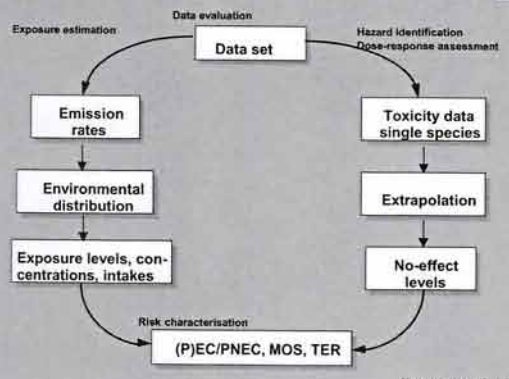
Uncertainties in Risk Assessment

Jan Linders,
Ecological Risk Assessment Workshop,
Santiago de Chile (Chile), 9 and 10 May 2015

Contents

1. Introduction
2. General Risk Assessment Scheme
3. Uncertainties
4. Deterministic RA versus Probabilistic RA
5. Advantages and Disadvantages
6. A Promising Way Forward?

General Risk Assessment



Sources of Uncertainty

- Every assumption in the risk assessment
- Every parameter in the models, if applied
- Every test carried out
- Even the dose itself

Example (1)

Three zones in the EU, Regulation 1107/2009

- Zone A — North
  - Denmark, Estonia, Latvia, Lithuania, Finland, Sweden
- Zone B — Centre
  - Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom
- Zone C — South
  - Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

Example (2)

Sewage treatment plant

Question: what dilution factor should be used in modelling for the discharge of a sewage treatment plant to surface water?

Action: collect information of all sewage treatment plants in NL and analyze the information.

Result: variation in dilution is huge (1 to 100,000), due to seasonal effects, daily variations, industrial activities, etc.

Conclusion and proposal: default dilution factor D = 10

Source: De Greef, J., and A.C.M. De Nijs (1990). Risk assessment of new chemical substances. Dilution of effluents in the Netherlands. Bilthoven, National Institute of Public Health and the Environment (RIVM), Report No. 670208001.

Tier 1: Aquatic Effect Assessment

Acute
- 96-h EC50 algae
- 48-h EC50 daphnids
- 96-h LC50 fish

Chronic
- 4-d NOEC algae
- 21-d NOEC daphnids
- 28-d NOEC fish

Tier 2: Aquatic Effect Assessment

Laboratory
- More single species studies
- Early Life Stage test
- Full Life Cycle test

Semi field
- Microcosm studies
- Mesocosm studies

Field
- Field studies
- Monitoring
- Recolonization studies
- Recovery studies

Endpoint?

Assessment Factors (EU, PPP)

# of Aquatic tests	AF
3 short term L(E)C50 (fish, *Daphnia*, algae)	100
3 long term NOECs (fish, *Daphnia*, algae)	10
Field data (*)	Case-by-case

(*) proposals by HARAP (1999) and CLASSIC (2001)

Assessment Factors (TGD)

# of Aquatic/Terrestrial Tests	AF
1 short term L(E)C50 (fish, *Daphnia*, algae)	1000
1 long term NOEC (either fish or *Daphnia*)	100
2 long term NOECs (from 2 trophic levels)	50
3 long term NOECs (from 3 trophic levels)	10
Field data	Case-by-case

Example (4)

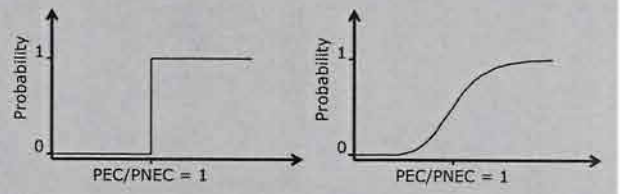
Dose

- Mixing and loading
- Application device
- Drift variations
- Wind effects

Deterministic vs Probabilistic Approach

Decisive Criteria

- PEC/PNEC or Statistically allowed exceedance
- Which is scientifically better?
- Risk assessors vs Risk managers



Decisive Criterion in Deterministic RA

- Risk is determined by the ratio

  PEC/PNEC (ROW) or TER (EU)

- PEC/PNEC ≤ 1: no risk
- PEC/PNEC > 1: potential risk, more data needed or denial
- TER > AF: No risk
- TER ≤ 1: potential risk, more data needed or denial
- Therefore: PEC/(PNEC*AF) = 1/TER or PEC/NOEC = 1/TER

Deterministic Approach (1)

Risk Characterization for water organisms:

- Calculate the ratio PEC over PNEC
- Conclude on safety
- Register or ask for more information

Deterministic Approach (2)

Exposure for example in an RA for aquatic organisms:

- Apply FOCUS scenarios (step 1, 2 and/or 3)
- Choose appropriate result(s) depending on
  - Region (North, Middle or South) (zonal approach)
  - Drainage or runoff scenario
  - Drift calculation
- Calculate appropriate PEC (at a certain time, TWA at 4, 28 or 365d)

Deterministic Approach (3)

Hazard Assessment for water organisms:

- Establish the lowest NOEC from all ecotoxicological studies
- Extrapolation needed?
- Apply appropriate assessment factor
- Determine the PNEC

Extrapolation

In a deterministic approach uncertainty is taken care of by extrapolation to a "safe" concentration.

Uncertainties exist in:

- Laboratory to field
- Intra-species variation (sensitivity)
- Inter-species variation (sensitivity)
- Solution: 10 * 10 * 10
- Unless sufficient data are available to lower the total AF
- Safe concentration
  - **i.e. $PNEC_{ecosystem}$ or $PNEC_{species}$**
- Human health equivalent: Margin of Safety (MOS = 100)

Methods:

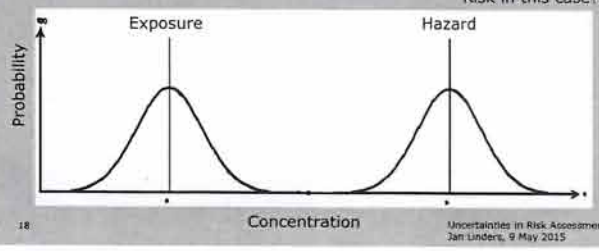
- EPA (preferred)
- Statistical approach

Mathematical Expression of Risk

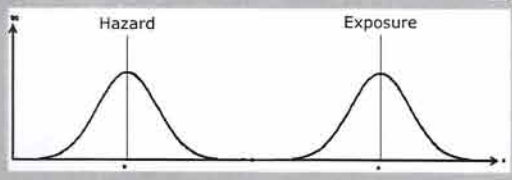
Risk (P_{effect}) = $P_{Exposure}$ • P_{Hazard}

Assumption: normal (Gaussian) distribution

Risk in this case?



Risk Occurrence



What is probabilistic risk assessment?

Risk assessments that use probabilities or probability distributions to quantify one or more sources of variability and/or uncertainty in exposure and/or effects and the resulting risk

and subsequently:

- Variability is defined as *Real variation in factors that influence risk*
- Uncertainty is defined as *Limitations in knowledge about factors that influence risk*
- Probability is defined as its *Frequency in repeated independent trials that it will occur and expressed as a proportion*
- Probability distribution is a *graph showing the relative probabilities of different values of a variable*
- Probabilistic risk assessment is defined as *the process of using probabilities and probability distributions to take account of variability and uncertainty in risk assessment*

The basic steps of a probabilistic assessment

- Define the objective of the assessment and decide what form of probability or distribution is required for the assessment output;
- Identify one or more inputs to the risk assessment, for which variability and/or uncertainty is to be considered, and quantify them using appropriate probabilities or distributions;
- Use appropriate methods to combine the different input distributions and produce the distribution for the assessment output, showing the variability and uncertainty of the predicted impacts.
- Interpret and communicate the results

Potential benefits of quantifying variability

- Increased realism through representing more fully variation in the real world and its influence on the risk
- The opportunity to replace worst-case assumptions with more realistic ones
- May be a more cost-effective option for refining the assessment than conducting higher tier laboratory or field studies
- Makes more use of the available data (i.e. variances or individual data points).

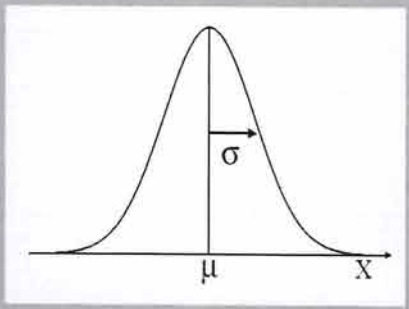
Potential benefits of quantifying uncertainty

- Provides an objective basis for discussions about reducing uncertainty factors (e.g. the TER thresholds of 10 and 100) when additional data is provided
- Provides an indication of the combined influence of the quantified uncertainties on the assessment outcome
- By identifying major sources of uncertainty, it may help the targeting of higher tier studies so as to maximize their cost-effectiveness in reducing uncertainty

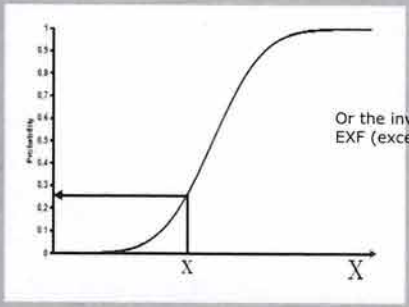
Potential disadvantages of probabilistic approaches

- A lack of reliable information for specifying distributions of many input parameters,
- Concerns about the validity of assumptions (e.g. representativeness of tested species),
- The lack of common standard methods for the statistical calculations

Probability density function (pdf) for a normal distribution



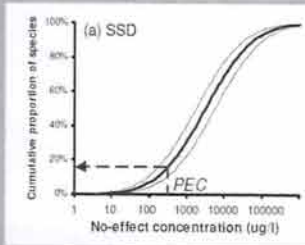
Cumulative distribution function (cdf) for a normal distribution



Or the inverse form:
EXF (exceedance function)

Potential Output (1)

CDF for hazard, SSD

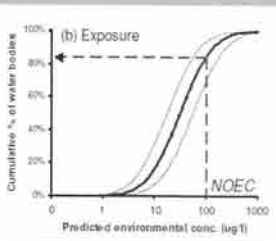


16% of species have no-effect concentrations at or below the predicted environmental concentration of 316 µg/l

i.e. this PEC will affect 16% of species

Potential Output (2)

CDF for exposure



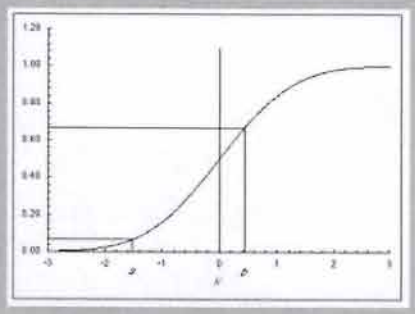
84% of water bodies have predicted environmental concentrations equal to or less than the no-effect level of 100 µg/l

So, by subtraction, 16% of water bodies have PECs greater than the NOEC

Probabilistic Decision Making (1)

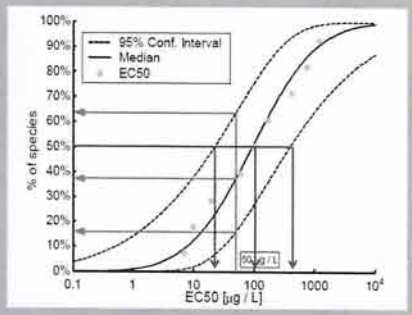
- Apply probabilistic modeling:
  - Using probabilistic input (rainfall, dilution, in principle all parameters may be used as probabilistic input)
  - Plot the results in a probabilistic density function or as a cumulative density function

Probabilistic Decision Making (2)



X could be PEC/PNEC on log scale

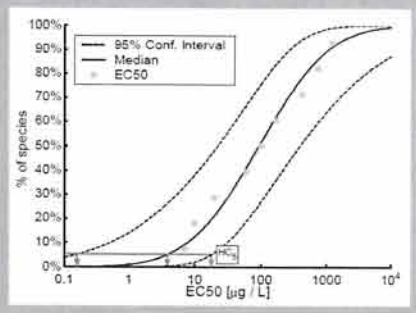
Confidence intervals



Grey:
37%
(16-63)

Red:
100 µg/L
(16-300)

Hazard Concentration (HC5)



HC5 (grey):
3.86 µg/L
(0.1-18)

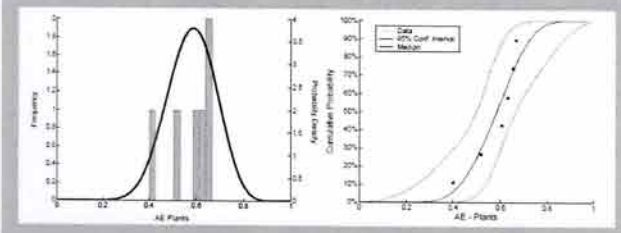
Probabilistic Decision Making (3)

- Generally a distinction is made in
  - Risk assessors (carry out the RA)
  - Risk managers (decide on RA results)
- What is considered acceptable risk, e.g. in relation to national or international policy?
  - In case of aquatic organisms:
    - No deaths?
    - 5% effect?
    - 50% deaths?
    - Confidence intervals?

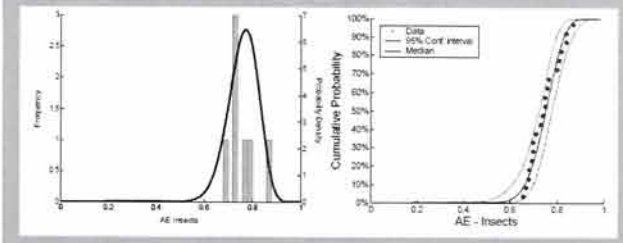
Data Needs

- PRA is very data intensive
- Example, terrestrial case study performed in EUFRAM
- Variables:
  - Assimilation energy (leaves, arthropods, weeds)
  - Probability that a lark is male or female
  - Body weight
  - Daily energy expenditure
  - Proportion of food taken from treated area
  - Gross energy (leaves, arthropods, weeds)
  - Moisture content (leaves, arthropods, weeds)
  - Proportion of different foods in skylark's diet
  - Residue per unit dose (leaves, arthropods, weeds)

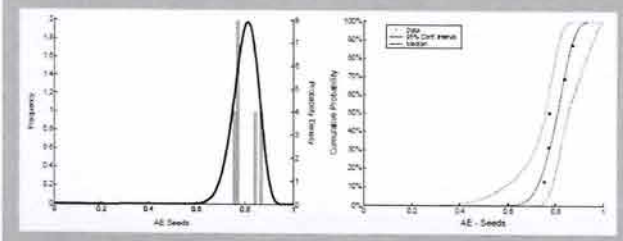
Assimilation Efficiency – Leaves (Dicotyles & Monocotyles)



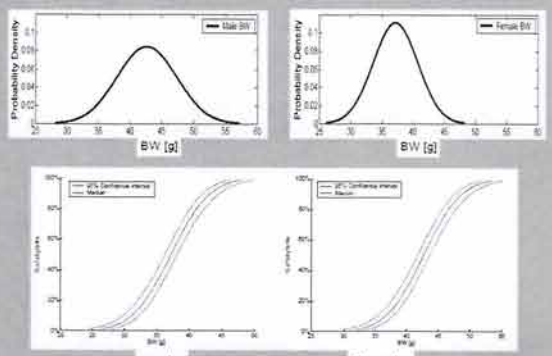
Assimilation Efficiency – Arthropods



Assimilation Efficiency
- Seeds (weeds and cereal weeds, mature, immature)



Body weight (male & female, estimation)



male female

PRA Tools

Software:

- Monte Carlo methods
  - 1D (combining distributions by taking large numbers of samples from each one at random)
  - 2D (separates uncertainty and variability)
- ETx, MS Excel®, Crystal Ball® and Risk Calc®, Splus®, R, and SIMLAB

Application of Probabilistic RA

- As research projects
- USA: ECOFRAM (1996 – 1999)
  - Aquatic
  - Terrestrial
- European Union: EUFRAM (2003 – 2006)
  - Several examples
- No official status in the regulatory system
- Reasons:
  - Insufficient data available
  - Insufficiently developed methodology
  - Insufficient guidance

A promising way forward?

- Yes, but not yet
- Many data needed in the form of a PDF, specific research
- Risk managers have to define the relevant decision criteria (% acceptable or not acceptable)
- Education needed for risk assessors and risk managers
- Only specialists are able to perform PRA
- Risk managers need to know how to interpret PRA results

Approaches to Uncertainty

- ECOFRAM (US-EPA)
  - http://www.epa.gov/oppefed1/ecorisk/ecorisk_ecofram.htm
- EUFRAM (EU) (preliminary study)
  - http://www.eufram.com/
- EFSA (EU)
  - Methodology currently under development
- Transatlantic cooperation (CAN, US, EU)
  - http://ec.europa.eu/health/risk_assessment/events/ev_20110126_program_en.htm

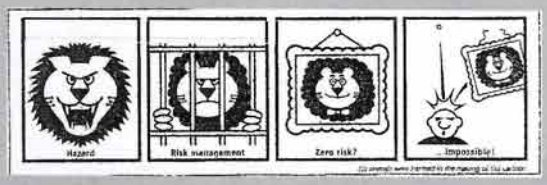
Risk Characterization

Jan Linders,
Ecological Risk Assessment Workshop,
Santiago de Chile (Chile), 9 and 10 May 2015

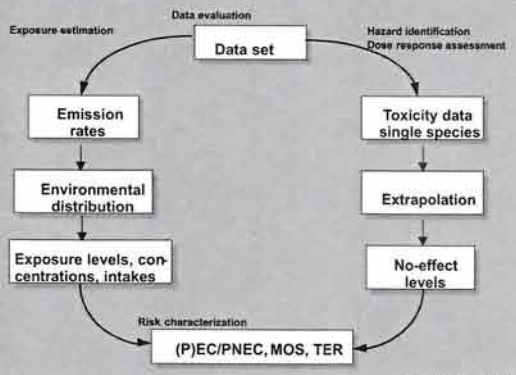
Contents

1. Introduction
2. General Risk Assessment
3. Tiered Approach
4. Environmental Risk Assessment
   1. Exposure Assessment
   2. Effect Assessment
5. Risk Characterization
6. Conclusions

The difference between risk and hazard



General Risk Assessment



Areas of Application

- Industrial Chemicals (REACH), tool: EUSES
- Pesticides, tools: FOCUS and Guidance Documents
- Biocides (non-agricultural): tools: EUSES and ESDs
- Veterinary medicines (environmental side effects)
- Human medicines (environmental side effects)
- Ballast Water (human, environment, ship)

Types of Risk Assessment

- Relation application and characteristics related to:
  - **Public health**
  - **Private applicant**
  - **Professional applicant**
  - **Bystanders**
  - **Environment**
- Active substance/organism, metabolites and the product
- Taking into account:
  - **Type of product (spray liquid, seed dressing, granulate, gas)**
  - **Mode of application (spraying, pouring)**
  - **Time of application (spring, autumn; use phase, application phase, waste phase)**
  - **Place of application (crop, home, greenhouse, other)**

Protection Target Groups

- Environment
  - Aquatic ecosystem
  - Terrestrial ecosystem
  - Sediment ecosystem
  - Predators (through worms and fish)
  - Micro-organisms in STP
- Human
  - Direct at the workplace
  - Direct through use of consumer products
  - Indirectly via the environment

Topics

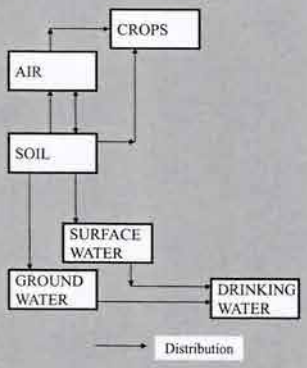
Compartments:

- Soil
- Groundwater
- Surface water
- Air
- Crops
- Drinking water

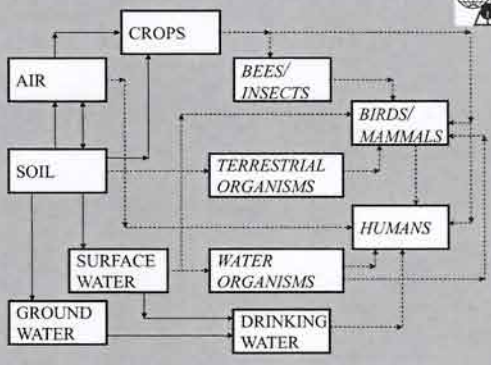
Organisms:

- Aquatics organisms
- Terrestrial vertebrates
- Soil microflora
- Earthworms
- Non-target arthropods
- Honeybees
- Non-target higher plants

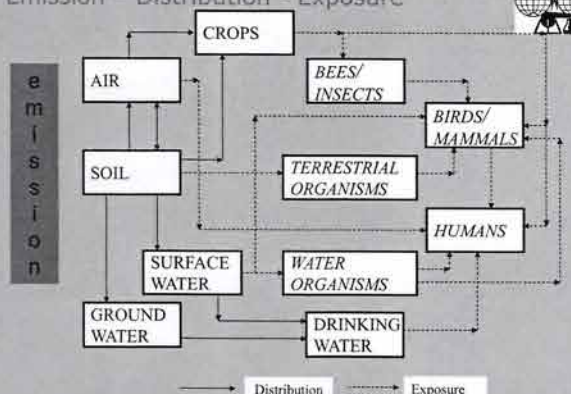
Environmental distribution



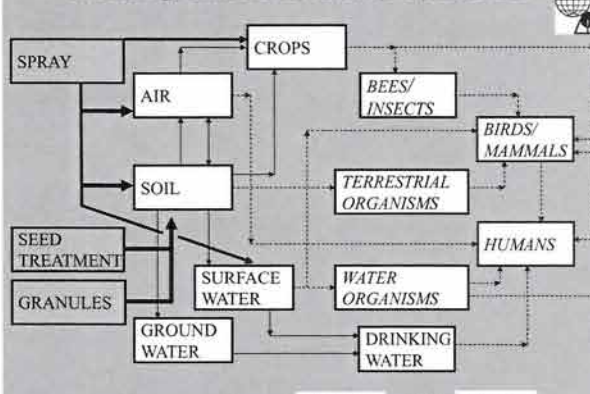
Environmental distribution and exposure to organisms



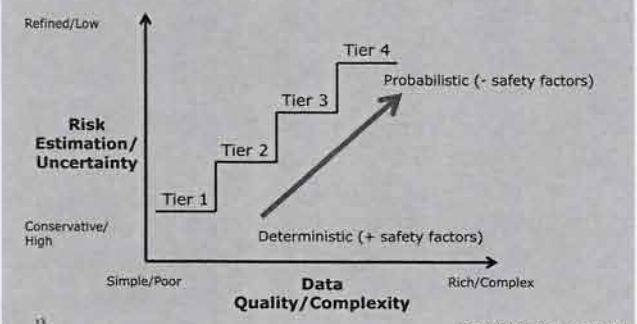
Emission - Distribution - Exposure



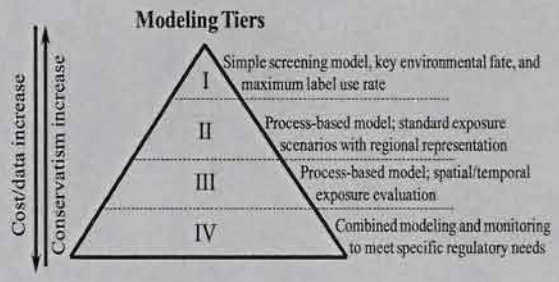
Including emissions, example pesticides



Risk Assessment a Tiered Process

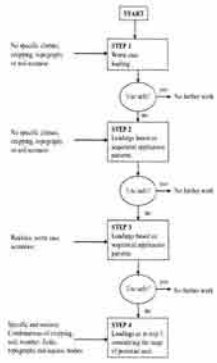


Environmental Risk Assessment

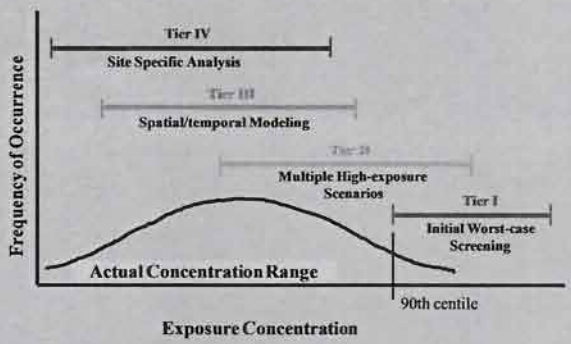


Tiered System

- **STEP 1:** **single application, fixed scenario**
- **STEP 2:** **Multiple application, regional variation in Europe**
- **STEP 3:** **Advanced modelling specific European Scenarios**
- **STEP 4:** **Site specific calculation**



Accuracy & Variability



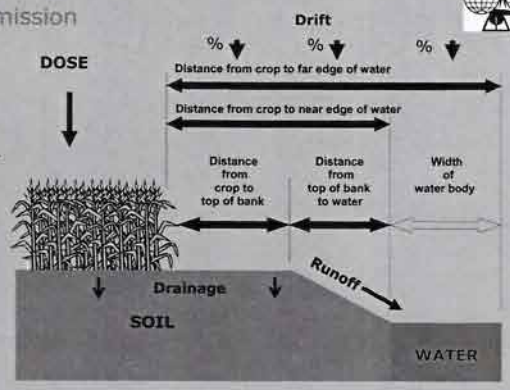
Data Set

- Application
- Physico-chemical characteristics
- Fate and behaviour (tiered)
- (Eco)toxicity (tiered)
- Residues (crops)
- Quality (GLP, GIGO)
- Evaluation (choosing RA data)
- Scenarios (protection goals)

Application

- Active Substance
- Dose
- Frequency
- Interval

Emission



Fixed characteristics

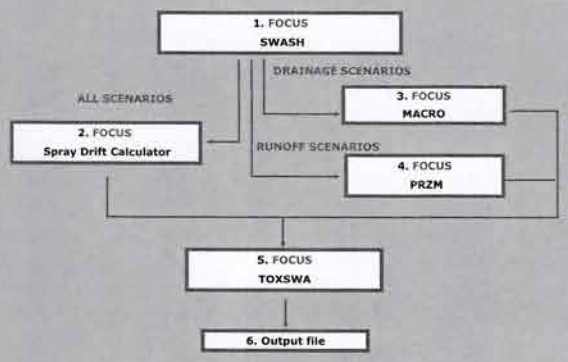
Dimensions

Type of water body	Width (m)	Total length (m)	Distance from top of bank to water (m)
Ditch	1	100	0.5
Pond	30	30	3.0
Stream	1	100	1.0

Sediment Characteristics

Concentration of suspended solids in water column (mg L^{-1})	15
Sediment layer depth (cm)	5
Organic carbon content (%)	5
Dry Bulk density (kg m^{-3})	800
Porosity (%)	60

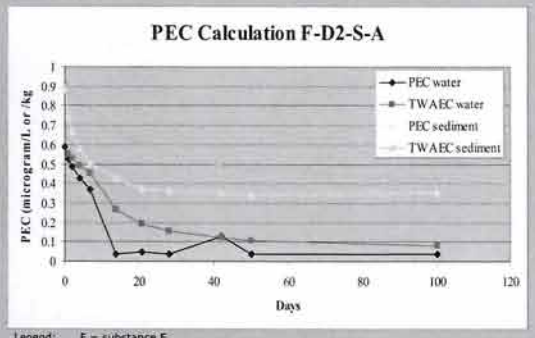
Interaction of Models



Output Exposure Assessment

PEC		TWAEC
• **PEC0 = Initial PEC**		• ---
• **PEC1**	short	• **TWAEC1**
• **PEC2**		• **TWAEC2**
• **PEC4**		• **TWAEC4**
• **PEC7**	long	• **TWAEC7**
• **PEC14**		• **TWAEC14**
• **PEC21**		• **TWAEC21**
• **PEC28**		• **TWAEC28**
• **PEC42**		• **TWAEC42**
• **PEC50**		• **TWAEC50**
• **PEC100**		• **TWAEC100**

Exposure Example



Legend: F = substance F
D2 = scenario D2
S = stream
A = autumn application

Example Risk Assessment

- **Assessment of surface water**
  - **Exposure**
    - **Emission**
    - **Distribution**
    - **Concentrations**
- **Assessment of aquatic organisms**
  - **Hazard**
    - **Single species**
    - **Extrapolation**
    - **No effect concentrations**
- **Comparison**

Tier 1: Aquatic Effect Assessment

Acute
- **96-h EC50 algae**
- **48-h EC50 daphnids**
- **96-h LC50 fish**

Chronic
- **4-d NOEC algae**
- **21-d NOEC daphnids**
- **28-d NOEC fish**

Tier 2: Aquatic Effect Assessment

Laboratory
- **More single species studies**
- **Early Life Stage test**
- **Full Life Cycle test**

Semi field
- **Microcosm studies**
- **Mesocosm studies**

Field
- **Field studies**
- **Monitoring**
- **Recolonization studies**
- **Recovery studies**

Endpoint?

Extrapolation

- Species
- Community
- Ecosystem
- Safety factor or Assessment factor
  - **Intraspecies (10)**
  - **Interspecies (10)**
  - **Lab to field (10)**
- Safe concentration
  - **i.e. $PNEC_{ecosystem}$ or $PNEC_{species}$**

10 X 10 X 10

Assessment Factors (EU; PPP)

# of Aquatic tests	AF
3 short term L(E)C50 (fish, *Daphnia*, algae)	100
3 long term NOECs (fish, *Daphnia*, algae)	10
Field data (*)	Case-by-case

(*) proposals by HARAP (1999) and CLASSIC (2001)

Assessment Factors (TGD)

# of Aquatic/Terrestrial Tests	AF
1 short term L(E)C50 (fish, *Daphnia*, algae)	1000
1 long term NOEC (either fish or *Daphnia*)	100
2 long term NOECs (from 2 trophic levels)	50
3 long term NOECs (from 3 trophic levels)	10
Field data	Case-by-case

Predicted No-Effect Concentration (PNEC)

- Acute and/or chronic
- Most sensitive species
- Related to duration of study
- Example (hypothetical):
  - **Fish:** **96h-LC50=0.5 and 0.15 mg/L**
    28d-NOEC=0.01 and 0.06 mg/L
  - ***Daphnia*:** **48h-EC50=0.13 mg/L**
    21d-NOEC=0.05 mg/L
  - **Algae:** **96h-EC50=100 mg/L**
    96h-NOEC=40 mg/L

Formulae

acute **chronic**

$$PNEC_{acute} = \frac{L(E)C50}{AF_{acute}} \quad and \quad PNEC_{chronic} = \frac{NOEC}{AF_{chronic}}$$

With: AF_{acute}=100 and $AF_{chronic}$=10

Output Effect Assessment

- **$L(E)50_{most\ sensitive\ species}$** 48h-EC50(*Daphnia*)=0.13 mg/L
- **$PNEC_{acute}$** =0.0013 mg/L
- **$NOEC_{most\ sensitive\ species}$** 28d-NOEC(fish)=0.01 mg/L
- **$PNEC_{chronic}$** =0.001 mg/L
- **$PNEC_{ecosystem}$** =0.0001 mg/L

Risk Characterisation

- Comparison of estimated concentration and effect concentration
- Risk quotient (RQ):
  - **PEC/PNEC (OECD)**
  - **TER (EU)**
  - **Acute**
  - **Chronic**

$$\frac{InitialPEC}{PNEC_{acute}} < 1$$

$$\frac{TWAEC}{PNEC_{chronic}} < 1$$

Decisive Ratios

$$\frac{PEC_{acute}}{PNEC_{acute}} = \frac{InitialPEC}{L(E)C50/100} < 0.01^{*}$$

$$\frac{PEC_{chronic}}{PNEC_{chronic}} = \frac{TWAEC_{4,21,28}}{NOEC_{4,21,28}/10} < 0.1^{*}$$

* Including AF (100 for acute and 10 for chronic)

Comparison US LOCs and EU triggers

Ecological Receptor	Assessment Endpoint	US LOC (+if RQ > LOC)	EU Trigger (+ if TER < trigger)	Converted EU trigger
Avian/ Mammalian	Acute	0.5 0.1 (endangered)	10	0.1
	Chronic	1.0	5	0.2
Aquatic Organisms	Acute	0.5 0.01 (endangered)	100	0.01
	Chronic	1.0	10	0.1
Terrestrial Plants	Growth	1.0 1.0 (endangered)	5	0.2
Aquatic Plants	Growth	1.0 1.0 (endangered)	5	0.2

Risk management & Risk Mitigation

- Exposure assessment
  - More realistic modelling (assumptions)
  - Monitoring
- Hazard assessment
  - Micro- or mesocosm studies
- Mitigation measures
  - No crop zones (drift reduction)
  - Limit use area (emission reduction)
  - Additional toxicity data (assessment factor reduction)
  - Probabilistic risk assessment (increase of realism)

Conclusions

- Straightforward with possibilities for increasing realism
- Clear decision making criteria
- Well documented and scientifically sound
- Still some gaps identified
  - **Compartment air**
  - **Terrestrial ecosystem**
- State of the art
- Mechanism for updating
- Widely accepted in EU

Information

http://viso.ei.jrc.it/focus/index.html

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents/active_substances_en.htm

http://www.epa.gov/pesticides/about/overview_risk_assess.htm

WASHINGTON STATE UNIVERSITY

Ecological Risk Assessment Workshop
Santiago, Chile: May 9-10, 2015

Risk Mitigation and Refinement

Allan Felsot
Washington State University
Department of Entomology
College of Agriculture Human & Natural Resources Sciences
School of the Environment; School of Biological Sciences

AGRICULTURE YOUTH & FAMILIES HEALTH ECONOMY ENVIRONMENT ENERGY COMMUNITIES

1

The Agenda

- Review of U.S. EPA Registration Authority and Ecorisk Assessment Procedures
- Case Study I
  - ✓ Diazinon: Aquatic hazard & urban watershed ubiquity was the driver for risk mitigation resulting in the loss of urban uses
- Case Study II
  - ✓ Chlorfenapyr: No outdoor uses allowed due to bird toxicity concerns
- Case Study III
  - ✓ Sulfoxaflor: How EPA used risk mitigation/refinement resulting from Tier II honey bee studies to defend registration of this neonicotinoid

2

The Almighty FIFRA

(Federal Insecticide Fungicide & Rodenticide Act)

3

4

FIFRA Rules

- Policies, regulations, & standards set under the mandate of the Federal Insecticide, Fungicide & Rodenticide Act govern pesticide use (in the broadest sense--the whole technology)
- Although pesticides are arguably the most intensely scrutinized and regulated chemical technology, the law historically allowed consideration of benefits of use as well an assessment of risks
  - ✓ Currently only applicable to worker protection and ecological effects
  - ✓ Only risk considered when protecting consumers

5

U.S. Pesticide Law 101

FIFRA (1947) ← FEPCA (1972)

FFDCA (1938) ← **Miller** (1954), **Delaney** (1958)

Risk Assessment → Tolerance ("MRL")

Ecological | *Human Health*

Labeling → **Registration**

FQPA (1996)

6

Regulatory Authority for EPA Comes from the U.S. Congress

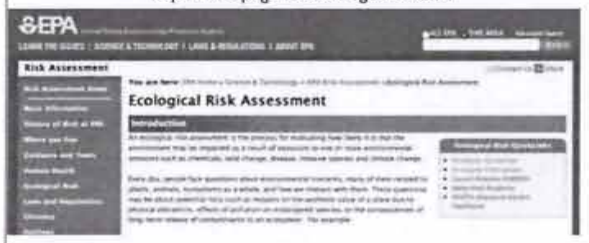
- FIFRA section 3(c)(5): "the Administrator shall register a pesticide if the administrator determines that…it will perform its intended function without unreasonable adverse effects on the environment
  - ✓ "Unreasonable adverse effects are defined as "(1) any unreasonable risk to man or the environment, taking into account the economic social and environmental costs and benefits of the use of any pesticide."
- Section 3(c)(7)(C): the Administrator may conditionally register a pesticide with new AI "for a period reasonably sufficient for the generation and submission of required data"
  - ✓ Must meet all risk criteria, meaning not likely to cause any unreasonable adverse effects on environment, and pesticide use is in the public interest
- Section 18: Adminstrator can exempt State & Federal agencies for requirements of the act to allow use of a pesticide under four types of emergency conditions that will avert…
  - ✓ Significant economic loss; significant risk to endangered and threatened species; risk to beneficial organisms

Regulatory Authority for EPA Comes from the U.S.

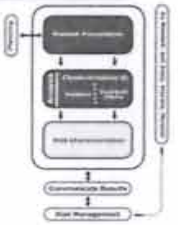
- FIFRA 3(c)(1)(F): EPA has authority to require data to support an application for pesticide registration
- FIFRA 3(c)(2)(B): EPA has authority to require additional data on currently registered products
  - ✓ Data must be "required to maintain in effect an existing registration
- FIFRA Section 6(a)(2): Required that pesticide registrants inform EPA of any relevant adverse effects information, even if not formerly requested
  - ✓ Includes new information derived from scientific studies, including efficacy failures and pest resistance; incidents from use of pesticide products

EPA Provides Guidance for Ecorisk Assessments

http://www.epa.gov/risk/ecological-risk.htm



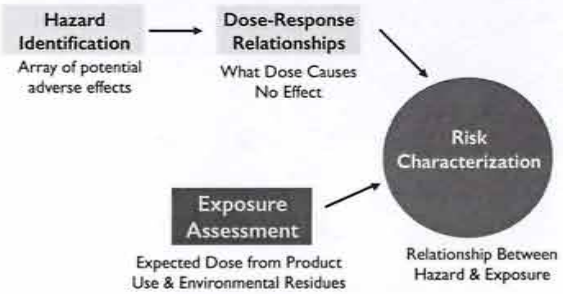
The Guidance Information Is Generic & Idealistic



- EPA has generic guidelines for conducting ecorisk assessments, but pesticide ecorisk assessments follow a simple pattern of using mostly acute toxicity data but allowing for considering of risks & benefits as allowed under the Federal Insecticide Fungicide Rodenticide Act (FIFRA)
  - ✓ Under other laws, EPA may only consider risks
- Thus, EPA generally relies on a worst-case scenarios to derive deterministic risk quotients; these are analgous to Tier 1 analyses
  - ✓ However, the agency can engage a higher tier analyses that may culminate in a narrative description of risk rather than a quantitative description
  - ✓ The use of higher tier analyses is one form of risk mitigation when it leads to a decision to register a pesticide but with caveats that will lead to risk below EPA's levels of concern

10

A Simplified View of Risk Assessment-- Estimating the Probability of Harm



11

Ecological Risk Assessment Dilemma

- Millions of species to protect
- Infinitesimal exposure scenarios
- EPA's Solution: Deterministic Risk Assessment
  - ✓ Choose the most sensitive species studied
    - Focus on acute toxicity (use the LC50)
    - Focus on chronic toxicity (use the NOEC)
  - ✓ Use modeling to estimate residue levels
  - ✓ Use differential safety factors depending on the nontarget organisms to be protected
    - For example, use a larger safety factor if endangered species are of concern

12

Eco Hazard Assessment: The Sentinel Animals & Plants

- Rodents (small mammals)
- Birds
- Fish
- Aquatic arthropods (usually a Crustacean in the genus *Daphnia*)
- Honey Bees
- Nontarget Plants
  - ✓ For herbicides, the question to be answered is, will drift cause a problem to non-crop species

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Eco Hazard Assessment: What Is Measured & Used by EPA

- Acute Toxicity
  - ✓ Mortality following short-term exposure to the pesticide (estimated as LC_{50})
    - Aquatic invertebrates: 48 hour exposure
    - Fish: 96 hour exposure
- Chronic Toxicity
  - ✓ Reproductive and/or developmental adverse effects following exposure during the reproductive part of the lifecycle (seeking the NOAEC)
    - Aquatic invertebrates: Typically one month
    - Fish: Depends on the species

14

Eco Exposure Assessment for Terrestrial Organisms

- EPA uses a nomogram to generate data on food resources of terrestrial animals
- Based on a database of direct overspray studies conducted ~35 years ago and updated in 1994 (a.k.a. Kenaga nomogram)

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The "Kenaga" Nomogram for Estimating Terrestrial Exposure

Food Items	Maximum EEC (ppm)	Mean EEC (ppm)
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants; small insects	135	45
Fruits, pods, seeds, large insects	15	7

Need to know proportion of body weight consumed per day

EEC = "Expected" Environmental Concentration

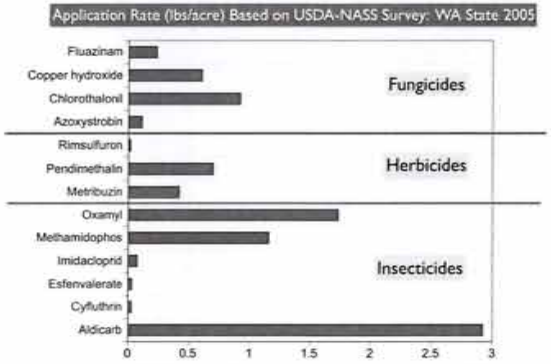
Eco Exposure Assessment: Aquatic Habitat

16

- EPA estimates aquatic nontarget organism exposure using computer simulation models
- Aquatic Pesticide Fate Simulation Model
  - ✓ PRZM (Pesticide Root Zone Model): translocation to water body
  - ✓ EXAMS (Exposure Assessment Model): fate in water
- Assumptions
  - ✓ 25 acre watershed is treated multiple times at the maximum label rate
  - ✓ Rainfall occurs after spraying, creating runoff to a receiving pond
  - ✓ The pond is 1 ha x 2 m deep
  - ✓ The volume of water does not change, nor is volatilization to the air considered

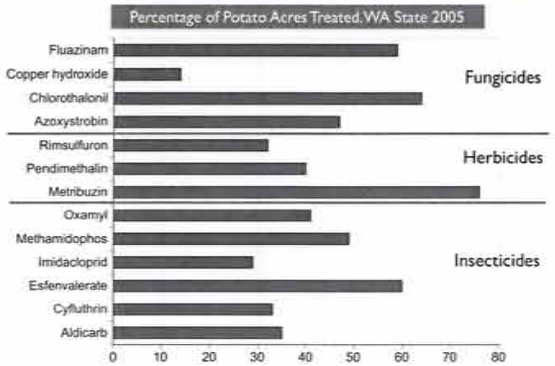
Modeling Incorporates Application Rates

17



Modeling Can Incorporate Percentage of Acres Treated

18



19

EPA's Pesticide Eco Risk Characterization Guidelines

"Safe" level is based on use classification & organism status

Risk Category	Risk Quotient (RQ) Calculation	Level of Concern (LOC)	Effective Safety Factor
Acute High	EEC/LC50	**0.5**	2
Acute Restricted	EEC/LC50	**0.1**	10
Endangered Species	EEC/LC50	**0.05**	20
Chronic	EEC/NOEC	**1**	1

EEC = "Expected" Environmental Concentration

20

An "Acceptable" Risk Quotient

Rainbow Trout **LC_{50}**

2,4-D Sodium Salt Concentration Lethal to 50% of Exposed Fish

101 mg/L (ppb), water

Aquatic Weed Control

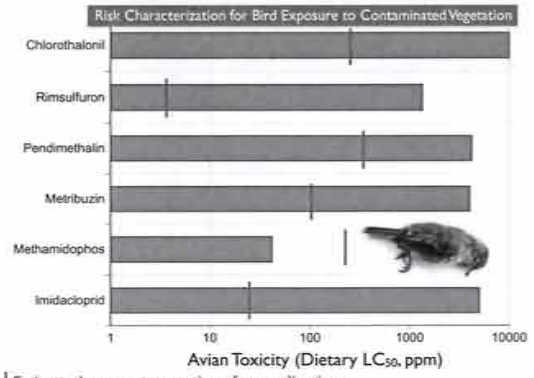
Maximum 2,4-D ppm = 4 (= EEC)

$$RQ = \frac{EEC}{LC_{50}} = \frac{4}{101} = 0.04$$

RQ < 0.05 = A-OK for endangered species

21

A Graphical Perspective of Risk Characterization



| Estimated ppm on vegetation after application

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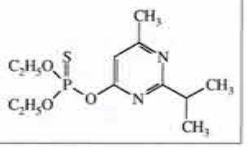
Case Study: EPA's Ecorisk Assessment for Diazinon

- Ecorisk characterizations for pesticides are published in a document called the Registration Eligibility Decision (RED)
- Includes human health and ecological fate and effects assessments
- Starts with overview of chemical, registration history, uses
- Discusses environmental chemistry & fate
- Discusses terrestrial and aquatic toxicity data & choice of most sensitive species
- Discusses results of exposure modeling
- Lists resulting RQs

Discusses management decision

Outcome of Human Health RA:
Diazinon dietary & residential exposure did not exceed the acute & chronic RfD or the MOE



23

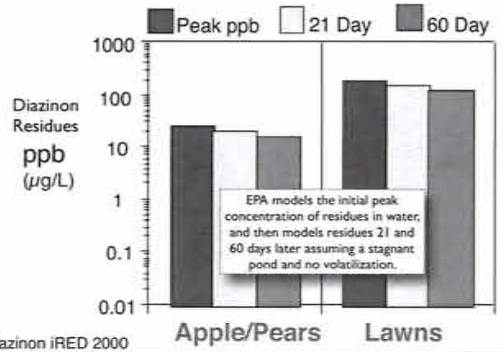
The Most Sensitive Aquatic Species Chosen by EPA in the Diazinon Ecological Risk Assessment

Species	Acute Toxicity LC50 (µg/L)	Chronic Toxicity NOEC (µg/L)
Rainbow Trout	90	--
Brook Trout	--	0.55
Scud	0.2	--
Water flea	--	0.17

1 µg/L = 1 ppb

24

Modeled Concentrations of Diazinon in Water Two Application/Use Scenarios



Diazinon iRED 2000

25

Puget Sound USGS NAWQA Results: Insecticides

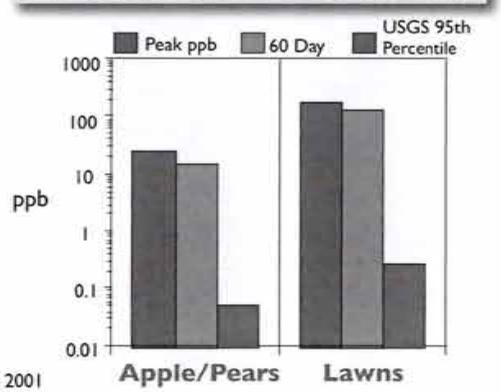
USGS = U.S. Geological Survey

NAWQA = NAtional Water Quality Assessment
Pesticide Synthesis Project

Active ingredient and trade name[1] example in parentheses	Freshwater aquatic-life criteria, in parts per billion (-- no aquatic-life criteria exist)			Concentration, in parts per billion (ppb) (RMC, recommended maximum concentration; Chronic aquatic-life criteria)
	Acute	Chronic	RMC	0.001 0.01 0.1 1 10
Insecticide				
Carbaryl (Sevin)	[4]0.17	[4]0.017	[2]0.02	
Chlorpyrifos (Dursban)	[3,7]0.083	[3,7]0.041	[2]0.001	
Diazinon (Diazinon)	[6]0.16	[6]0.04	[2]0.009	
gamma-HCH (Lindane)	[3]0.95	[7]0.08	[2]0.02	
Malathion (Malathion)	--	[3]0.1	[2]0.008	

26

Modeled vs. Empirical Residues of Diazinon in Water



Felsot 2001

27

EPA's Pesticide Eco Risk Characterization Guidelines

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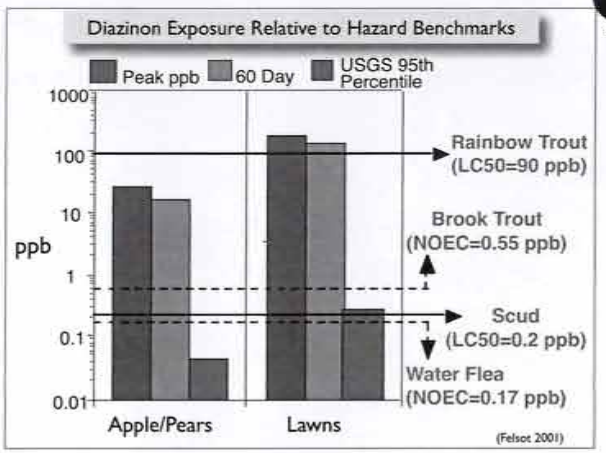
Chronic	EEC/NOEC	**1**	1

EEC = "Expected" Environmental Concentration

28



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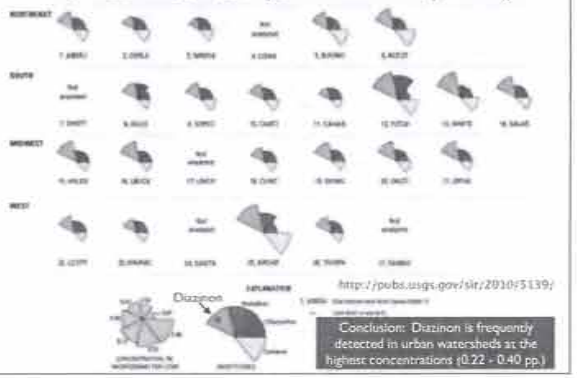
RQs for Diazinon
Modeled and Empirical Residue Levels

Exposure Scenario	Exposure Duration	Fish	Invertebrates
Apple/Pear	Acute	0.28	126
Apple/Pear	Chronic	28	121
Lawns	Acute	2.0	912
Lawns	Chronic	235	928
	USGS 95th%tile		
Urban Sites	Acute	0.01	1.2
Urban Sites	Chronic	0.44	1.4
Agric. Sites	Acute	0.0005	0.21
Agric. Sites	Chronic	0.08	0.25

30

A Perspective Based on USGS NAWQA Data for Urban Watersheds

NAWQA = NAtional Water Quality Assessment *Pesticide Synthesis Project*



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EPA "Decisions" for Diazinon

- Based on EPA modeled exposure (the EEC), all RQ's far exceeded the levels of concern
  - ✓ However, the RQ's were orders of magnitude lower if the USGS NAWQA database data were used
  - ✓ Nevertheless, the RQ's for endangered species concern would still be exceeded
- Because most of the diazinon hits were in urban watersheds (with the exception of the San Joaquin River Basin in California), EPA focused on mitigation in these areas
  - ✓ Basically, the manufacturers of diazinon (Syngenta & Makhteshim Agan) agreed to pull the pesticide off the urban use market
  - ✓ EPA restricted use and applications rates in other crops with registrations
  - ✓ Thus, risk mitigation & refinement resulted in the elimination of ~75% of diazinon uses (~5 million kg)

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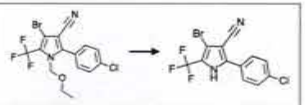
Chlorfenapyr Case Study

- Pyrrole class pro insecticide oxidatively N-dealkylated to metabolite acting as mitochondrial uncoupler of oxidative phosphorylation
- Registration request first submitted by American Cyanamid (purchased by BASF) in 1994
  - ✓ In 1995 Section 18 issued for 'emergency' use on cotton (beet armyworm outbreak)
  - ✓ Based on preliminary review of data indicating exposure would not result in human health concerns
  - ✓ Quick qualitative review of ecological hazards (no documentation in Section 18s)
- For consideration of Section 3 registration, no human health concerns (i.e., risk characterizations did not exceed EPA LOCs (levels of concern)
- However, major hazards to birds cited in more quantitative risk analysis (circa 1998)



Test	Result (mg/kg/d)	Tox Endpoint
LD50, oral	626	LD50
LD50, dermal	>2000	LD50
90-Day Dietary	24	NOAEL
2-year Dietary	3.6	NOAEL
RfD / PAD	0.05	NOAEL/100
Dermal / Oral Absorption %	13 / 20	@ 8 hr
Metabolism & Excretion	>90%	@ 48 h
Highest Dietary Risk Acute / Chronic	35 / 9.4	% of RfD

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Chlorfenapyr Ecorisk Assessment-Nontarget Tox

Most Sensitive Test Organisms	Exposure (time)	Acute LD50, LC50 or Chronic NOAEC	Highest Risk Quotient (RQ)
Rainbow Trout	Acute (96 h) Chronic (30 d)	7.44 µg/L 3.68 µg/L	0.56 0.66
Water flea (Daphnia)	Acute (48 h) Chronic (21 d)	5.83 µg/L 3.57 µg/L	0.71 0.77
Redwing blackbird Mallard duck Mallard duck	Acute Oral (1 d) Subacute Dietary Dietary (14 d)	2.21 mg/kg bw 1.63 mg/kg/d 0.059 mg/kg/d	Preliminary Assessment: All Endpoints Exceed LOC

Risk Refinements for Avian Risk Analysis

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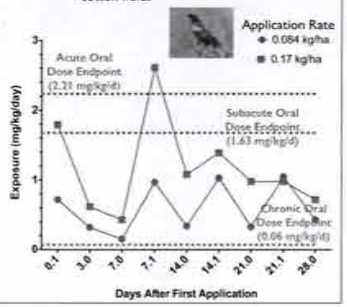
- All bird species studied were highly susceptible to chlorfenapyr, and thus in preliminary risk assessment using the Kenaga nomogram for exposure residues, all RQs exceeded LOCs
- In seeking to refine exposure assessment at a higher tier level, AmCy (BASF) submitted a semi field pen study
  - ✓ Later BASF submitted a probabilisitic risk analysis (PRA)
- EPA found flaws with the field study, but decided the residue values could be used to refine the risk characterization
  - ✓ The probabilistic risk analysis was also rejected with the conclusion of flawed assumptions
    - Note that the PRA was also analyzed by the FIFRA Scientific Advisory Panel (SAP), and EPA's conclusions were validated
- EPA re-ran the exposure assessments accounting for residue degradation on avian food sources and considering different application rates
  - ✓ The analysis used species likely to be visiting cotton fields



Avian Risk Mitigation for Chlorfenapyr

35

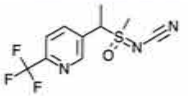
- After refining the exposure analysis, EPA calculated the RQs (based on red-winged blackbird) for acute, subacute, and chronic toxicity
- A refined risk analysis also assumed that only 10% of food source was from treated cotton field
  - ✓ RQs were still above the LOCs, leading to EPA canceling the Section 18 emergency use on cotton and a refusal to register chlorfenapyr for use on field crops, especially cotton
- The only registration for chlorfenapyr is the formulation Python miticide/insecticide for use on ornamental crops & fruiting vegetable crops in commercial greenhouses

Toxicity Test	Endpoint (mg/kg/d)	RQ Range (0.084 kg/ha)
Acute (Singe Oral Dose) LD50	2.21	0.07 - 0.48
Subacute Oral Dose (NOAEL)	1/63	0.09 - 0.64
Chronic Oral Dose (NOAEL)	0.059	2.46 - 17.81

Case Study: Sulfoxaflor, a New Neonicotinoid Insecticide from DowAgrosciences: Unconditionally Registered by EPA, May 2013

36

- Sulfoxaflor is considered a fourth generation neonicotinoid insecticide (chemical classification is sulfoximine)
  - ✓ It's mode of action is agonism of the nicotinic acetylcholine receptor, similarly to other neonics like imidacloprid
- Two products have labels, Transform & Closer
  - ✓ No residential uses; no seed treatments
  - ✓ Meant for foliar spray at application rates in the range of 0.02-0.05 lbs ai/acre
- Low acute oral & dermal toxicity to rats (1000 mg/kg & >5000 mg/kg, respectively)
- Dermal absorption is very low, <3%
- Body half-life (blood) is less than 12 hours
  - ✓ The main metabolite is not of toxicological concern



N-(methyloxido(1-(6-(trifluoromethyl)-3-pyridinyl)ethyl)gamma(4)-sulfanylidene) cyanamide

- The most sensitive endpoint of concern, decreased neonatal survivability in a developmental neurotoxicity study, yielded a NOAEL of 1.8 mg/kg
  - ✓ Based on this endpoint, the RfD (=PAD) for acute dietary exposures was 0.06 mg/kg/day
  - ✓ Risk characterization of dietary exposure based on expected food residues at the proposed tolerance level was at most 16% of the PAD (children 1-2 yrs)

37

Sulfoxaflor Has Low Toxicity to Aquatic Organisms & Birds

Most Sensitive Organism	Exposure (time)	Acute LC50 or Chronic NOAEC (mg ai/L = ppm)	Risk Quotient (RQ)
Bluegill sunfish Fathead minnow	Acute (96 h) Chronic (30 d)	363 0.66	<0.0001 0.08
Water flea (Daphnia)	Acute (48 h) Chronic (21 d)	>400 50.5	<0.0001 0.001
Midge	Chronic (28 d)	0.037 (=37 ppb)	--
Mallard Duck	Dietary (8 d)	5620	<0.01

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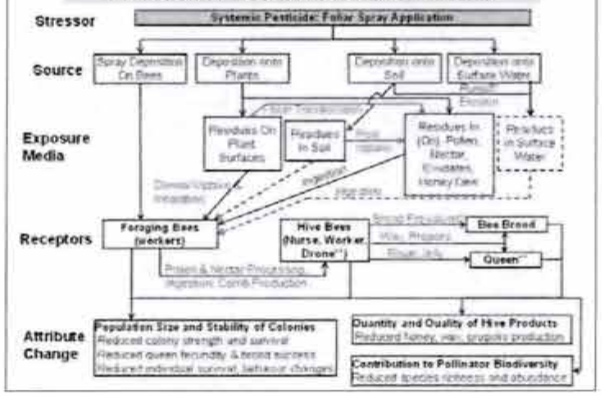
Generic Conceptual Model of Systemic, Foliar-Applied Pesticides for Honey Bee Risk Assessment (Problem Formulation)



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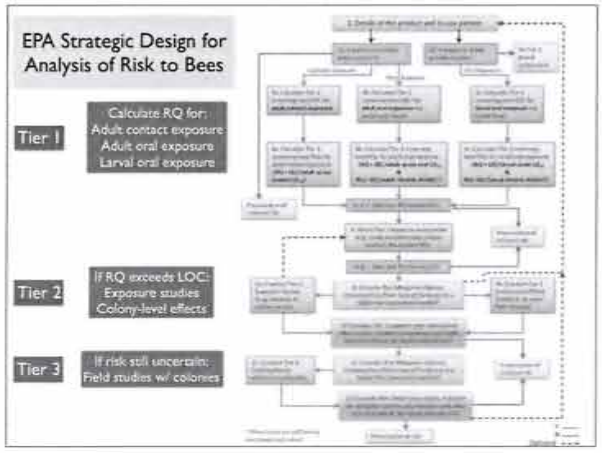
EPA Strategic Design for Analysis of Risk to Bees



40

Hazard ID for Bees: Relevant Endpoints

- Lethal Effects
  - ✓ Increased rate of mortality among dosed bees compared to undosed control bees
    - Exposure via lab or semi-field exposure to "spiked" sugar water
    - Field exposure (controlled plot spraying or soil application)
- Sublethal effects
  - ✓ Dosed colonies or individuals exhibit modified performance with respect to growth, fecundity, longevity or behavior
  - ✓ At colony level, performance measures include...
    - Rate of increase in colony mass
    - Activity at hive entrance or remote feeder
    - Quantity of brood produced
  - ✓ At individual bee level, performance measures include...
    - Learning ability
    - Rate of food uptake
    - Level of locomotory Activity

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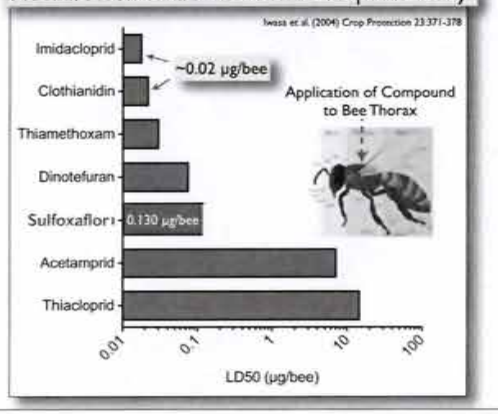
Not All Neonics Are Created with Equal Potency



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Bees: A Horse of a Different Color

Tier I exposure values of honey bees to pesticides applied via foliar applications

Life Stage	Exposure Type	Dose (µg a.i./bee per 1 lb a.i./A)[1]	Sulfoxaflor Dose for Max Application Rate (µg a.i./bee per 0.133 lb a.i./A)	Acute RQ[2][3]
Adult	Diet (nectar + pollen)	32	4.3	83
Adult	Direct contact	2.7	0.72	2.8

Risk characterization based on a 48-h acute oral LD50 of 0.052 µg ai/bee and acute contact LD50 of 0.130 µg ai/bee

For bee risk characterization and determination of level of concern (LOC), EPA uses an RQ of 0.4; as you can see, the screening level Tier I analysis "failed", with the exposure scenarios exceeding EPAs LOC

Refined Tier I Analysis Using Adjusted Residue Concentrations Based on Actual Measurements

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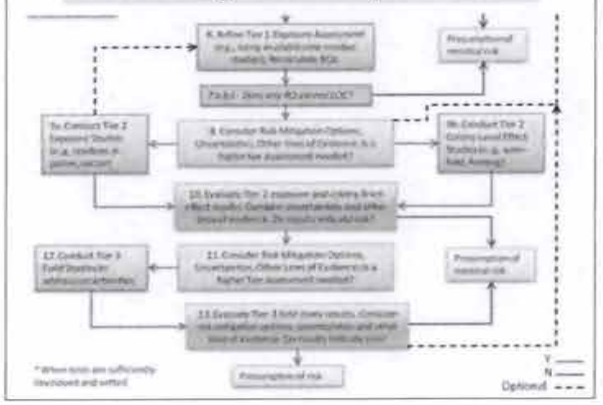
Life Stage	Cast/Task	Average Age (d)	Total food Consumption (mg/d)	Estimated Oral Dose (ug ai/bee/d) [2]	Acute RQ [2,4]
Larvae	Worker	days 4+5	119	0.151	<0.8
	Drone	Days 5+6	152	0.153	<0.8
Adult	Worker (cell cleaning and capping)	0-10	65	0.095	1.8
	Worker (brood and queen tending, nurse bees)	6-17	149	0.200	3.9
	Worker (comb building, cleaning and food handling)	11-18	62	0.072	1.4
	Worker (foraging for pollen)	>18	43.5	0.044	0.9
	Worker (foraging for nectar)	>18	292	0.294	5.7
	Worker (maintenance of hive in winter	0-90	31	0.042	0.8
	Drone	>10	235	0.236	4.6
	Queen	0+	unknown	unknown	unknown

Higher Tier Risk Analysis

44



Tier II Risk Analysis

45

- A higher level risk analysis for bees was carried out by using actual colonies in semi-field studies
  - ✓ The results of these studies are descriptive and not as amenable to a RQ calculation
- EPAs conclusions (as written in the Registration Eligibility Decision document)
  - ✓ "Results form Tier 2 semi-field studies suggest that at the application rates used (4-150% of U.S. maximum), the direct effects of sulfoxaflor on adult forager bee mortality, flight activity and the occurrence of behavioral abnormalities is relatively short lived, lasting 3 days or less."
  - ✓ "With regard to brood development..."no catastrophic effects are expected from use of sulfoxaflor."
  - ✓ "The colony strength of hives exposed to crops treated with sulfoxaflor at 4-150% of the proposed U.S. maximum rate was similar to control or pre-exposure hives in four studies where this endpoint could be evaluated."
- Although EPA generally was not concerned about sulfoxaflor effects on bees based on the Tier II study, some uncertainties about longer term effects remained

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Conclusions About Risk Mitigation & Refinement

- The pesticide risk assessment process at EPA is dynamic
  - ✓ Screening level assessments (Tier 1) are standard across all pesticides under consideration for registration or re-registration
  - ✓ Registrant hazard ID data packages are usually sufficient to conduct the needed risk analyses
  - ✓ Exposure is often assumed as "worst-case"
- When data are available, EPA will conduct higher tier assessments to refine the exposure analysis
  - ✓ Exposure can be more realistic and reflect environmental fate over time
- To mitigate risk, EPA can either refuse registration (for ex., on a particular crop or for a use area) and also require restrictions on the product label

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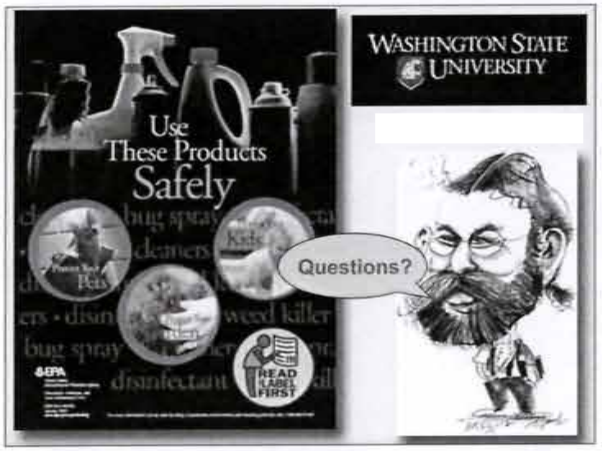

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Principles for Developing Regional Exposure Scenarios

Santiago de Chile, May, 2015

Ximena Patino, MSc, DMV
Bayer CropScience

CropLife

Outline

- Determining the Exposure Component
- Exposure Assessment Efforts in Latam
- Conclusions

2

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Determining the Exposure Component

Risk = Hazard x EXPOSURE

Exposure = f (scenario, PPP properties)

Environmental Fate Data Requirements in Latam

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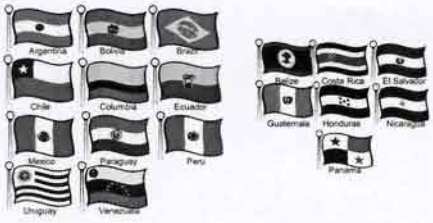

Environmental Fate Data Requirements in Latam

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Study Type	Required	Conditionally required
Soil aerobic degradation	18 *	1
Soil anaerobic degradation		13
Soil photolysis	8	
Mobility: Soil adsorption and desorption	19	
Mobility: column leaching	1	
Hydrolysis	19	
Phototransformation in water	18	
Ready biodegradability	1	
Water/sediment system degradation	12	
Soil dissipation		6
Other studies		5 *
Air: Vapor pressure and Henry's law constant	19	

Studies submitted as summaries or complete report
* spanish/portuguese summary

Determining the Exposure Component

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- **Scenario** is a set of parameters describing a series of agricultural production conditions and environmental conditions. It supports the environmental exposure models used.
- Parameters include
  - crop growth and development period,
  - meteorological data,
  - hydrological data,
  - physical and chemical properties of soils,
  - characteristic parameters of environmental organisms.

Determining the Exposure Component

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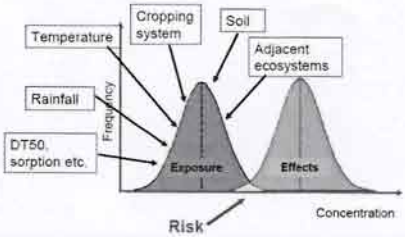

Modified from CLA/Andreas Huber 6 July 2007

How do we do integrate the scenario and PPP proerties?

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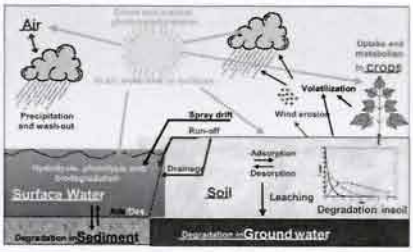
A MODEL can be used to calculate the exposure in different compartments



Model - Thoughts

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- A mathematical simulation of a natural system which allows investigating the behavior or effects of a chemical and making predictions
- But a model has limitations – It is not an identical copy of what it is simulating
- And the model must be related to the scenario!

Exposure Assessment Efforts in Colombia

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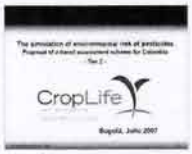

2001

2006 – CL - Agreement on crops, weather & soil databases

2007 - Workshop with Colombian regulators & adjustments to Tier III model

2010 - Official handout to Colombian Environmental Ministry

Background

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- 2001 - Implementation of ERA
- 2006 - Croplife initiated activities with Colombian regulators.
  - Agreement on crops, weather & soil databases
- 2007 - (July) Workshop with Colombian regulators & (Nov) Adjustments to Tier III model
- 2008 / 2009 - Presentations at SETAC, IUPAC.
- 2010 - Official handout to Colombian Environmental Ministry

Scenarios Selected

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- Tomato – Tomato and other vegetables (2 cycles)
- Potato – Potato and other vegetables (1 cycle)
- Banana
- Rice

Geographical & Weather Data

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Land Cover

GLC2000

USGS, vers. 2.0

Crop Statistics

FAO, 2007

Soil Map

FAO/ISRIC, 2005

Weather stations

NOAA - GSD

Tiered Schemes for SW

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Tier 1 + 2
(simple worst-cases FOCUS)
Tier 3
(realistic worst-case scenarios)

Tier 1
(simple worst-cases SCIGROW, GENEEC)
Tier 2
(realistic worst-case scenarios)

Colombia

Tier 1 + 2
(simple worst-cases GUS, SCIGROW, GENEEC)
Tier 3
(realistic worst-case scenarios)

Tiered Assessment Proposal

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Ecological focus

	Tier 1	Tier 2	Tier 3	Tier 4
Groundwater	GUS index	SCI-GROW		Field study/ Monitoring
Surface Water	Calculation based on water solubility	GENEEC GENRice	PRZM/ EXAMS + Colombian scenarios	Monitoring

Fixed by regulation

Assessing SciGrow Protectiveness

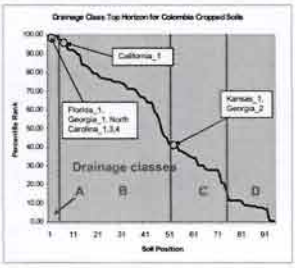
CropLife

Driving variables for pesticide leaching	Available data
Volume of leachate outflow Soil characteristics	Drainage classes of Colombian soils
Rainfall volumes	Rainfall data from Colombian stations
Sorption and degradation of pesticides Organic matter content	Organic matter content of Colombian soils
Temperature	Not considered

Soil Comparison

CropLife

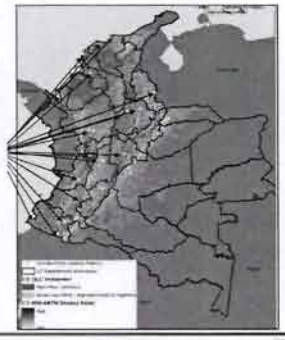
- Vulnerability of Colombian soils for pesticide leaching compared to SciGrow
  - SciGrow soils are primarily class A – highly vulnerable
  - Colombia: Very few soils are class A. >95% are class B, C, D.



Weather Analysis

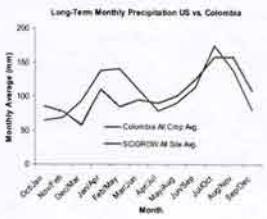
CropLife

Selected stations with complete data for > 10 yrs

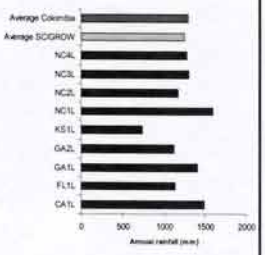


Weather Analysis
Rainfall

CropLife



Annual rainfall SCIGROW vs. Colombia



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SciGrow Protectiveness
Conclusion

CropLife

- SciGrow is likely to provide sufficiently conservative estimates for pesticide leaching under Colombian conditions
- SciGrow soils represent a clear worst case opposite typical agricultural soils in Col.
- Total annual rainfall volumes of SciGrow sites are comparable with Colombian weather conditions.
- Higher temperatures in Colombia were not considered in the assessment – faster degradation, no winter.

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Assessing Geneec Protectiveness

CropLife

Driving variables for surface runoff	Available data
Volume of runoff water Infiltration capacity, susceptibility for surface sealing, etc..	Not considered. Geneec uses a fixed runoff %
Pesticide mass available for runoff Rainfall re occurence	Rainfall data from Colombian stations

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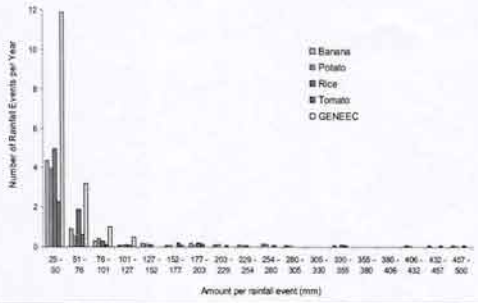
Weather Analysis
Rainfall



Geneec Protectiveness
Conclusion

- Geneec is likely to provide sufficiently conservative estimates for pesticide runoff under Colombian weather conditions here
  - Geneec represents a large number of small events which are more frequent than Colombian rainstorms.
    - -Short time intervals between application and event
    - -Lower runoff volume
    - -Higher concentrations
  - Large rainstorm events common in Colombia result in significant dilution in runoff
    - -Lower concentrations
    - -High mass loading into receiving waters

Surface Water - Rice
Genrice

- Proposed model - Genrice
  - Model based on Geneec but uses different geometry of water body to mimic rice paddies.
  - Conservatism of rice scenario is dependent on cropping practices (more or less independent from landscape factors).

Surface Water – Tier 3

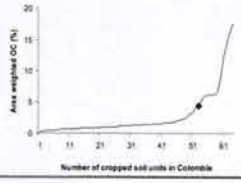
Colombian EXPRESS

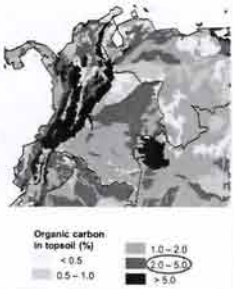
- Runoff scenarios were created for each location where min. 20 years of weather data was available.
  - Runoff dependent on timing between application and rainfall
  - Soil selected for worst case runoff

- Runoff scenarios were created and incorporated into the PRZM-EXAMS model shell (potato, tomato, banana)
  - Soil, climate and cropping data (digital form)

Soil Vulnerability

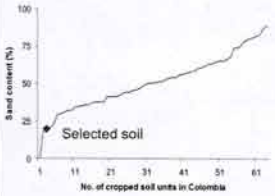
- Organic carbon content is a worst case for most cropping areas in Andean valleys.
- Organic carbon content is a typical case for lowland areas

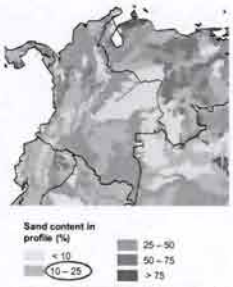




Soil Vulnerability

- Sand content is a worst case for runoff





Scenarios Created
Colombian EXPRESS

CropLife

Banana	Tomato (2 crop cycles)	Potato
Medellin Baranquilla	Medellin Cucuta Bogotá Huila Cali	Medellin Bogotá

Colombian Exposure Calculator
Colombian EXPRESS

CropLife

Opportunities for improvements

CropLife

- Clarify the objectives of the evaluation
  - Human health
  - Ecological risk
- Develop agreement and guidance on model inputs
  - Investigate the affect of different approaches to DT50, sorption coefficients
- Prepare framework for higher tier modeling
  - Effect of weather, soil on relative vulnerability to leaching and runoff
  - Interpretation of spatial analyses
  - Incorporating mitigation

Brazil

CropLife

- 2002
- 2009 - Croplife training session – Ibama
- 2012 – Croplife training focus on ERA – Ibama
  - A similar aquatic exposure tool was built (training purposes)
- 2014 – Workshop on Protection Goals – Ibama – Andef - Academia

BZMT – Brazil Modeling Tool

CropLife

- Tool to conduct Tier 3 Aquatic and Groundwater exposure assessments

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BZMT – Scenarios

CropLife

- Defined by Crop, Soil, Weather, and Receiving Water

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BZMT - Scenarios

CropLife

- Scenarios can be added to tool based on desired crop/soil combinations
- Examples provided for major sugarcane, soybean and potato production areas
  - ✓ Soil – Harmonized World Soils Database/
    -Predominate soil prone to runoff or leaching in area of major production
  - ✓ Weather – Global Historical Climatology Network (GHCN-DAILY), Version 2.91
  - ✓ Cropping (growing season length, root depth, maximum cover, etc.) from USEPA standard scenarios (adjusted to Brazil timing)

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BZMT – Sugarcane Scenario (Production Location, Soil, Weather)

CropLife

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BZMT – Soybean Scenario (Production Location, Soil, Weather)

CropLife

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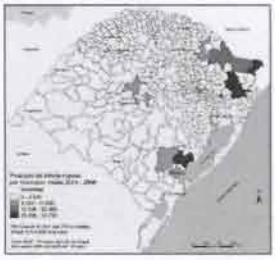
BZMT – Potato Scenario (Production Location, Soil)

CropLife



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Brazil Scenario – Selected Soil Properties

CropLife

Property	Sugarcane		Soybean		Potato	
	Runoff	Leaching	Runoff	Leaching	Runoff	Leaching
Soil Mapping Unit	12864	12711	12642	12656	12633	12620
Soil Unit Symbol (FAO 90)	FRr	LXh	FRx	FRr	ARh	ALu
Soil unit Symbol (FAO 90)	Rhodic Ferralsols	Haplic Lixisols	Xanthic Ferralsols	Rhodic Ferralsols	Haplic Arenosols	Humic Alisols
Topsoil Texture	Fine	Coarse	Medium	Medium	Coarse	Medium
Topsoil Sand Fraction (%)	13	91	75	75	89	49
Topsoil Silt Fraction (%)	25	3	5	7	5	28
Topsoil Clay Fraction (%)	62	6	20	18	6	26
Topsoil USDA Texture Classification	clay(heavy)	sand	sandy clay loam	sandy loam	sand	loam
Topsoil Reference Bulk Density (kg/dm3)	1.18	1.68	1.47	1.48	1.67	1.38
Topsoil Organic Carbon (% weight)	1.2	0.3	0.73	0.88	0.4	2.63
Topsoil pH (H2O)	5.3	6.4	5.2	4.3	5.5	5

- Source: Verelst, Luc. 2009. Harmonized World Soil Database Viewer (HWSD), Version 1.10 – March 2009 and Dijkshoorn JA, Huting, JRM and Tempel P, 2005. Update of the 1:5 Soil and Terrain Database for Latin America and the Caribbean (SOTERAC; version 2.0). Report 2005/01, ISRIC – World Soil Information, Wageningen. .

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Brazil Scenario – Selected Cropping Parameters

CropLife

PRZM Parameter	Variable	Sugarcane		Soybean		Potato	
Weather Station (Precip., Temp., ET)		San Paulo and Curitiba		Dourados		Ponta Grossa	
		Value	Source	Value	Source	Value	Source
Pan Evaporation Flag	IPEVAP	1	Temperature read from MET file	1	Temperature read from MET file	1	Temperature read from MET file
Evaporation Retention Minimum Depth (cm)	AMETD	20.5	PRZM Manual Figure 5-2	25	PRZM Manual Figure 5-2	22	PRZM Manual Figure 5-2
Crop Emergence Date	EMD,EMAY,NEM	15-Oct	Planting Oct. 5 (pick from Mar, Oct, Oct. winters)	15-Sep	Soybean and Corn Annual - Brazil Monthly Month Crop Cycle	1-Mar	American Potato Journal - Potato growing in Brazil
Crop Maturation Date	MAD,MAM,YRMAT	1-Jun	240 days after planting	27-Feb	139 days after emergence	15-May	75 days after emergence
Crop Harvest Date	HAD,HAM,DYRHAR	3-Oct	365 days after planting	13-Mar	171 days after emergence	15-Jun	105 days after emergence
Maximum Interception Storage (cm)	CINTCP	0.1	USEPA Standard MS Soybean Scenario	0.2	USEPA Standard MS Soybean Scenario	0.1	USEPA Standard ID Potato Scenario
Maximum Active Root Depth (cm)	AMXDR	150	USEPA Standard FL Sugarcane Scenario	80	USEPA Standard MS Soybean Scenario	60	USEPA Standard ID Potato Scenario
Maximum Areal Coverage (%)	CONMAX	100	USEPA Standard FL Sugarcane Scenario	100	USEPA Standard MS Soybean Scenario	40	USEPA Standard ID Potato Scenario
Runoff Curve Number for AMC II	CN (Leaching)	72, 72, 72	PRZM Manual Table 5-10 (A, row, pasc)	83, 78, 83	PRZM Manual Table 5-10 (B, row, gold, area)	78, 70, 74	PRZM Manual Table 5-10 (A, row, gold, pasc)
	CN (Runoff)	91, 91, 91	PRZM Manual Table 5-10 (D, row, pasc)	89, 86, 89	PRZM Manual Table 5-10 (D, row, gold, area)	86, 84, 86	PRZM Manual Table 5-10 (D, row, gold, pasc)
Max. Canopy Height	HTMAX	600	USEPA Standard FL Sugarcane Scenario	70	USEPA Standard MS Soybean Scenario	30	USEPA Standard ID Potato Scenario

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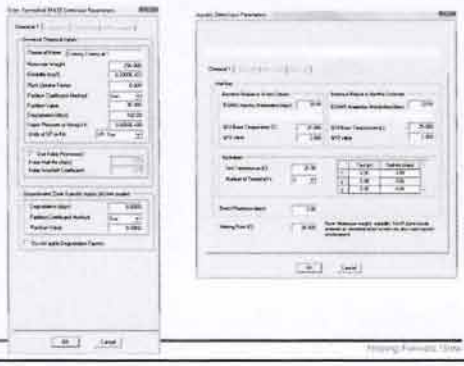
BZMT – Environmental Fate

CropLife



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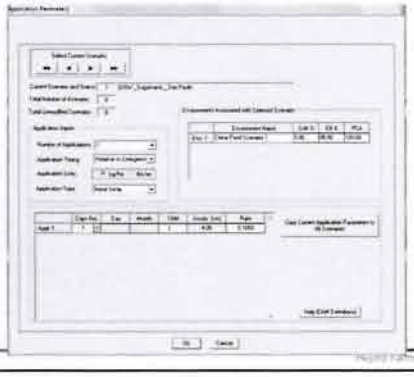
BZMT - Application

CropLife



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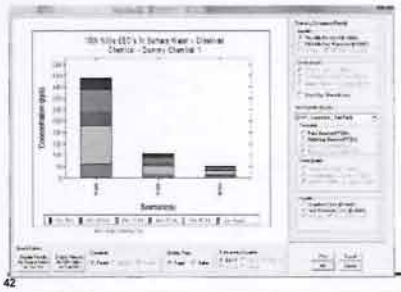
BZMT – Run and Results



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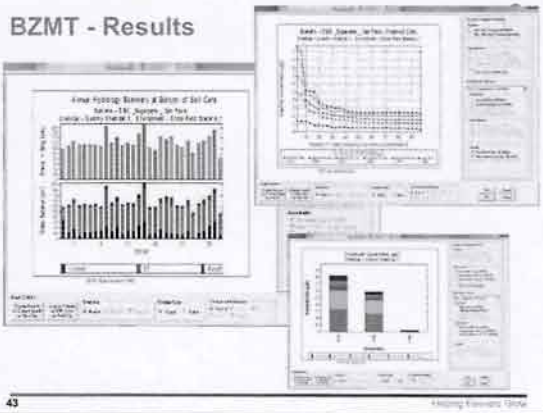
BZMT - Results



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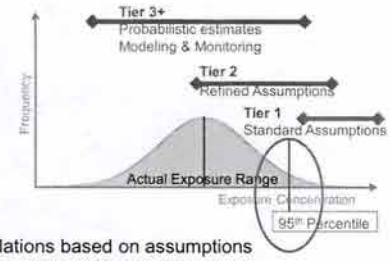
Exposure Tools Currently used in Brazil

CropLife

- Tier I
- Geneec
- SciGrow
- ARAqua
- T-Rex
- Terrplant

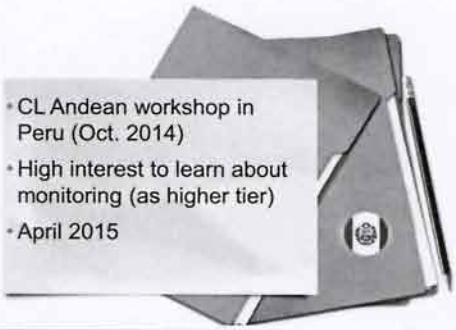
Exposure Assessment Options

CropLife



- Modeling
  - Simple calculations based on assumptions
  - Computer simulations of fate and transport
- Monitoring
- Integrated monitoring and modeling

Peru



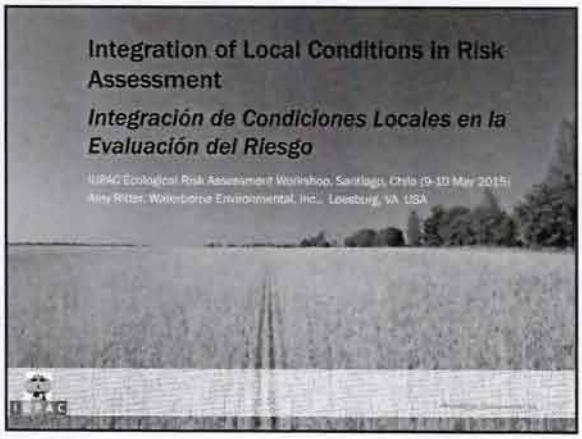
- CL Andean workshop in Peru (Oct. 2014)
- High interest to learn about monitoring (as higher tier)
- April 2015

Conclusions

- Modeling is a valuable tool for providing predictions of concentrations of pesticides prior to registration and use, but the scenario assumptions and model must relate to the field reality!
- Exposure assessment efforts in Latam – reasonable approaches

Questions?

Thank you!



Integration of Local Conditions

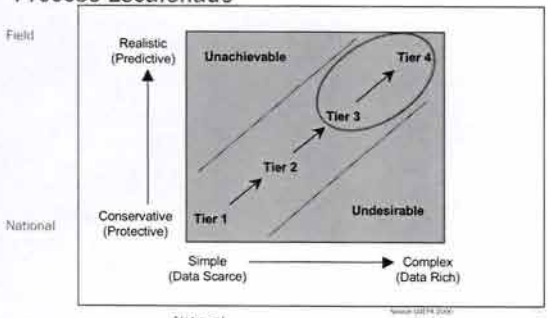
Integración de Condiciones Locales

- Tiered approach to ecological risk assessment – higher tiers
- Driving factors: exposure settings, landscape, processes, and use
  - Species: toxicity studies, protected species
  - Variation of exposure on a regional scale
  - Methods of best management practices for exposure reduction on a watershed scale
  - Methods of characterizing and reducing exposure on a field scale

2

Tiered Process

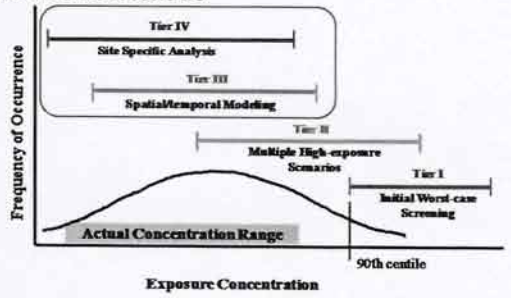
Proceso Escalonado



3

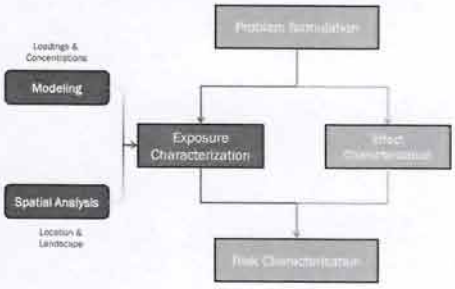
Tiered Process

Proceso Escalonado



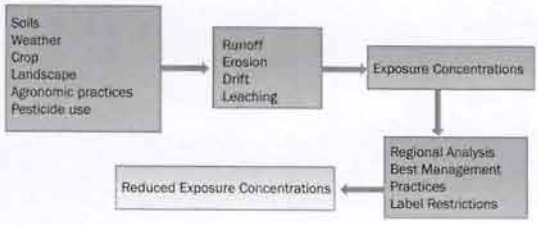
Risk Assessment

Evaluación de Riesgo



Ecological Exposure

Exposición Ecológica

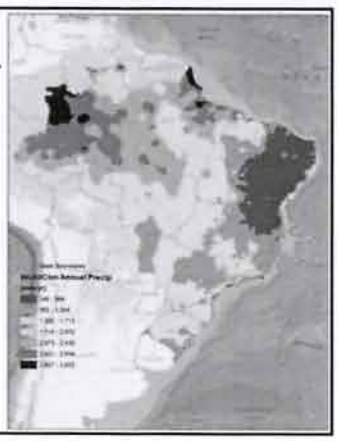


Soils
Suelos

- Texture of dominant topsoil

Weather
Clima

- Long-term annual average rainfall (1950 - 2000)



Crops
Cultivos

- 3 classes that represent general agriculture:
  - Rainfed croplands
  - Mosaic: Cropland/Vegetation
  - Mosaic: Vegetation/Cropland

Landscape

Paisaje

- Elevation and major rivers in Brazil
- The elevation is based on the 1 km Shuttle Topology Radar Mission (SRTM)

Pesticide Use and Agronomic Practices

El Uso de Pesticidas y Practicas Agronómicas

- Application Rate and Number of Applications
  - Maximum versus typical
- Method
  - Aerial, airblast, ground spray, incorporated, granular
- Timing
  - Pre-emergent (bare ground), later growth stage (crop interception), wet season
- Pesticide properties
  - Degradation, (ad)sorption
- Agronomic practices
  - Crop residues after harvest, irrigation, till versus no till, terracing and/or contouring

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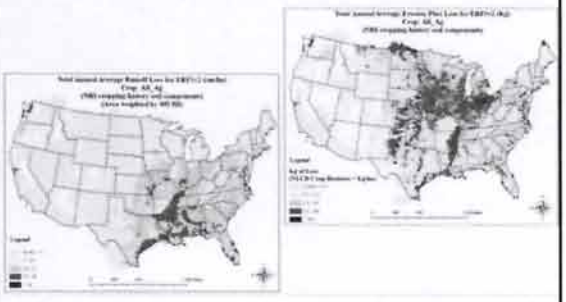
Runoff and Erosion Potential

Potencial para escorrentía y erosión



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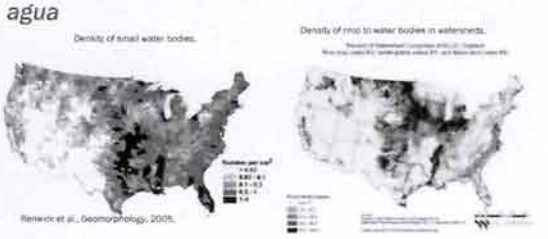
Leaching Potential

Potencial para Lixiviación

13

Drift Potential with Proximity to Water

Potencial de Derivación con la Proximidad al agua



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Landscape – Best Management Practices

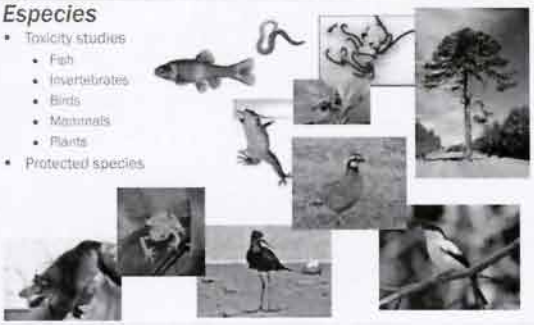
Paisaje- Mejores Prácticas de Gestión

15

Species

Especies

- Toxicity studies
  - Fish
  - Invertebrates
  - Birds
  - Mammals
  - Plants
- Protected species



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Variation of exposure on a regional scale

Variaciones de la exposición a nivel regional

17

Seasonal Rainfall

Lluvias Temporales

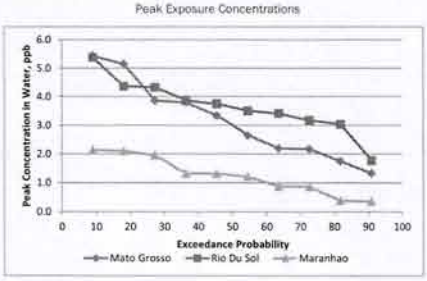
Corn Acreage

Terrenos con Milpa

18

Annual Maximum Series

Serie Maximo Anual



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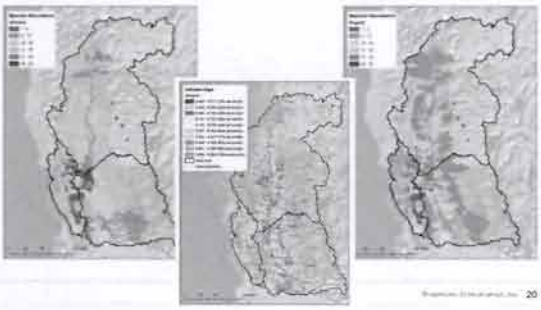
Co-occurrence Species Richness / Chemical Loadings

Co-ocurrencia de Riqueza de Especies/ Cargas quimicas



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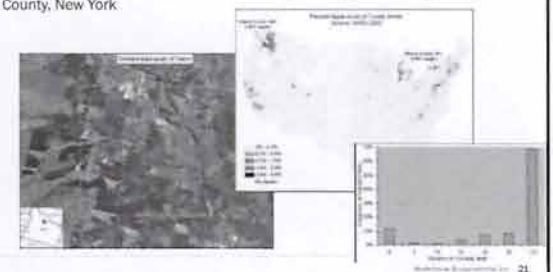
Field Proximity to Water

Proximidad del campo al agua

Orchard buffer characterization and potential for exposure of aquatic habitats to runoff near orchards in Yakima, Washington and Wayne County, New York



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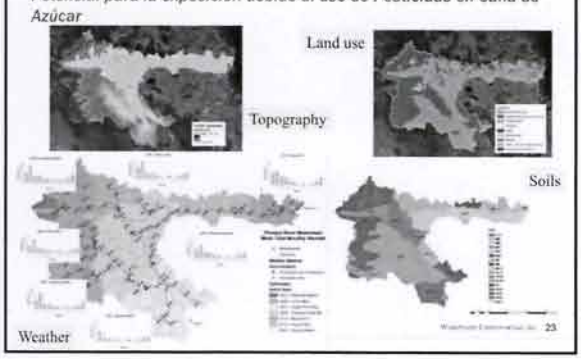
Example of best management practices on a watershed scale

Ejemplo de mejores prácticas de gestión a nivel de cuencas hidrográficas

22

Potential Exposure from Pesticide used on Sugarcane

Potencial para la exposición debido al uso de Pesticidas en Caña de Azúcar



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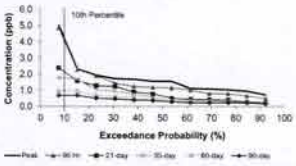
Combining all the Data Layers

Combinando todos las Capas de Datos

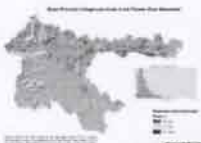
Frequency analysis on the maximum series



Best Management Practices (BMPs)

Mejores Prácticas de Gestión (MPGs)

- Application rate and timing
- Drift reduction
- Trash layer
- Cultivation practices (reduced tillage)
- Vegetative filter strip
- No application on slopes > 5%
- No application within 100 m of water



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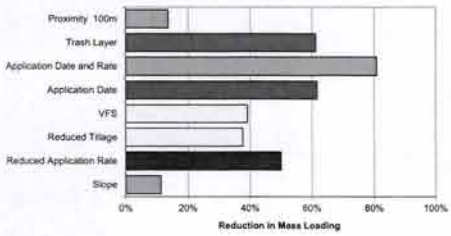
BMP Results

Resultados de las MPG

12-year average reduction in mass loading (total mass) in the watershed

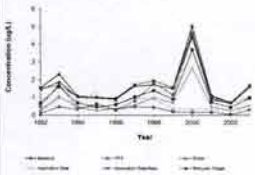


26

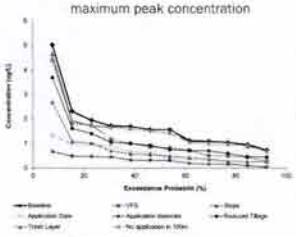
BMP Results

Resultados de las MPG

Annual maximum peak concentration



Frequency analysis of the annual maximum peak concentration



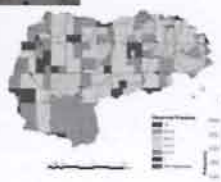
27

Field-scale Assessments and Restrictions
Evaluaciones y Restriciones a nivel del Campo

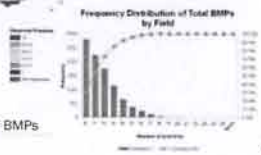
28

Field-scale BMP Assessment
Evaluacion de MPG a nivel del Campo

Use of high-resolution photography to identify on-the-ground management practices



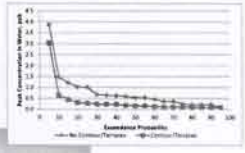
Practices are determined at the field level



Distribution of BMPs

9

Contours/Terraces
Contornos / Terrazas

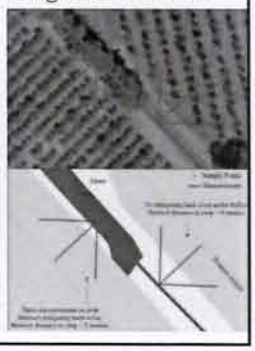


30

Variability of Exposure along Perimeter

Variabilidad de la exposición a lo largo del Perímetro

- Mitigating land cover in the buffer can include dense trees, sparse trees, hedgerows, scrub, etc.



Characterizing buffers

Caracterizando las franjas de protección

- Analyze the width and land cover types within the buffer, when a buffer exists
- Document land cover type and length from crop to water

Class	Total # of measurements	Total # measurements to crop	Total # analyzed (shortest distance to crop)	Average Buffer Width (m)
Streams	3,004	1,803	662	32
Rivers	2,582	1,036	478	41
Canals	60,904	50,193	10,512	14
Ponds	49,648	38,226	10,685	17
All Water	116,148	91,258	22,337	16

Implementation of drift and runoff mitigation is possible, based on composition of land cover between crop and water

Characterization of Potential Exposure

Caracterización de la Exposición Potencial

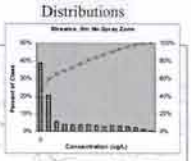
Simple Measurements

Class	Percent Crop Within Margin				
	5m	10m	15m	20m	25m
Streams	8%	24%	36%	43%	48%
Rivers	0%	0%	0%	1%	1%
Canals	28%	44%	54%	60%	64%
Ponds	6%	18%	29%	37%	42%
All Water	23%	40%	50%	56%	60%

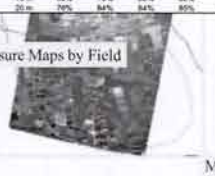
Selected Percentiles

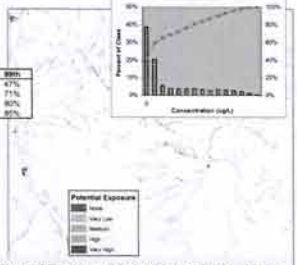
Class	Margin	50th	75th	80th	85th	90th
Streams	5 m				7%	47%
	10 m	55%	70%	71%	71%	71%
	15 m	69%	79%	80%	80%	80%
	20 m	70%	84%	84%	85%	85%

Distributions



Exposure Maps by Field



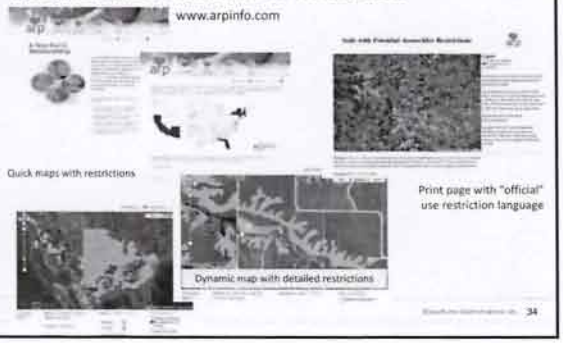


Maps of Exposure Variability by Water Body

Field-scale Restrictions based on Soils

Restricciónes basadas en los suelos

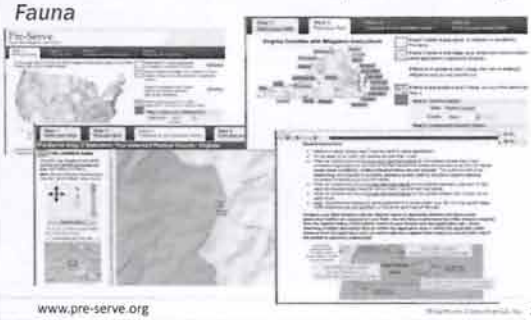
www.arpinfo.com



34

Field-scale Restrictions based on Species

Restricciónes basadas en las Especies de Flora y Fauna



www.pre-serve.org

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Discussion

Discusión

- More complex data can provide more realistic exposure concentrations and higher confidence
- Best management practices and mitigation can reduce exposure
- Spatial analysis can help to characterize risk down to a field scale
- Restrictions on labels can prevent growers from using the product in vulnerable fields

Thank You

Gracias

- Any questions?

WASHINGTON STATE UNIVERSITY

Ecological Risk Assessment Workshop
Santiago, Chile: May 9-10, 2015

1

Implementation and Enforcement

Allan Felsot
Washington State University
Department of Entomology
College of Agriculture Human & Natural Resources Sciences
School of the Environment; School of Biological Sciences

AGRICULTURE | YOUTH & FAMILIES | HEALTH | ECONOMY | ENVIRONMENT | ENERGY | COMMUNITIES

The Agenda

2

- Implementation authority as practiced in the U.S.
  - ✓ Overview of U.S. pesticide law
  - ✓ How amendments to FIFRA have affected implementation of risk mitigation ("Reduced Risk Pesticide Program")
  - ✓ The product label has the force of U.S. Federal law
- Enforcement authority as practiced in the U.S.
  - ✓ Federal Insecticide Fungicide Rodenticide Act (1947 & amendments)
  - ✓ State Departments of Agriculture & Environmental Protection Agencies (or similar)
  - ✓ Examples of enforcement actions at Federal & State level
- Intrusion of Federal courts into EPA activities
  - ✓ Role of 'citizen' lawsuits and court judgements
  - ✓ Case Study: Salmon Stimulated Lawsuits

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U.S. Pesticide Law 101

FIFRA (1947) → FEPCA (1972) → Risk Assessment

FFDCA (1938) → Miller (1954), Delaney (1958) → Tolerance ("MRL")

Ecological | Human Health

Labeling → **Registration**

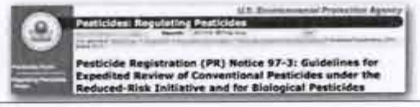
FQPA (1996)

4

Using Congressional Mandates to Implement Risk Reduction

EPA's Reduced Risk Pesticide Initiatives

- First started in 1993, before the FQPA (Food Quality Protection Act)
- Updated after the FQPA (1996) to provide incentives to manufacturers
  - ✓ Expedited chemical review and significantly quicker commercial registration
- By 1997, EPA had already approved 22 new active ingredients as "reduced risk"
  - ✓ Given timeline for research, development & market entry (>6 yr.), chemical companies were way ahead of government policy



5

Reduced Risk Pesticides

- A term used by the EPA to designate a pesticide with one or more (ideally all) of the following properties
  - ✓ Low impact on human health
  - ✓ Low toxicity to non-target organisms (birds, fish, plants)
  - ✓ Low potential for water contamination
  - ✓ Lower use rates
  - ✓ Low potential for development of pest resistance
  - ✓ Compatibility with IPM (e.g., low toxicity to parasitoids & predators)
- The above properties are examined in comparison to older conventional pesticides already on the market (e.g., OP, CB, and pyrethroid insecticides)

6

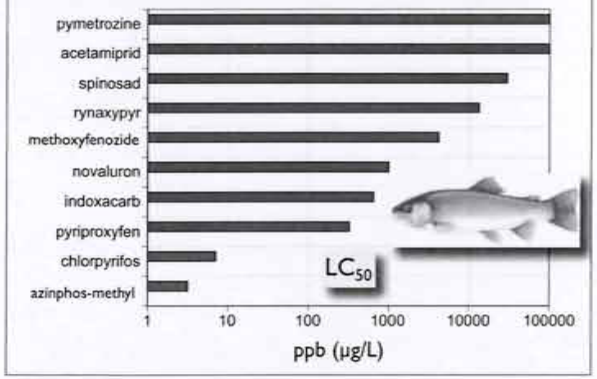
7

Selectivity of New Insecticides (Commercialization post 1990)

Active Ingredient	Formulation	Oral LD50 (mg/kg)	Dermal LD50	NOAEL (mg/kg/d)
Azinphos-methyl	Guthion	4.4	155	0.149
Chlorpyrifos	Lorsban	223	222	0.03
Acetamiprid	Assail	1064	>2000	7.1
Indoxacarb	Advion	1277	>5000	2
Pyriproxyfen	Esteem	4253	>2000	35
Methoxyfenozide	Intrepid	>5000	>2000	10.2
Novaluron	Rimon	>5000	>2000	1.1
Pymetrozine	Fulfil	>5000	>2000	0.377
Spinosad	Success	>5000	>2000	2.7
Rynaxypyr	Altacor	>5000	>5000	158

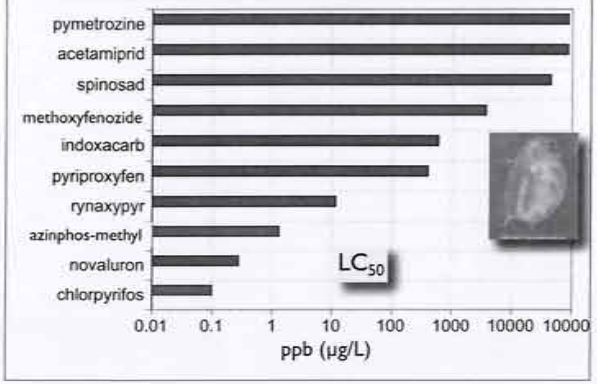
8

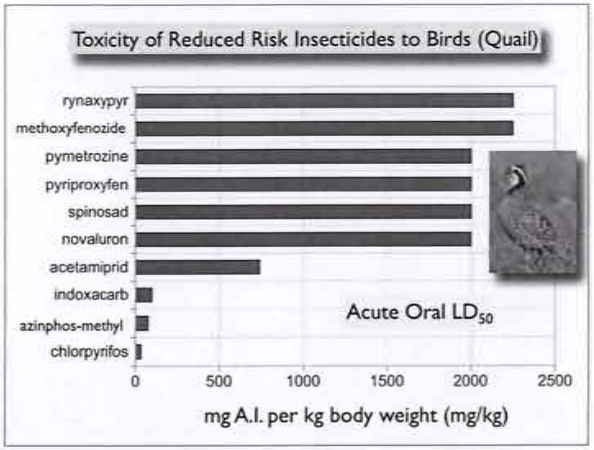
Toxicity of New Insecticides to Fish (Rainbow Trout)



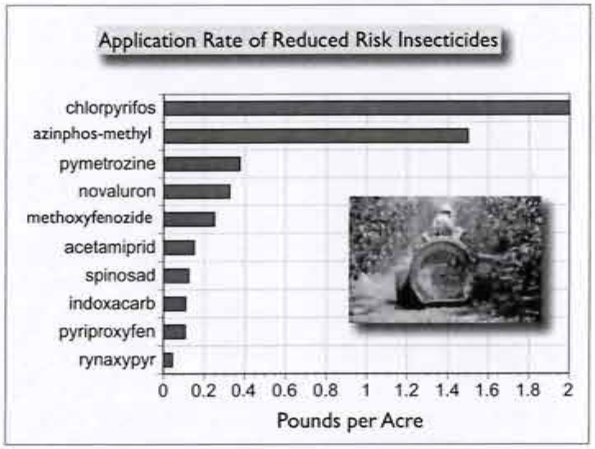
9

Toxicity of Reduced Risk Insecticides to *Daphnia*

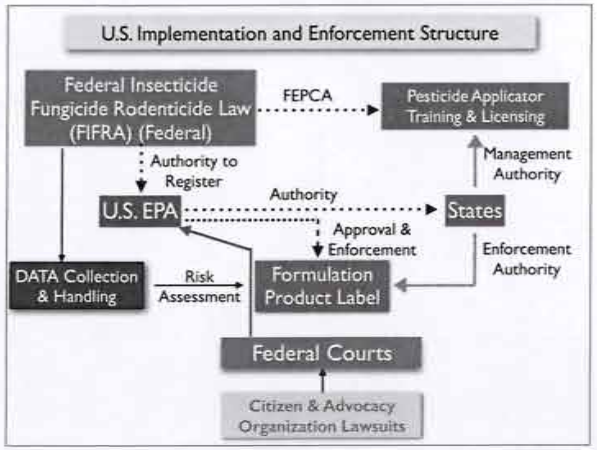



Toxicity of Reduced Risk Insecticides to Birds (Quail)
rynaxypyr
methoxyfenozide
pymetrozine
pyriproxyfen
spinosad
novaluron
acetamiprid
indoxacarb
azinphos-methyl
chlorpyrifos
Acute Oral LD50
0
500
1000
1500
2000
2500
mg A.I. per kg body weight (mg/kg)

10

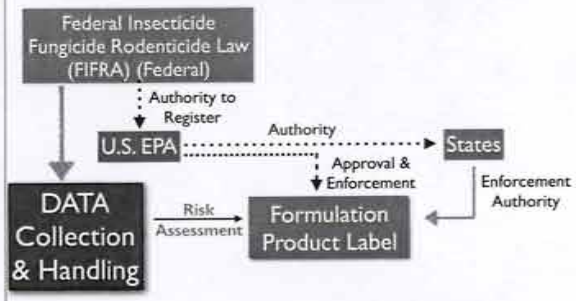

Application Rate of Reduced Risk Insecticides
chlorpyrifos
azinphos-methyl
pymetrozine
novaluron
methoxyfenozide
acetamiprid
spinosad
indoxacarb
pyriproxyfen
rynaxypyr
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
Pounds per Acre

11


U.S. Implementation and Enforcement Structure
Federal Insecticide Fungicide Rodenticide Law (FIFRA) (Federal)
FEPCA
Pesticide Applicator Training & Licensing
Authority to Register
Management Authority
U.S. EPA
Authority
States
Approval & Enforcement
Enforcement Authority
DATA Collection & Handling
Risk Assessment
Formulation Product Label
Federal Courts
Citizen & Advocacy Organization Lawsuits

12

U.S. Implementation & Enforcement Works through the Label



13

Authority to Require Data

B. Authority to Require Data

By law, the Agency has the authority to obtain data under three provisions of FIFRA:

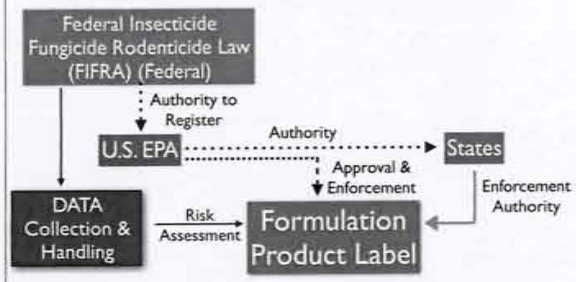
FIFRA 3(c)(1)(F) - Authorizes the Agency to require data to support an application for registration of a pesticide. OPP's data requirements are set forth in 40 *CFR* Part 158, but EPA has broad authority to ask for additional data or waive requirements, as appropriate. These data requirements are discussed under Section IV of this document.

FIFRA 3(c)(2)(B) - Provides the authority to require additional data on currently registered products. These data must be "required to maintain in effect an existing registration of a pesticide." If EPA imposes a data requirement under this authority, EPA must allow enough time to design the study and generate data. In addition, EPA must comply with the Paperwork Reduction Act.

FIFRA Section 6(a)(2) - Requires that pesticide registrants inform the Agency of any relevant adverse effects information relating to their products, even though it was not formally requested by EPA. Information reportable under this provision includes new information derived from scientific studies, such as efficacy failures of antimicrobial products and pest resistance. Incidents of adverse effects resulting from the use of pesticide products are also reported. The information collected under 6(a)(2) is tracked and regularly distributed to the various divisions in OPP, as appropriate. [See 40 *CFR* 15

14

U.S. Implementation & Enforcement Works through the Label



15

The Label Is the Law!

Prime Mechanism of Controlling Pesticide Use

Guthion® Solupak

50% WETTABLE POWDER CROP INSECTICIDE IN WATER SOLUBLE PACKETS

STATEMENTS OF PRACTICAL TREATMENT

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

16

The Label is the Law in the U.K....but Not as Obvious

IMPORTANT INFORMATION – *or words of the same meaning e.g. Key Information*

FOR USE ONLY AS AN AGRICULTURAL HERBICIDE

Crops:	Winter wheat, winter barley and oilseed rape
Maximum individual dose:	Winter wheat and barley: 2 litres product/ha Oilseed rape: 1 litre product/ha
Maximum number of treatments:	Winter wheat and barley: 2 per crop
Maximum total dose:	Oilseed rape: 3 litres product/ha/crop
Latest time of application:	Winter wheat and barley: Before second node detectable stage Oilseed rape: 14 days before harvest
Other specific restrictions:	This product must not be used on durum wheat

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS

Sample generic label from U.K. Health & Safety Executive

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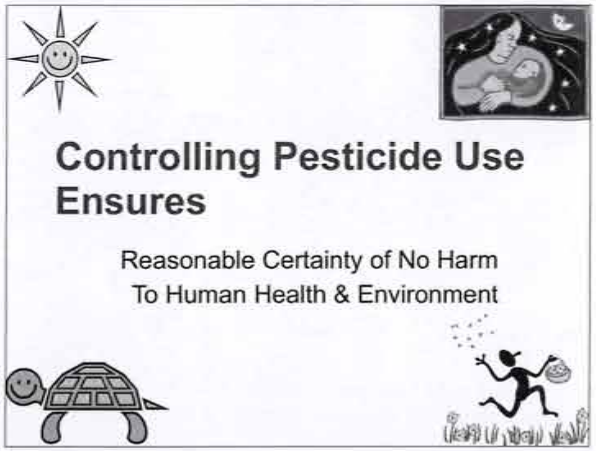
The Pesticide Label: It's the Law

- All registered active ingredients formulated into commercial products
  - ✓ All individual products must be registered, but registration not given until label developed and approved
- The label is the governing law
  - ✓ Identification of active ingredient and contents
  - ✓ Legal uses (crops, maybe specific pests)
  - ✓ Rates of application; application methods
  - ✓ Personal protective equipment
  - ✓ Restrictions on use (no application near water; regional restrictions; avoiding drift)
  - ✓ Directions for disposal
- Prime mechanism for controlling pesticide use

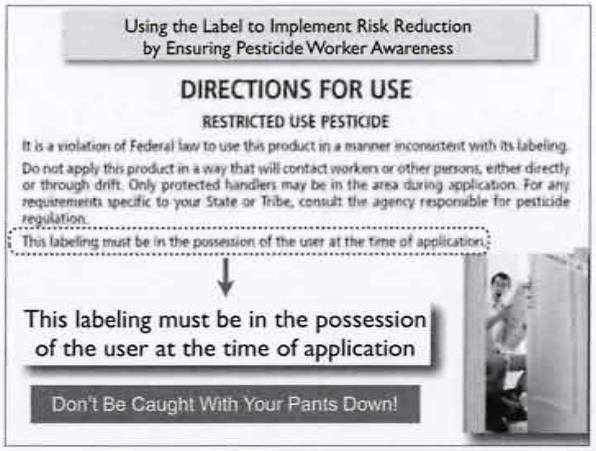
18


Controlling Pesticide Use Ensures
Reasonable Certainty of No Harm
To Human Health & Environment

19

Label Interpretation Help Is a Click Away
Pesticides: Topical & Chemical Fact Sheets
Read the Label First
http://www.epa.gov/opp00001/label/

20


Using the Label to Implement Risk Reduction
by Ensuring Pesticide Worker Awareness
DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.
This labeling must be in the possession of the user at the time of application.
This labeling must be in the possession of the user at the time of application
Don't Be Caught With Your Pants Down!

21

Using the Label to Implement Risk Reduction by Restricting Use to Certified Licensed applicators

22

RESTRICTED USE PESTICIDE

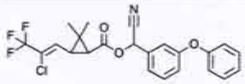
DUE TO TOXICITY TO FISH AND AQUATIC ORGANISMS

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS, OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

Using the Label to Implement Risk Reduction thru Hazard Communication

23

Karate



lambda cyhalothrin

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms and toxic to wildlife.

For terrestrial uses: do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

PHYSICAL AND CHEMICAL HAZARDS

Combustible liquid. Do not use or store near heat or open flame.

Using the Label to Implement Risk Reduction thru Hazard Communication

24

PRECAUTIONARY STATEMENTS

Warrior II with Zeon Technology

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

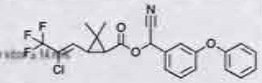
Skin exposure may also result in a sensation described as a tingling, itching, burning, or prickly feeling. Onset may occur immediately to 4 hrs. after exposure and may last 2 – 30 hrs., without damage. Wash exposed areas once with soap and water. Relief from the skin sensation may be obtained by applying an oil-based cream.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for Category G on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, Category G, such as barrier laminate or vitonF2 14 mils
- Shoes plus socks
- Protective eyewear



lambda cyhalothrin

Using the Label to Implement Risk Reduction by Guiding Users to Good Practices

25

GENERAL DIRECTIONS FOR USE

SPRAY DRIFT PRECAUTIONS

Observe the Following Precautions When Spraying in the Vicinity of Aquatic Areas Such as Lakes; Reservoirs; Rivers; Permanent Streams, Marshes, or Natural Ponds; Estuaries and Commercial Fish Farm Ponds:

- Do not apply by ground within 25 ft., or by air within 150 ft. of lakes; reservoirs; rivers; permanent streams, marshes, pot holes, or natural ponds; estuaries and commercial fish farm ponds. Increase the buffer zone to 450 ft. when ultra-low volume (ULV) application is made.

Remarks

- Apply as required by scouting, or locally prescribed corn growth stages, usually at intervals of 4 or more days. Timing and frequency of applications should be based upon insect populations reaching locally determined economic thresholds or other locally recommended methods and should be targeted for control before insects enter the stalk or ear.
- Apply with ground or air equipment using sufficient water and application methods to obtain full coverage of foliage and ears (if present). When applying by air, apply in a minimum of 2 gal. of water per acre.
- For control of adult corn rootworm beetles (Diabrotica species) as part of an aerial applied corn rootworm control program use a minimum of 0.025 lb. a.i. (1.60 fl. oz. of product) per acre.
- Do not apply within 1 day of harvest.
- Do not allow livestock to graze in treated areas or harvest treated corn forage as feed for meat or dairy animals within 1 day after last treatment. Do not feed treated corn fodder or silage to meat or dairy animals within 21 days after last treatment.

continued...

Warrior II with Zeon Technology

The Agenda

26

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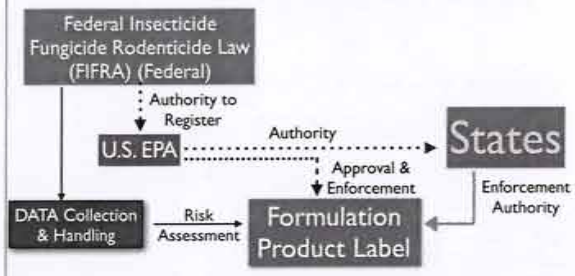
U.S. Implementation & Enforcement Works through the Label

27



WA State Dept. of Agriculture (WSDA) Legal Responsibility

- Enforce FIFRA under a mandate from EPA
- Enforce requirements for applicator training
  - ✓ FEPCA mandated that commercial and private pesticide applicators & handlers (mixers/loaders) pass certification/licensing if using restricted use pesticides
  - ✓ Pesticides classified as restricted use when deemed risky to environment and/or humans
- State registration of pesticides (must approve labels of products sold in states)
- Inspections for record keeping, proper pesticide use, etc.
- Can impose pesticide use restrictions in local areas

28

Enforcement at the Federal & State Level

29

Violations of Pesticide Containment & Container Rules

EPA Fines Agricultural Companies for Pesticide Violations

Helena Chemical and Wilbur-Ellis operate hundreds of pesticide facilities nationwide

Print Email 0 Tweet 0 Like A A A

SAN FRANCISCO, Calif. - The U.S. Environmental Protection Agency has reached a settlement with two companies over storage and containment of pesticides.

CENTRAL COAST NEWS KION 46

San Francisco based agricultural products company Wilbur-Ellis was ordered to pay $62,080 in civil penalties and, Collierville, Tenn. based agricultural products company Helena Chemical was ordered to pay $12,800 in civil penalties.

"Failing to meet standards for properly managing pesticides puts workers and the environment at risk," said Jared Blumenfeld, EPA's Regional Administrator for the Pacific Southwest. "Regulated facilities must ensure that protection of our health and environment is a top priority."

"Both companies had unsealed cracks in the floors and/or walls of the pesticide containment areas among other violations, said EPA officials."

30

EPA Enforcement: Stop Sale Order in Light of Phytotoxicity

31

New Turfgrass Herbicide Recalled; Avoid Composting Clippings

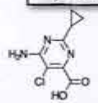
IOWA STATE UNIVERSITY
Extension and Outreach

This article was published originally on 8/24/2011

Imprelis herbicide (active ingredient aminocyclopyrachlor) is being recalled by the E.I. duPont de Nemours and Company because of damage and death to nontarget trees. Homeowners, and landscape and pest control professionals are also being warned not to compost grass clippings from Imprelis-treated lawns.

Imprelis herbicide received conditional registration from the U.S. Environmental Protection Agency (EPA) in October 2010 as safe for use in residential, industrial, and institutional lawns and on golf courses to control broadleaf weeds. But applications adjacent to white pine, Norway spruce, and other evergreen trees have caused twisting and curling of new growth, which progressed to the browning and death of affected of trees. See photos below.

The U.S. EPA issued a 'stop sale' order for Imprelis (EPA Registration Number 352-793) effective August 11, 2011. This involves cease sale, use, and removal of the product. DuPont is planning a product return and refund program.



aminocyclopyrachlor (auxin agonist)

Violation of Section 6 Adverse Effects Reporting Rule

32

EPA

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You are here: EPA Home » Newsroom » News Releases from Headquarters » EPA Settl

News Releases from Headquarters

EPA Settles with DuPont over Violations of Federal Pesticide Laws that Led to Widespread Tree Deaths and Damage/ DuPont to pay $1,853,000 penalty to resolve alleged violations of pesticide reporting and distribution laws

Release Date: 03/15/2014
Contact Information: Jennifer Colazzi, Colazzi.jennifer@epa.gov, 202-564-5677

WASHINGTON – The U.S. Environmental Protection Agency (EPA) today announced a settlement with the E.I. du Pont de Nemours and Company (DuPont) for alleged violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). DuPont will pay a $1,853,000 penalty to resolve allegations that the company failed to submit reports to EPA about potential adverse effects of an herbicide product called Imprelis, and sold it with labelling that did not ensure its safe use. When customers applied the enclosed Imprelis product, it led to widespread death and damage to trees.

Waste Disposal Violations Under FIFRA & Several Other Environmental Laws

33

Wal-Mart to Pay $81 Million Settlement for What EPA Calls 'Environmental Crimes'

By Elizabeth Harrington | May 29, 2013 | 1:44 PM EDT

167
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Facebook | Twitter | Email | More

(CNSNews.com) – Wal-Mart has agreed to pay $81.6 million for violating what the Environmental Protection Agency (EPA) calls "environmental crimes," concluding a decades-long investigation by the agency and the FBI.

Wal-Mart settled with the EPA and the Justice Department in three criminal cases on Tuesday, for improperly disposing of hazardous waste and pesticides. The settlement is a result of cases brought by the DOJ in San Francisco, Los Angeles and Missouri, and a civil case filed by the EPA.

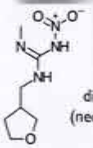
One federal prosecutor said she hopes the settlement will "send a message" to employers that they will be held accountable to the environment.

In this Feb. 20, 2012, file photo, customers walk into and out of a Wal-Mart store in Methuen, Mass. (AP Photo/Elise Amendola, File)

What Happens When the Label Is Ignored

34

Bee deaths a result of pesticide Safari; count upped to 50,000 dead insects



dinetofuran
(neonicotinoid)

OREGONLIVE
The Oregonian

BEE DEATHS

Bee deaths a result of pesticide; count upped to 50,000 dead

Bumblebee memorial scheduled for Sunday at Wilsonville Target

Dead bees discovered in Hillsboro

Insecticide temporarily banned

State Enforcement Authority: Applicator Fined

35

Bumblebee incidents result in pesticide violations

Oregon company fined $16,000 for pesticide spraying that killed 1,000 bees in Eugene

November 10, 2014

Implementation of Hazard Mitigation through Local Policies

36

Spokane bans chemical that may kill bees

The City Council voted to ban the city's purchase and use of neonicotinoids. The ban covers about 30 percent of the land in Spokane and doesn't apply to private use.

By NICHOLAS K. GERANIOS
The Associated Press

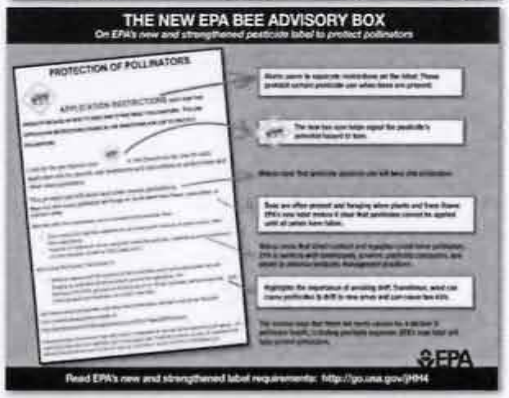
SPOKANE — Spokane is among cities that have restricted the use of pesticides that are chemically similar to nicotine because they may be killing bees.

The City Council in late June voted to ban city purchase and use of neonicotinoids. The ban does not apply to private use.

"There is enough evidence that it is harmful to bees," said City Council president Ben Stuckart, who pushed for the ban. "We should be a good global citizen and set an example."

"There is enough evidence that it is harmful to bees"

Facilitating Enforcement by Implementing Label Changes



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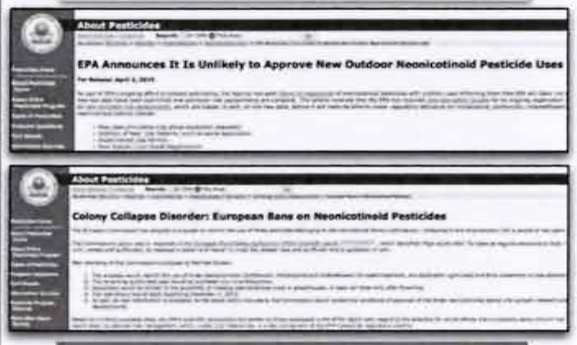
Implementing Risk Mitigation Through Policy



But Are These Policies Based on Risk Analysis?

38

The Agenda

- Implementation authority as practiced in the U.S.
  - ✓ Overview of U.S. pesticide law
  - ✓ How amendments to FIFRA have affected implementation of risk mitigation ("Reduced Risk Pesticide Program")
  - ✓ The product label has the force of U.S. Federal law
- Enforcement authority as practiced in the U.S.
  - ✓ Federal Insecticide Fungicide Rodenticide Act (1947 & amendments)
  - ✓ State Departments of Agriculture & Environmental Protection Agencies (or similar)
  - ✓ Examples of enforcement actions at Federal & State level
- Intrusion of Federal courts into EPA activities
  - ✓ Role of 'citizen' lawsuits and court judgements
  - ✓ Case Study: Salmon Stimulated Lawsuits

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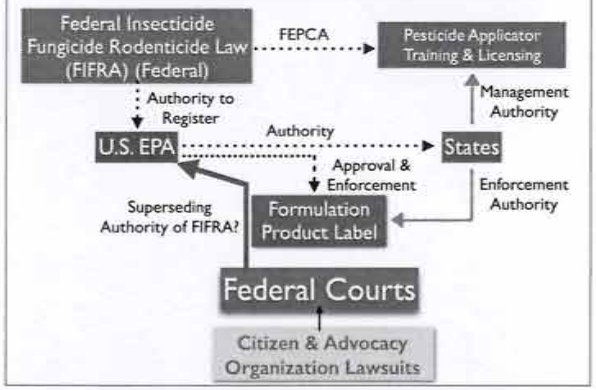
U.S. Implementation and Enforcement Structure

40



Two Major U.S. Laws Have Impacted Pesticide Technology Clean Water Act & Endangered Species Act

41

- The CWA & ESA contain provisions that advocacy groups interpreted as affecting EPA's actions in the registration of pesticides or in the rules applied to registered pesticides
- Advocacy groups sued the EPA, which wound up in Federal Court, notably the Circuit Court of Western WA and the 9th Circuit Court of Appeal
- The decisions made by these courts impacted EPAs authority to be the sole arbiter of rules about pesticides set forth in FIFRA
  - ✓ Thus, over the last two decades, lawsuits and specific court decisions have somewhat supplanted the provisions of FIFRA and the EPA

Mandated No Spray Buffer Zones

42

Clean Water Act

43

- Clean Water Act
  - ✓ The Clean Water Act (CWA) establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters. The basis of the CWA was enacted in 1948 and was called the Federal Water Pollution Control Act, but the Act was significantly reorganized and expanded in 1972.
  - ✓ "Clean Water Act" became the Act's common name with amendments in 1972.
    - Unlawful to discharge any pollutant from a point source into navigable water unless a permit is obtained
      - National Pollutant Discharge Elimination System (NPDES) permit program controls discharges
  - ✓ Following a law suit and appeal, the NPDES was extended by the judicial branch to include aquatic pesticide applications

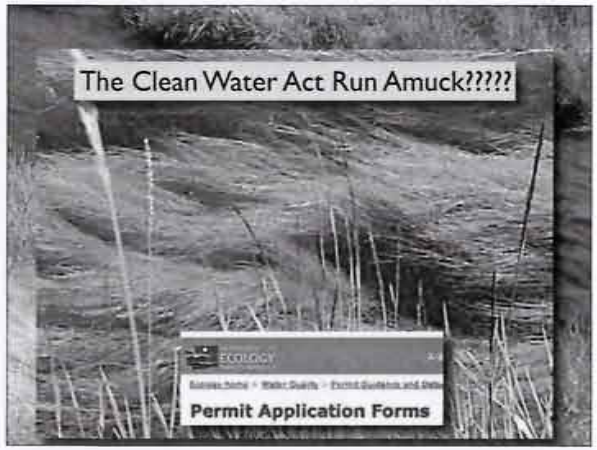
http://www2.epa.gov/laws-regulations/summary-clean-water-act

44

Talent Irrigation District Case

45

- Earth Justice (EJ), a Seattle based law firm, representing the the environmental group Headwaters, sued Talent Irrigation District (TID) under the pretense of a violation of the Clean Water Act
  - ✓ Premise: NPDES (National Pollution Discharge Elimination System) Permit needed for aquatic pesticide applications
  - ✓ Lower district courts ruled in favor of TID, but Ninth Circuit Appeals Court reversed the decision in favor of Headwaters
    - Despite the conflict with FIFRA
      - i.e., FIFRA had been interpreted to give EPA primacy over control of pesticides, including registering them for control of aquatic weeds without the need for permitting
  - ✓ However, the judiciary ruling interpreted the CWA as having primacy when water was being affected
    - Because all waters connected, the concept of navigable water under the CWA, included irrigation canals
  - ✓ Thus, all aquatic pesticide applications need an NPDES permit



46

Endangered Species Act (ESA)

http://www.fws.gov/endangered/laws-policies/esa.html

- Passed by Congress as Public Law 93-305 in 1973
- Congress finds and declares that...
  - ✓ "various species of fish, wildlife, and plant in the United States have been rendered extinct as a consequence of economic growth and dvelopment untempered by adequate concern and conservation
  - ✓ "other species of fish, wildlife, and plants have been so depleted in numbers that they are in danger of or threatened with extinction"
- Purposes of ESA as declared by Congress
  - ✓ "...to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide program for the conservation of such endangered species and threatened species, and to take such steps as may be appropriate to achieve the purposes of the treaties and conventions set forth..."

U.S. Fish & Wildlife Service
Endangered Species

http://www.fws.gov/ENDANGERED/laws-policies/esa.html

NOAA FISHERIES

http://www.nmfs.noaa.gov

47

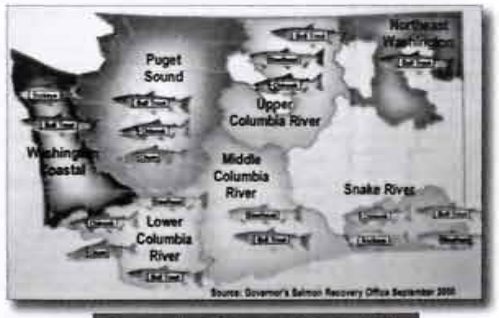
Section 4 Provisions of the ESA

- Section 4 (Factors for Listing Determination)
  - ✓ Present or threatened destruction, modification, or curtailment of its habitat or range;
  - ✓ Over-utilization for commercial, recreational, scientific, or educational purposes;
  - ✓ Disease or predation;
  - ✓ Inadequacy of existing regulatory mechanisms;
  - ✓ Other natural or manmade factors affecting its continued existence.

48

About 75% of WA State Land Mass Is Impacted by the Listing of Salmon Runs as Threatened or Endangered

49



Threatened or Endangered Species Listings in Salmon Recovery Regions

ESA Section 7 Provisions: Interagency Cooperation

50

- SEC. 7. (a) FEDERAL AGENCY ACTIONS AND CONSULTATIONS
  - ✓ "All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this Act by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 4 of this Act"
  - ✓ "Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (...an "agency action") is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption"

The Lawsuit Argument

51

- Section 7(a)(2) of the ESA requires any entity engaging in an activity that may affect listed species to consult with agencies administering the ESA (includes National Marine Fisheries Service and Fish & Wildlife Service)
- A single registration of a single pesticide is considered a single agency action that could affect salmon
- Earth Justice argued the case successfully before the US District Court of Western WA

The ESA Consent Decree

52

- EPA will consult with NMFS (i.e., NOAA Fisheries) on 54 targeted pesticides
- Mitigation needed if deemed harmful to salmon
- Court received new petition from WA Toxics Coalition (represented by Earth Justice) for injunctive relief (11/26/02)
  - ✓ Prohibit use of listed pesticides unless 300 ft buffer around salmon-bearing streams is established for aerial application or 60 feet for ground application
- Injunction became effective in 2004; known as interim measures
  - ✓ Interim measures effective until consultation is completed with NOAA Fisheries issuing a Biological Opinion (a.k.a. a BIOP)

The Argument for an Injunction

53

- Indeterminate amount of time will be required for EPA to consult with NMFS about the 54 pesticides under re-registration review
- Then, NMFS must issue a biological opinion about "safety" of a pesticide to a salmon population and what action should be taken to protect salmon
- Salmon in danger in interim until consultation and biological opinion finished, thus need protection
- No-spray buffer zones of 60 and 300 ft for ground & aerial application, respectively
- Only certified applicators have access to 13 urban use pesticides

And the Lawsuit Lumbered Along...

54

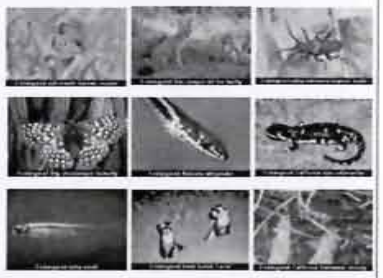
- Western WA District Court Judge issued a final ruling on January 22, 2004
- Indicated evidence of harm shown by plaintiffs, although they had no burden to prove so
- Defendants (EPA) & intervenor (Crop Life America) showed no information to contrary
- Buffers will stand as proposed unless EPA makes a determination of no effect

EPA Independently Assesses Effects of Pesticides on Endangered Species

55

http://www.epa.gov/espp/

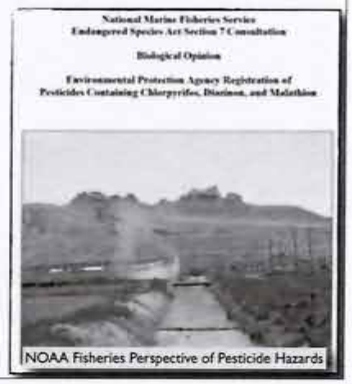
- EPA's Endangered Species Protection Program (ESPP) helps promote the recovery of listed species
- The ESPP is a program designed to determine whether pesticide use in a certain geographic area may affect any listed species
- If limitations on pesticide use are necessary to protect listed species in that area, the information is relayed through Endangered Species Protection Bulletins



For All "Listed" Species, EPA Must Consult with Relevant Agencies (U.S. Fish & Wildlife; NOAA Fisheries)

56

- Relevant agencies issues a BiOP (Biological Opinion)
- Relevant agencies make suggestions for management provisions, such as increased no spray buffer zones
- Relevant agencies get sued, just like the EPA


National Marine Fisheries Service
Endangered Species Act Section 7 Consultation

Biological Opinion

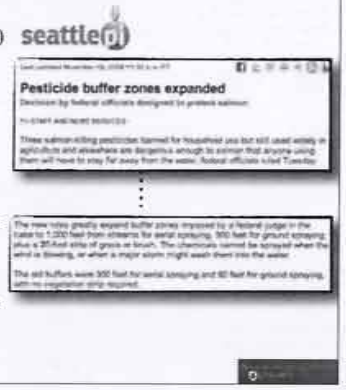
Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon, and Malathion

NOAA Fisheries Perspective of Pesticide Hazards

NOAA Fisheries

57

- In "Biological Opinions" (BiOPs) issued by NOAA Fisheries (formerly the U.S. National Marine Fisheries Service) for three OP insecticides (chlorpyrifos, diazinon, & malathion)...
  - ✓ Ground Applications: "Do not apply pesticide products within 500 ft (152. 4 m) of salmonid habitats"
  - ✓ Aerial Applications: "Do not apply pesticide products within 1,000 ft (304.8 m) of salmonid habitats"



WSDA Perspective of NOAA Fisheries Opinion

58

Buffer Width (ft)	Acres of agricultural lands affected	Percent of agricultural lands affected
100	4,845	9%
500	25,992	48%
1,000	40,578	75%

EPA Responds to NOAA BiOP

59

- "EPA intends to require differential spray drift buffers adjacent to waters within the range of the listed Pacific salmonids. The extent of such buffers will differ based on three factors: application rate, spray droplet spectrum, and water body size but in no case will be less than 100 feet..."
  - ✓ Note: This self-imposition will not allow risk-based considerations in EPA's proposed drift label language
  - ✓ EPA had developed a pilot buffer zone calculator for use by applicators in areas with listed endangered species

Product Label Mandated Buffers

60

Dow AgroSciences
Lorsban®-4E

Observe the following precautions when spraying Lorsban-4E adjacent to permanent bodies of water such as rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries, and commercial fish ponds.

The following treatment setbacks or buffer zones must be utilized for applications around the above-listed aquatic areas with the following application equipment:

Application Method	Required Setback (Buffer Zone) (feet)
ground boom	25
chemigation	25
orchard airblast	50
aerial (fixed wing or helicopter)	150

Bulletins Alive: New Requirement on Applicators to Check for Endangered Species Listings & Restrictions

61

Bulletins Live!

First Version

Protecting Endangered Species

Meanwhile, Back in the Courts

62

- After the BIOP for chlorpyrifos, diazinon, and malathion came out, DowAgroSciences, Makhteshim Agan, and Cheminova sued NMFS in the Fourth Circuit of the U.S. Court of Appeals
- Court vacated NMFS BIOP, stating:

"On appeal, we reverse, concluding that the BiOp was not the product of reasoned decisionmaking in that the Fisheries Service failed to explain or support several assumptions critical to its opinion. To enable a renewed agency process, we vacate the BiOp and remand this case to the district court with instructions to remand it to the Fisheries Service for further proceedings consistent with this opinion."

Meanwhile, Back at the EAGs (Environmental Advocacy Groups)

63

- Northwest Coalition for Alternatives to Pesticides (NCAP) through EarthJustice) sues EPA again for not implementing the actions proposed (i.e., the "extreme" buffers) in the BIOPs (November 2010)
- In August 2014, Western District of the U.S. Court of Appeals (where original case was heard in 2001) rules that buffers from 2004 injunction relief (i.e., the interim measures) would be reinstituted in the affect states (i.e., WA, OR, CA)

Risk Mitigation: Salmon Mapper Developed by EPA

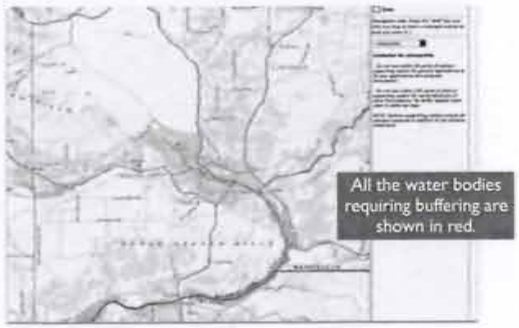
64

- Buffer zones will remain in place until EPA has completed implementation of any mitigation actions, based on reinitiated consultations with NMFS
- The reinstated buffers are part of the final court order; however, they will not be included as labeling requirements under FIFRA
- By Sept. 30, 2014 EPA will have an interactive map (Salmon Mapper) to include the current list of chemicals subject to the restrictions, with the most recent geospatial data depicting stream reaches where the buffer zones apply.

http://www2.epa.gov/endangered-species/salmon-mapper#background

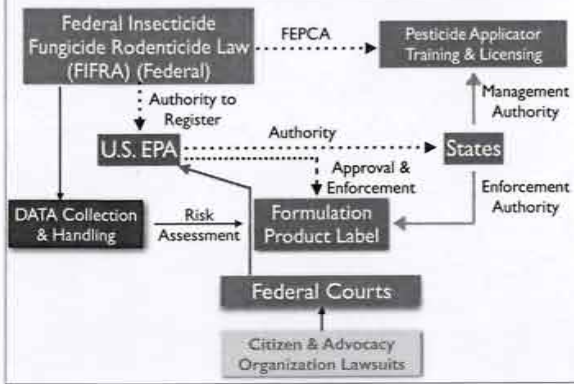
Using Salmon Mapper

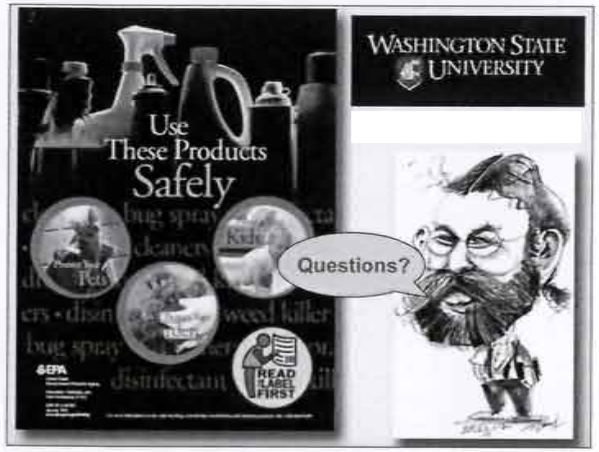
65



U.S. Implementation and Enforcement Structure

66





WASHINGTON STATE UNIVERSITY

WASHINGTON STATE UNIVERSITY

Ecological Risk Assessment Workshop
Santiago, Chile: May 9-10, 2015

1

Risk Perception, Communication & Management

Allan Felsot
Washington State University
Department of Entomology
College of Agriculture Human & Natural Resources Sciences
School of the Environment; School of Biological Sciences

AGRICULTURE YOUTH & FAMILIES HEALTH ECONOMY ENVIRONMENT ENERGY COMMUNITIES

2

"We Have Met the Enemy & He Is Us"

- Several years ago, a meeting of state noxious weed control managers asked me to give a talk with the following title:
  - ✓ "The Semantics of Risk Management: Winning the Communication Battle for Sensible Pesticide Use"

3

Presentation Objectives

- Why do you need risk communication?
- Who is your audience (constituency)?
- What do your audiences & constituencies perceive?
- What do we know about consumer perceptions of chemical technology risks?
- What do you know about what information is needed
- Are you ready to provide it?
- How can you improve communication with your constituents?

4

5

"Lucy, you got a lot of 'splaining to do"

- Yes, you probably do need risk communication
- But who is really your audience?

6

7

Newsday.com

http://www.newsday.com/news/local/longisland/ny-pesth017.story

Two Efforts Seek to Halt Pesticide Use

By Dan Fagin
Staff Writer

April 19, 2002

Long Island environmentalists and some key allies in the State Legislature this week launched a two-pronged assault on chemical weed-killers, including a far-reaching proposed state law that would ban many lawn chemicals that cause cancer in lab animals.

Environmentalists?
Consumers?
Legislators; Councilman?
Landowners?

8

Proposition

- If I were talking to weed managers or farm managers, I'd tell them they need to see their legislators (i.e., elected, policy makers, & staff) as their prime audience
- For PCOs (residential & commercial pest control operators/specialists), all the above is true, but they are more like medical doctors, called in by the public for a "cure"
- Thus, we need to communicate concepts about risk as needed to people with different societal roles
- But we also need to communicate benefits

9

Risk Perceptions

- You must understand how public perceives risk before you can communicate its magnitude and help clients make a management decision

Wealthier, Healthier… & More Worried

- Increased ability to measure trace levels
- Increased dependence on complex, powerful technologies
- Occurrence of catastrophic mishaps
- Increased litigation
- When more to lose, tendency to be more cautious
- Change in nature of today's risks
  - ✓ More people exposed to complex, interconnected systems
- Publicizing of risk problems
- Benefits of technology taken for granted
- Frustration over lack of control of involuntary risks

Slovic 1991

10

Media Role

- Four Recurrent Themes in News Stories
  - ✓ Fear
  - ✓ Confusion
  - ✓ Hope
  - ✓ Mistrust
- Soundbite driven
- No context
- Conflict seeking
- But, do not blame the media

11

Role of the Media Conventional Wisdom

- Negative bias
- Dependency of the public on media information
  - ✓ Especially when risk issues were exceptional, new, and countervailing independent analysis was absent

12

Role of the Media: New Wisdom

13

- Media coverage entrenches preexisting prejudices
  - ✓ Exception: when risk is novel, media is influential
  - ✓ Consumers seek information, but not likely listening to messages about how worried to be

- Media emphasizes the qualitative (human interest) aspect
  - ✓ Commitment to balancing a story results in an overemphasis on minority opinion
  - ✓ Need for a villain
  - ✓ Tendency to focus on conflict

"You've Got a Friend"

14

- Media is dependent on credible and articulate sources of information
  - ✓ Media need more encouragement and assistance for a more continuous involvement with risk communication programs

- Thus, media can be a " friend " if sought out, encouraged, and assisted in becoming involved with risk communication programs
- The advent of the Internet has resulted in democratization of the ability of any organization to get their message to a community

Developing a Perception of Risk

15

- How one perceives risk is not simply dependent on receiving, processing, and analyzing factual information about an activity
  - ✓ Difficulties in understanding science behind chemicals or other technology only a small part of judging technology as too risky (i.e., unsafe)

- Must understand the factors that influence how risk is received
  - ✓ Research shows that risks have qualitative factors or dimensions that people are perceiving (or feeling)

Perceived Risks for 10 Technologies & Activities

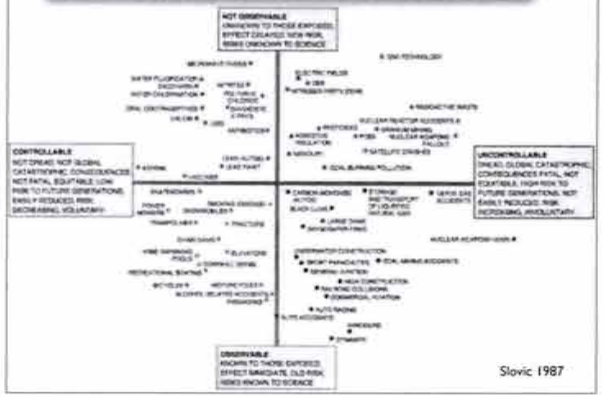
16

Activity/Technology	League of Women Voters	College Students	Experts
Nuclear power	1	1	20
Motor vehicles	2	5	1
Handguns	3	2	4
Smoking	4	3	2
Motorcycles	5	6	6
Alcohol	6	7	3
Aviation	7	15	12
Police work	8	8	17
Pesticides	9	4	8
Surgery	10	11	5

Slovic 1987

Risk Perception Dimensions

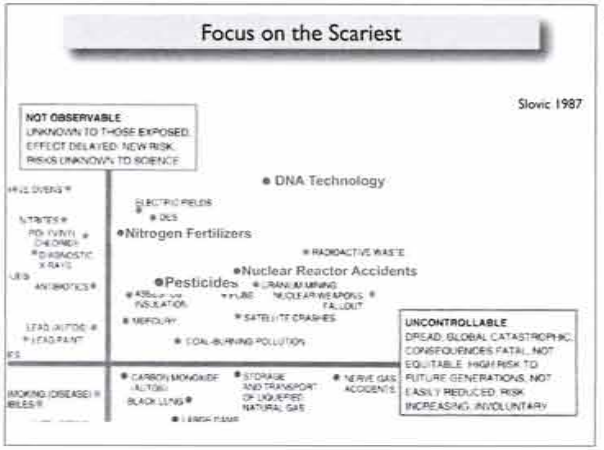
17



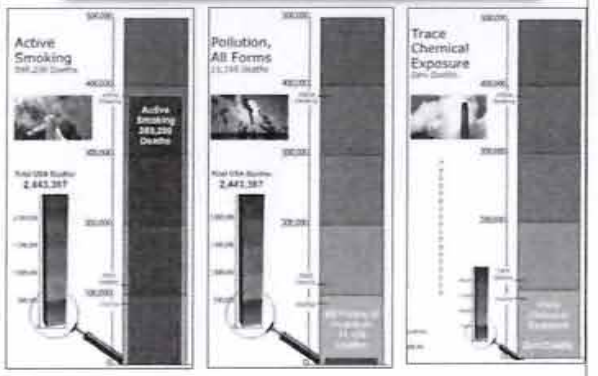
Slovic 1987

Focus on the Scariest

18



Reality Belies Perception



19

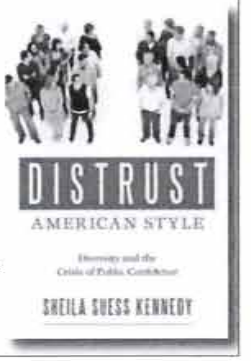
Why Pesticides Perceived as Dread and Unfamiliar Risk

- The technology is not understood
- Involuntary risk
- Threat to self great
- Low degree of control & involvement
- Lack of trust in decision makers
- Contradictory information about hazards
- Benefit seen for users but not self

20

Decline of Deference
Why Is the Public Distrustful of Experts?

- Uncertainty about risk
  - ✓ Information is not available or is poorly understood
- Perceived bias
  - ✓ Everyone, including scientists, has a viewpoint
- Feeling that experts are not listening
- Alienation due to complexity of subject and terminology
  - ✓ Risk messages necessarily compress technical info., leading to misunderstanding, confusion, and distrust
- General alienation with political institutions



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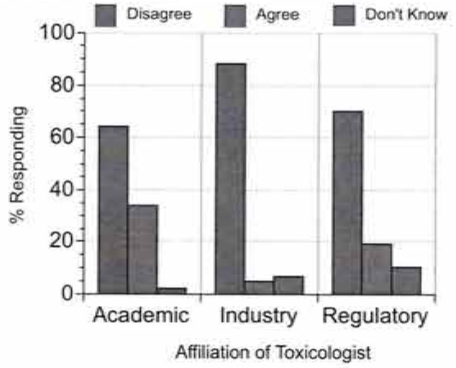
22

Scientific Illiteracy Is Not the Culprit!!

- Although "experts" placed pesticides in the "dread/ unknown" quadrant, they placed it closer to the graph axes, suggesting less feeling of dread than nonexperts
- Nevertheless, research has shown disagreement among experts about what they think & their risk perception

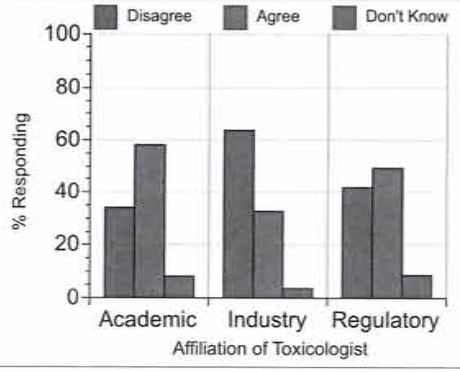
23

Statement: There is no safe level of exposure to a cancer-causing agent



24

Statement: Our society has perceived only the tip of the iceberg with regard to the risks associated with chemicals



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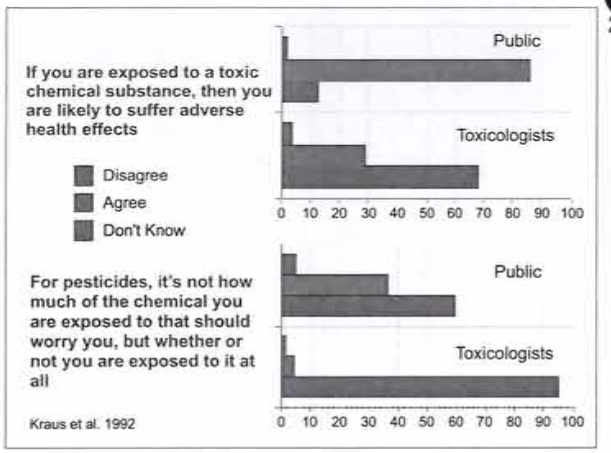

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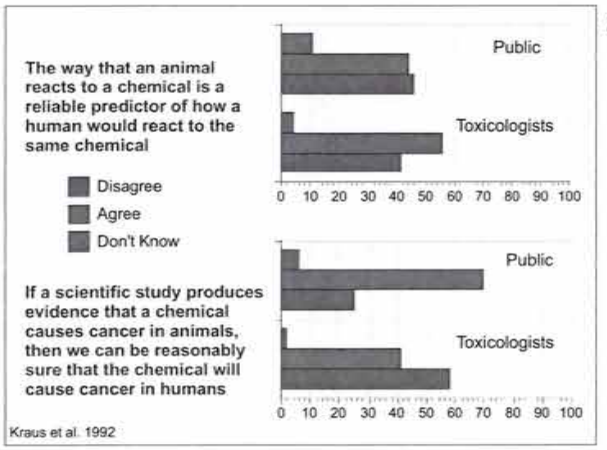

27

Legislator & Staff Perceptions Survey

Question	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
If a scientific study produces evidence that a chemical causes cancer in animals, then we can be reasonably sure that the chemical will cause cancer in humans	6.1	41.2	34.2	4.4	14.0
I believe that if you are exposed to a toxic chemical then you are likely to suffer adverse health effects	1.7	40.5	45.7	6.0	6.0
In my opinion, there is no safe level of exposure to a cancer-causing agent	15.3	52.5	12.7	9.3	10.2

(Cohen 1997)

28

Legislator & Staff Perceptions Survey

Question	Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know
Our society has seen only the tip of the iceberg with regard to the risks associated with chemicals	4.3	30.4	43.5	13.9	7.8
I feel that a risk assessment can pinpoint the extent of a risk with great certainty	9.6	47.4	31.6	0.9	10.5
In my experience, scientific information often is used to justify decision made on political grounds	1.7	21.4	55.6	13.7	7.7
I believe we should use risk assessments to decide how to allocate government resources to different pollution control programs	1.7	16.1	63.6	11.9	6.8

(Cohen 1997)

29

Perhaps the Public Is Less Concerned than We Think?

Opinions About Environmental Problems in WA State, 1995

Question: In your opinion is [topic inserted] a problem in your community?

Topic	% Yes	% Somewhat	% No
Outdoor air quality	13.3	9.0	76.6
Drinking water quality	11.1	4.4	82.3
Workplace hazards	9.5	4.1	85.5
Solid waste management	7.3	2.7	88.2
Pesticide use & control	7.1	2.8	84.3
Wastewater management	7.0	2.3	86.8
Hazardous waste sites	6.3	1.6	86.8
Air quality inside home	2.6	2.6	93.6

LaFlamme & VanDerslice (2004)

30

Survey of Desired Information Needs Among Legislators & Staff

Rank	Type of Information	Mean (1-7 scale)
1	How regulatory agencies like the EPA use risk assessment	5.61
2	The strengths & weaknesses of risk assessments	5.58
3	Risks of a particular technology or situation	5.44
4	How a risk assessment is conduced, using a specific chemical as an example	5.40
5	Backgrounder on what risk assessment is & how it is used	5.29
6	Backgrounder on what cost-benefit analysis is & how it is used	5.23
7	How do different constituency groups view risk assessment	5.15
8	Effective methods for communicating about environmental risk to the public	5.08
9	Information on why people react differently to different risks	4.94

(Cohen 1997)

Are You Ready to Provide People with the Information Needed or Requested?

31

- What is the difference among toxicity, hazard, & risk?
- What is the difference between risk assessment & risk management?
- Are you familiar with all the laws regulating pesticide technology & the interrelationships among them?
- What are the four steps of a risk assessment?

More Than Mere Semantics

32

- Hazard: potential of a substance or activity to cause harm (adverse effects) under a specific set of conditions
  - ✓ Do not confuse toxicity with hazard
    - * Toxicity is the innate capacity to cause harm
    - * Results from the specific 3-D structure and specific biochemical targets
- Risk: probability (likelihood) of adverse effects occurring
  - ✓ Function of the magnitude of exposure (or contamination)
  - ✓ No zero risk

Separate But Not Equal

33

- Risk assessment: scientific endeavor for determining the hazards of a substance, potential exposures, and the likelihood of adverse effects
  - ✓ Mandated by statutory and administrative (regulatory) law
  - ✓ Mostly science based activity: hypothesis, experiment, observation
- Risk management: social endeavor for avoiding adverse effects
  - ✓ Mandated by statutory law
  - ✓ Implementation defined by administrative law
  - ✓ Influenced by politics, economics, social goals

Toxicity Definitions

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- Acute vs Chronic Toxicity
  - ✓ Acute toxicity refers to signs & symptoms appearing immediately after a single exposure to a substance
    - Most common endpoint is death
  - ✓ Chronic toxicity refers to adverse effects occurring from multiple exposures
    - Common endpoints include blood, organ, developmental, reproductive, and carcinogenic effects
    - Note that risk assessment decisions are based on studies of chronic exposure

Risk Assessment Acronyms

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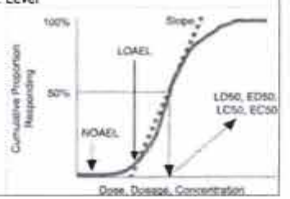
- LD50
  - ✓ A chemical dose lethal or otherwise adverse to 50% of test animals
- LOAEL
  - ✓ Lowest Observable Adverse Effect Level
- NOAEL
  - ✓ No Observable Adverse Effect Level
- RfD
  - ✓ Reference Dose
- PAD
  - ✓ Population Adjusted Dose
- MOE
  - ✓ Margin of Exposure



U.S. Pesticide Law 101

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FIFRA (1947) ← FEPCA (1972)

FFDCA (1938) ← **Miller** (1954), **Delaney** (1958)

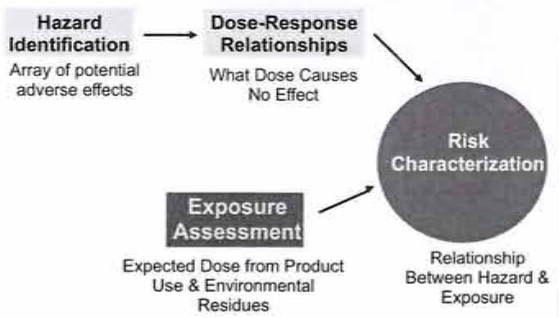
Risk Assessment → Tolerance ("MRL") ←

Labeling → **Registration**

FQPA (1996)

Risk Assessment-- Estimating the Probability of Harm

37



Risk Communication: Common Misconceptions

38

- Unrealistic expectation of what can be accomplished
  - ✓ Cannot always reduce conflict and smooth risk mgt.
  - ✓ Risk mgt. decisions benefit some, harm others
  - ✓ People do not all share common values and interests
  - ✓ Even if people understood risk comparisons, it is not necessarily easier to make a decision
    - Other factors besides risk magnitude involved

Risk Communication: Common Misconceptions

39

- Single overriding problem that could be overcome simply (for ex., scientific illiteracy)
- Mistaken beliefs about what scientific research can contribute
  - ✓ Cannot resolve all risk issues
  - ✓ Research not done or results are equivocal
  - ✓ Disagreement between "experts"

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Risk Communication: Common Misconceptions

- Unrealistic to expect easy identification and understanding of values, preferences, and information needs of audience
- Stereotypes about the way intermediaries and recipients react to risk messages
- Failure to understand that perception of risk magnitude & seriousness differ

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Why Better Risk Communication Efforts Are Not Adequate to Resolve Technological Choices by the Public

- Conflicts inherent in a democratic system
- Risk assessment is value-laden and not politically neutral
- Issues are greater than just health impacts
- Risk communication is political discourse

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Risk Messages Are Neither Neutral or Objective

- Research is conducted within a political context
- The players have viewpoints
- There are disagreements over interpretation of data

However, the message will "go down better" if you build trust (& a rapport) with your audience.

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Risk Communication: Two Major Problems

- Institutional & Political Systems
- Risk Communicators and Recipients

44

Institutional & Political Systems

- Cannot be changed (cope with it)
- Legal considerations
  - ✓ Statutory mandates
  - ✓ Liability
  - ✓ Informed consent
  - ✓ Right-to-know
- Risk management cumbersome because of democratic process
- Divided authority and responsibilities
- Systematic bias

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Risk Communicators & Recipients

- Can change
- Establishing & recognizing credibility
- Making messages understandable
- Preparing messages in an emergency
- Capturing & focusing attention
- Accessing information
- Understanding scientific information & probability

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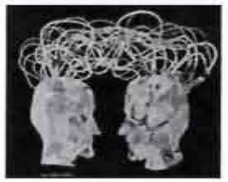
What is needed for more effective risk messages?

- Two-way communication (discourse)
  - ✓ What does the audience want information about?
- Risk comparisons between risks perceived to have similar qualitative characteristics
- Use graphs and tables more wisely to express quantitative data
- Use comparisons and language relevant to target audience



47

Risk Communication Perspectives Continuum

- One-Way Communication
  - ✓ Telling them what has been decided or done
  - ✓ Telling them what to do
  - ✓ Giving them information about estimated risk magnitudes
  - ✓ Letting them interpret it and decide on their own
  - ✓ Helping them interpret without interjecting bias
  - ✓ Letting them decide on their own
  - ✓ Finding out what their concerns are
  - ✓ Including their concerns in the risk asessment
  - ✓ Helping them interpret the results and helping them use ways to affect the decision
- Two-Way Communication

Informing Audience

Empowering Audience

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Improving Risk Communication
General Strategies

- Set a specific goal (i.e., what do you need risk communication for?)
  - ✓ Alert people to a risk for which they are unaware
  - ✓ Achieve a convergence in knowledge
  - ✓ Cause people to seek information, help & protect themselves, change their behavior, make more informed decisions, or participate effectively in decisions
  - ✓ Organizational survival and damage control
  - ✓ Overcome opposition to a decision
  - ✓ Achieve informed consent and enhance public participation

Improving Risk Communication
General Strategies

- Know your audience, what they know, and their concerns
  - ✓ Inactives
  - ✓ Voting specialists
  - ✓ Parochial participants
  - ✓ Communalists
  - ✓ Campaign activists
  - ✓ Complete activists

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Improving Risk Communication
General Strategies

- Establish trust and credibility
- Use understandable language
- Be honest (and ethical)
- Move from informing to empowerment

50

Opinion: Enumerating risks does not negate the use of a chemical…

- …if the beneficial use of that chemical outweighs adverse effects.
- Risk can be lowered by proper management

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Improving Risk Communication Some Suggestions

- Find out what people know
  - ✓ Conduct periodic surveys to find out what people actually know
  - ✓ Help with understanding the smallness of numbers (or the largeness of numbers)
    - When dealing with probabilities less than 0.1, predictions of outcome are poor

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Comparing Risks

- Compare risks of similar qualities
  - ✓ Don't compare voluntary and involuntary risks
    - Remember the risk dimensions graphic
    - Be sure that risks being compared share similar attributes
  - ✓ If talk about toxicity, compare risk of pesticide exposure to some other chemical that is consumed routinely but that is known to be "toxic"
    - Vitamin A
    - Alcoholic beverages

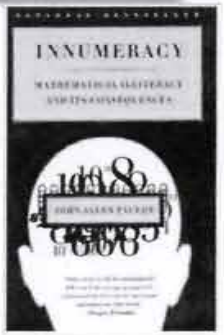
54

Thou Shalt Overcome

- Innumeracy
- Counter Intuitive Propositions
- The limitations of human brain to understand probability

Innumeracy
Mathematical Illiteracy & Its Consequences

- "An inability to deal comfortably with the fundamental notions of number and chance"
  - ✓ Misperception of the magnitude of numbers
  - ✓ Ignorance of the mathematics of probability



55

Consequences of Innumeracy

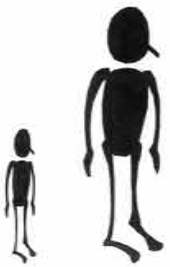
- Lack of numerical perspective
- Exaggerated appreciation for meaningless coincidences
- Credulous acceptance of pseudoscience
- Inability to recognize social tradeoffs

John Allen Paulos (1988)

56

How Big Is Big?

- 1 million
  - ✓ 1,000,000
- 1 billion
  - ✓ 1,000,000,000
- 1 trillion
  - ✓ 1,000,000,000,000



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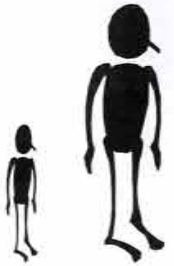
58

How Small Is Small?

- 1 millionth
  - ✓ 0.000001
- 1 billionth
  - ✓ 0.000000001
- 1 trillionth
  - ✓ 0.000000000001



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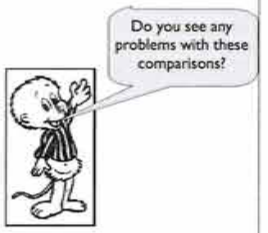
Innumeracy
The Inability to Understand the Magnitude of Numbers

- ppm (one part per million)
  - ✓ 1 bad apple in 2,000 barrels
- ppb (one part per billion)
  - ✓ 1 bad apple in 2 million barrels
- ppt (one part per trillion)
  - ✓ 1 bad apple in 2 billion barrels



1 barrel = 500 apples

60

How Pure is Pure?
Significance of substance purity by percentage

- 99.9999% pure
  - ✓ 0.0001% impurities
  - ✓ 1 part per million of impurities
- 99.9999999% pure
  - ✓ 0.0000001% impurities
  - ✓ 1 part per billion of impurities
- 99.9999999999% pure
  - ✓ 0.0000000001% impurities
  - ✓ 1 part per trillion of impurities

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Ivory Snow

Only 99.4% pure!!!

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Scales of Contamination

Consider a pesticide with molecular weight 300

- 1 ppb in water contains
  - ✓ 2×10^{15} molecules
- 1 ppt in water contains
  - ✓ 2×10^{12} molecules

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Food & Water with 1 ppq of pesticide residue has a mind-boggling number of molecules in it

1 part per quardrillion (ppq) =

- 0.000000000001 grams/liter of water
  - ✓ (1×10^{-12} g/L)
- 2,000,000,000 molecules/liter of water
  - ✓ (2×10^{9} molecules/L)

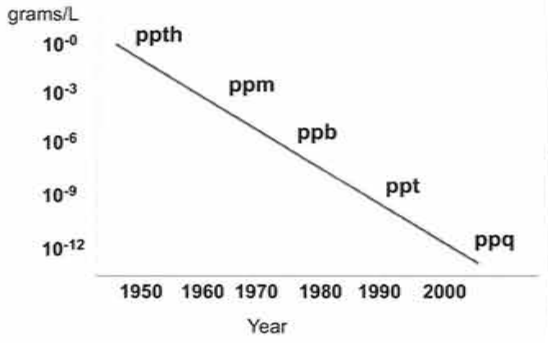
Scales of Contamination

64

- The bottom line: there is some amount of everything in almost everything else!
- Thus, don't try to hide the fact of contamination behind small numbers
- It is better to explain that biological responses are not observed at such small levels

Analytical technology has advanced faster than biological understanding

65



Innumeracy

66

- "gap between scientists' assessments of various risks and the popular perceptions of those risks…"
  - ✓ John Allen Paulos (1988)
- The result is known as risk perception divergence

Consequences of Increased Analytical Capabilities

67

- Pesticides seem to occur in places that we had never seen them before
- Tendency to lower regulatory limits to increasingly unrealistic levels
- A notion that synthetic chemicals are everywhere in our environment

Risk Assessment vs. Risk Management

68

- Even if the risk of a biological effect is trivial
- A democratic society has the choice to manage trivial risks

Overcoming Confusion from Counterintuitive Propositions

69

- Counterintuitive propositions are ideas that do not seem to be true according to gut feeling or intuition
  - ✓ For example, the earth is ~5 millions miles closer to the sun during the winter than during the summer
  - ✓ Exposure to a toxin does not result in sickness

70

Effective Approach for Teaching Counterintuitive Ideas

- State the lay theory obstructing understanding
  - ✓ Are vitamins poisonous?
- Acknowledge its plausibility
  - ✓ We need vitamins to survive
  - ✓ Doctors recommend vitamins
- Demonstrate its inadequacy
  - ✓ Did you know that if a pregnant woman takes too much vitamin A, the baby can get birth defects?

Rowan 1990

71

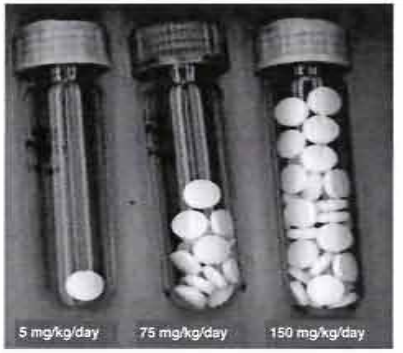
Effective Approach for Teaching Counterintuitive Ideas

- State the orthodox scientific theory
  - ✓ Too much of any substance, natural and synthetic, can be poisonous
  - ✓ All organisms have the ability to breakdown any substance if its amount is not too high nor consumed too quickly
- Establish its greater adequacy
  - ✓ The Dose Makes the Poison Theory explains why we do not become drunk after one glass of wine

Rowan 1990

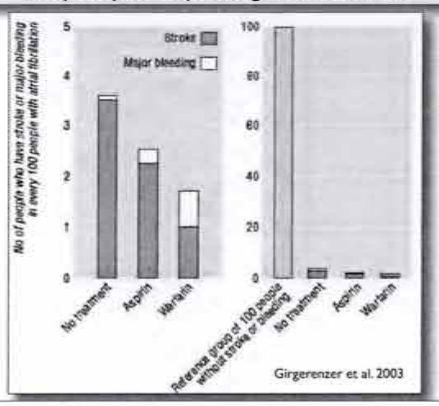
72

A Picture Is Worth a Thousand Words



Frequency for Expressing Absolute Risks

73

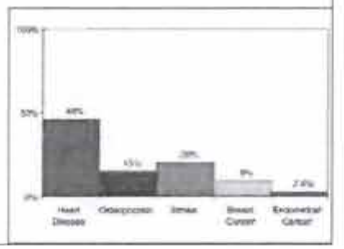


Use of Frequency Graphs to Illustrate Risk

74

Depicting a lifetime breast cancer risk of 9%

Schapira et al. 2001



Improving Risk Communication Some Suggestions

75

- Comparing Risks: Safe, Acceptable, Tolerable
  - ✓ Use "tolerable risk" rather than "acceptable risk"
    - * Safe is often interpreted as meaning zero risk
    - * Acceptable connotes good, but risks are viewed as bad
    - * More agreeable to talk about tolerable
      - - Agreeing to put up with a small amount of something undesirable, rather than embracing something bad
    - * Must make the benefits clear

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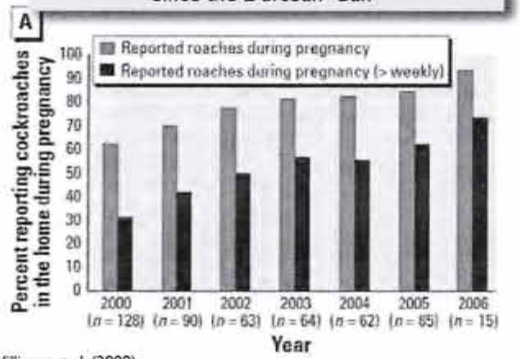
Brainstorm Benefits Messages

- What are the problems with pests?
- What advantage do pesticides have over other methods?
- What programs are in place to reduce pesticide use to the minimal effective amount?
- How has the technology changed--for the better?

77

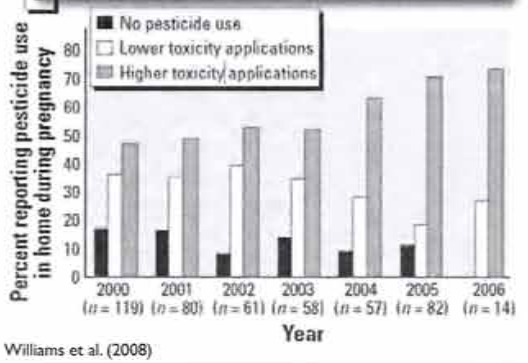
Recent Studies Show Increased Pest Problems Since the Dursban "Ban"



Williams et al. (2008)

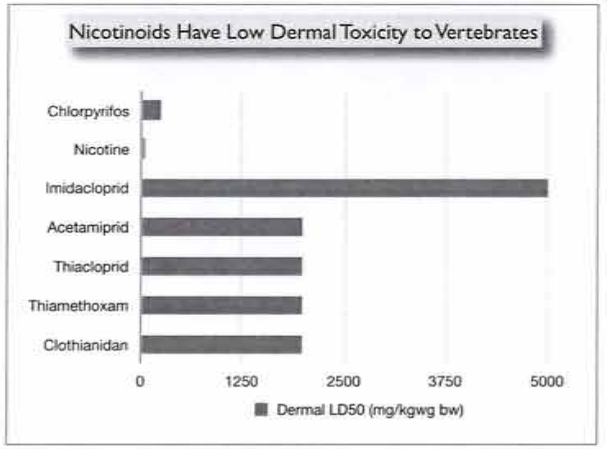
78

Pyrethroids Were Substituted for Dursban & Use Has Increased, Not Decreased



Williams et al. (2008)

79


Nicotinoids Have Low Dermal Toxicity to Vertebrates
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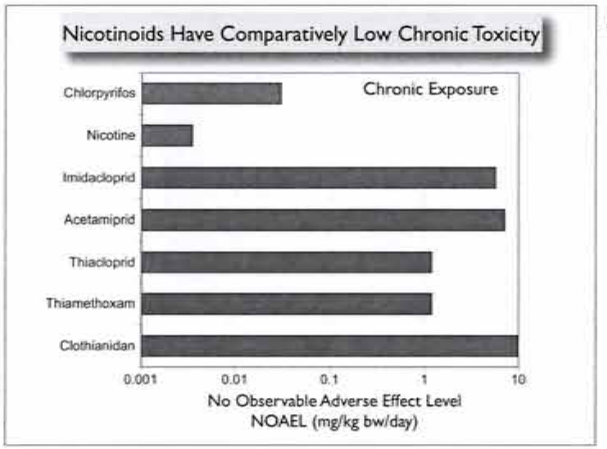
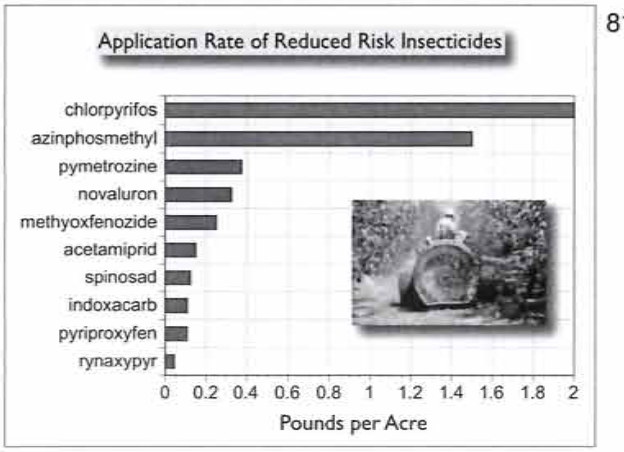
Nicotine
Imidacloprid
Acetamiprid
Thiacloprid
Thiamethoxam
Clothianidan
0
1250
2500
3750
5000
Dermal LD50 (mg/kgwg bw)

80


Nicotinoids Have Comparatively Low Chronic Toxicity
Chronic Exposure
Chlorpyrifos
Nicotine
Imidacloprid
Acetamiprid
Thiacloprid
Thiamethoxam
Clothianidan
0.001
0.01
0.1
1
10
No Observable Adverse Effect Level
NOAEL (mg/kg bw/day)

81


Application Rate of Reduced Risk Insecticides
chlorpyrifos
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pymetrozine
novaluron
methyoxfenozide
acetamiprid
spinosad
indoxacarb
pyriproxyfen
rynaxypyr
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
Pounds per Acre

82

Novel Low Impact Ways to Control Termites

83

Hand Weeding Requirements

Hours Labor Required/Acre

Crop	No Herbicide Use	Use of Herbicides
Carrots	75	14
Corn	60	5
Cotton	67	13
Spinach	209	20
Total Laborers Needed	70 million	7 million

Gianessi LP, Reigner NP. 2007. The value of herbicides in U.S. crop production. Weed Technology 21: 559-566.

84

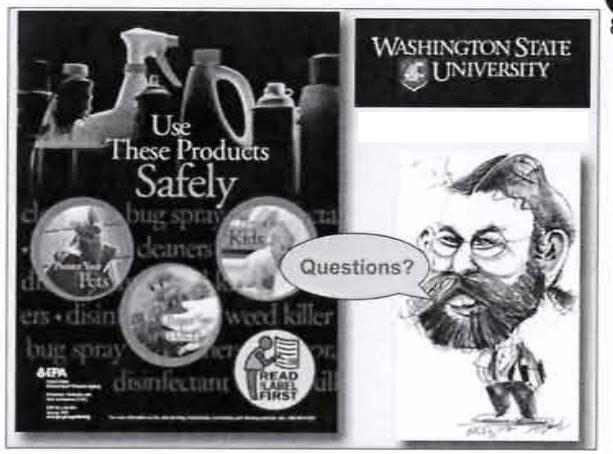
Value of Pesticide Use

- Transforming "saved" or "protected" yield to dollars, the ratio of costs to net returns for insecticide use in U.S. crop production has been estimated to be nearly 20:1

Value ($ Billions) of pesticides in US crop production

	Herbicides (2005)	Insecticides (2008)	Fungicides (2002)	Total All Pesticides (2002-2008)
Cost to growers	7.1	1.2	0.9	9.2
Non-use cost increase	9.7	--	--	9.7
Yield benefit	16.3	22.9	12.8	52
Net benefit	26	21.7	12	59.7
Return ratio: benefit/cost	3.7	18.1	13.3	6.5

Popp (2011) J.Verbr. Lebensm. 6:S105-S112


Use
These Products
Safely
bug spray
cleaners
Kids
Pets
weed killer
bug spray
disinfectant
READ LABEL FIRST
EPA
WASHINGTON STATE UNIVERSITY
Questions?

CropLife

Road Map for Conducting Risk Assessments - Latam

Santiago de Chile, May, 2015

Ximena Patino, MSc, DMV
Bayer CropScience

Principles of Risk Assessment

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- A practice that determines the nature and likelihood of effects on organisms and the environment as a cause
- Risk estimated from the relationship between exposure and effects made with some degree of uncertainty
- Two basic elements evaluated
  - Exposure: the interaction of stressors with receptors
  - Effects: nature and magnitude of effects with exposure

* SETAC Technical Issue Paper. 1997. Ecological Risk Assessment

2

Scheme

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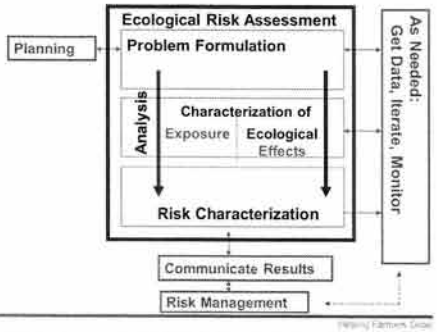
Ecological risk assessment EPA (1992 adopted 1998)



Schemes

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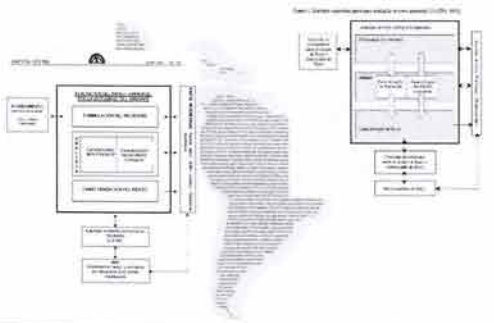

First Step: Problem Formulation

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- Provides a clear description of the objectives, characteristics of the "stressor" - pesticide?, ecosystem potentially at risk?, potential effects?
- Includes a conceptual model (written description and visual representation of predicted relationships between ecological entities and the pesticide to which they may be exposed)
- Outline, how the analysis will be conducted and the required data (analysis plan)

Conceptual Model - example

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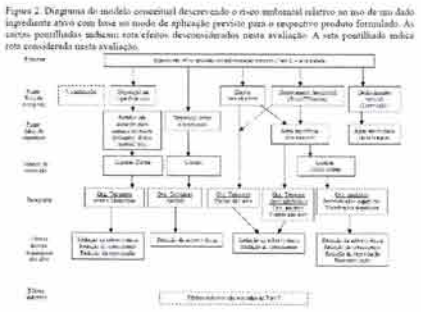

First Step: Problem Formulation

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- Protection goals incorporated into risk assessment problem formulation to
  - meet the needs of the risk manager
  - enable effective risk communication to public
- A conceptual model is developed for each protection goal from information about stressors, potential exposure and predicted effects on an ecological entity (the assessment endpoint)
- Valuation of ecological entity and its assessment endpoint given in protection goal
- Need a practical process with options

The Second Step: Data Analysis

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Exposure Data
- Environmental properties
- Use pattern
- Environmental behavior

Effects Data
- Aquatic organisms
- Terrestrial organisms
- Short term
- Long term

Tiered Approach

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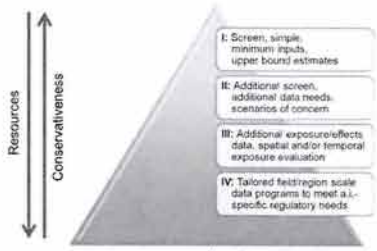

Alternatives:
Tier III: Identify mitigation measures
Tier IV: Define mitigation measures as needed

Ecotoxicology Testing

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- Indicator species and testing tiers - Advantages
  - Global data package enables efficiencies in joint review
  - Standardized test guidelines generally result in robust endpoints
  - Proven success in husbandry
  - Availability of a large data set to determine relative sensitivity to many substances - general acceptance as indicators of adverse effects
  - Minimizes unnecessary testing of vertebrate animals
  - Can be tested in more realistic exposure pattern (microcosm) to evaluate effects outside guideline conditions
  - Potential for waiving requirement when exposure does not occur

Ecotox Testing

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Need for Non-Standard Species?

- There may be value in testing additional taxa
  - Protection goal may require testing of an important local organism not covered by standard species
    - Example: silkworm in Japan and China
  - Adds value to higher tier assessment by defining species sensitivity distributions
  - At higher tiers, testing in more realistic semi-field and field studies bring in additional multiple taxa, allowing evaluation of population and community level effects
- Utility determined by structure of assessment program and use of data

Exposure Estimation

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- Exposure assessment made possible for active ingredients by physico-chemical property testing and the core environmental fate laboratory studies
- Range of estimation methods available
  - Simple spreadsheet with exposure assumptions
  - In-field/edge-of-field process models for a generic scenario
  - In-field/edge-of-field process models for specific scenarios
  - Possible landscape-scale modelling
  - Monitoring study targeted to a specific question

Resources ↔ Conservativeness

- Point estimates or distributions for input and output

Risk Characterization

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- Risk = Hazard x Exposure
- At its simplest: Risk Quotient
  - (Exposure < Hazard) = No Risk

    Therefore
    - (Exposure/Hazard <1) = No Risk

      Or
    - (Hazard/Exposure >1) = No Risk

Note: Hazard = "toxicity" or "effects"

Use of Risk Quotients

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Use of Risk Quotients

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- Risk Quotients method used on first tiers, as first protective characterization of the risk
- Risk Quotients (RQ)
  - If risk quotient less than 1 (exposure < hazard): there should be no risk
  - However, uncertainty ("safety") factors sometimes used to account for untested species or species that require additional protection
  - In such cases a Level of Concern (LOC) is set and the RQ must be lower than a value less than 1 (e.g. 0.1)
- If RQ is >LOC, then the assessment should be refined before making a decision.

Risk Characterization

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Related to the six dimensions of the SPG

Ecological entity:	individual – meta population – functional group – ecosystem
Attribute:	behaviour – survival/growth – abundance/biomass – process – biodiversity
Magnitude:	negligible effect – small effect – medium effect – large effect
Temporal scale:	days – weeks – months – seasons – > 1 year
Spatial scale:	in crop – edge of field – nearby off-crop – watershed/landscape
Degree of certainty:	low – medium – high*

Can an RQ account for these attributes?

Risk Characterization

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- Practical tiered scheme
- Accounting for uncertainty
  - Data vs. safety factors
- Sound and defendable environmental risk assessments that allow sustainable agriculture without unacceptable effects on the environment
- Appropriate exposure models & data on effects to meet these protection goals
- Risk – benefit analysis
- Communicating effectively risk

How are risk assessment approaches developed?

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- Societal expectations determine the protection goals
- Laws, regulations, environmental policies provide the framework
- Risk managers set the goals
- Scientific disciplines provide methodology and data
  - Inputs from government, academic and industry researchers, NGO's, trade associations, professional societies
- Farmers, applicators, land managers contribute reality check, practicality, representativeness

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Questions?

Thank you!

Feeding Farmers Grow