



**EPA and Aquatic Pesticide
Registration -
No Unreasonable Adverse Effects
on Man or the Environment**

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Outline

- Applicable Statutes for Pesticide Registration
- Legal Ways to Apply Pesticides
- Data required for a Dietary Risk Assessment
- Data required for an Ecological Risk Assessment
- How EPA Uses A Risk Assessment
- Registration Review
- Notes on - MCLs and NPDES
- Aquatic Herbicide Successes

Applicable Statutes

Food Quality Protection Act
(FQPA) (1996)

Pesticide Registration
Improvement Act (2004)

Federal Food Drug
And Cosmetic Act
(FFDCA)

Federal Insecticide Fungicide
And Rodenticide Act
(FIFRA) (1947)

Tolerance Established

Product Registered

Federal Insecticide Fungicide and Rodenticide Act (FIFRA)

- Registration
 - FIFRA allows for registration if a product will perform its intended function without unreasonable adverse effects on the environment.
 - FIFRA is a risk benefit/statute.
 - FIFRA takes into account economic, social and environmental costs and benefits.

Federal Food Drug and Cosmetic Act (FFD&C)

- Tolerance setting
 - Tolerances for pesticides are established by EPA under the FFD&C Act.
 - General standard for tolerances is that there will be a reasonable certainty that no harm will result from residues of pesticides in food or feed.
 - It is a risk statute.
 - It does not take into account economic, social or environmental costs and benefits.

Food Quality Protection Act 1996

- Set a general standard for tolerances – a reasonable certainty that no harm will result from aggregate exposure
- Periodic pesticide registration
- Endocrine disruptors – development and implementation of a comprehensive screening program
- Special provisions for infants and children taking into account food consumption, neurological development and in utero exposure.
- Use of percent of crop treated for chronic dietary risks

Pesticide Registration Improvement Act (PRIA)

- FIFRA was amended by requiring a registration service fee system
- EPA review time frames were established for all actions
- Extending time frames is by mutual consent
- EPA retains discretion to expedite any action

Example

| <u>Action*</u> | <u>Decision Time</u> <u>(Months)</u> | <u>Fee**</u> |
|-----------------------------------|-----------------------------------------|--------------|
| | | RD |
| New ai food use | 24 | \$569,000 |
| New ai nonfood use | 21 | \$395,000 |
| New food use | 15 | \$60,000 |
| New non food use | 15 | \$24,000 |
| Amendment (change in labeling) | 4 | \$4,000 |

* 58 PRIA action codes for RD

**Rounded to nearest 1,000

Legal Ways to Use a Pesticide

- Section 3 –federal registration
- Section 5 –experimental use permit
- Section 18 –emergency use
- Section 24 (c) –state registration

Federal Registration

- Pesticide product label is federal license for use of a pesticide
- Still requires individual state registration
- Product must be used in accordance with its labeling
- “Use” includes handling, mixing, storage loading, transportation as well as use

Experimental Use Permit

Aquatic Uses

- Permit required if testing over 1 surface acre of water
 - Gather data for registration
 - Crop destruct, temporary tolerance or limit use of water
- Authorized for 1 to 2 years
- Permit not required if testing 1 or less surface acre of water

Emergency Use

- Authorizes an unregistered pesticide use to state or federal agencies for:
 - Significant economic loss or
 - Significant risk to threatened or endangered species or
 - Prevent the introduction or spread of a new pest or
 - Control a pest that will cause a significant risk to human health
- Must be an urgent, non routine situation
- Authorized for 1 to 3 years

State Registration

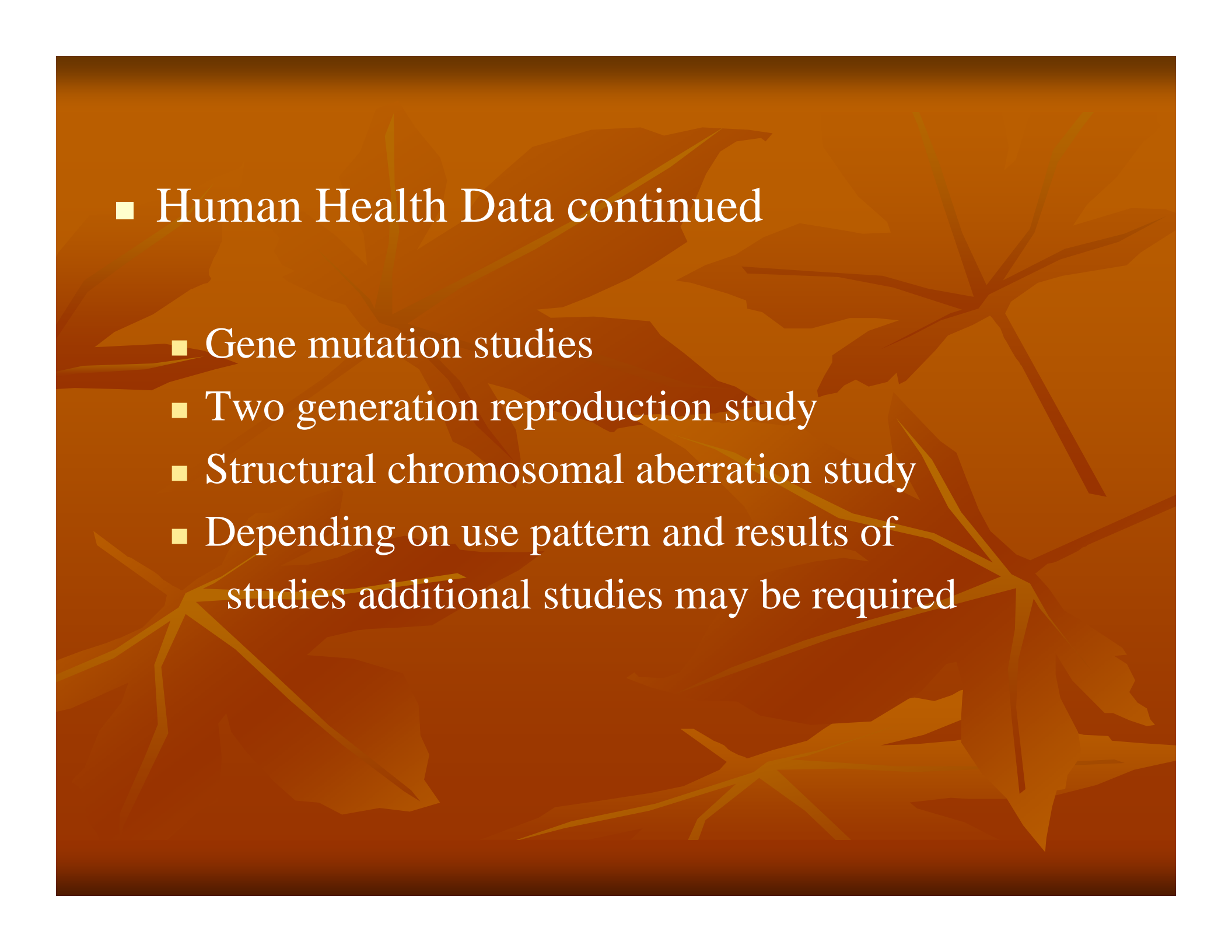
- States may register an additional use of a federally registered pesticide product
- “Additional use” is broadly defined
- EPA reviews 24(c) registrations, and may disapprove them if:
 - The use is not covered by necessary tolerances
 - The use has been previously denied disapproved, suspended or canceled

Unique Items to be Addressed in Registering an Aquatic Pesticide

- Fish tolerances
- Shell fish tolerances
- Irrigated crops
- Swimmers
- Drinking water

Data Required for a Dietary Risk Assessment

- Human Health Data
 - Acute toxicity studies
 - Subchronic toxicity testing
 - Chronic toxicity
 - Oncogenicity
 - Developmental toxicity

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- The background of the slide features a pattern of overlapping autumn leaves in various shades of brown and orange, set against a darker brown gradient background.
- Human Health Data continued
 - Gene mutation studies
 - Two generation reproduction study
 - Structural chromosomal aberration study
 - Depending on use pattern and results of studies additional studies may be required

Data Required for a Dietary Risk Assessment

- Residue Chemistry Data
 - Chemical identity
 - Nature of residues
 - Magnitude of residues
 - Analytical methods for residue detection

What does EPA do with all this Data?

- It conducts a human health risk assessment to evaluate the likelihood that an adverse human health risk may occur as a result of exposure to a pesticide via direct or indirect contact, or by ingestion of treated foods.
- How does it do this?

- It does this by determining:
 - what hazards need to be addressed - commonly referred to as toxicity endpoints of concern
 - Determining the no effect level for those hazards
 - Applying these no effect levels to various exposure scenarios
 - Acute
 - Chronic and
 - Carcinogenic
 - Add a uncertainty factor (Toxicity endpoints of concern and a 100 fold safety factor)

Acceptable Risks

EPA uses a no observable adverse effect level (NOAEL) from the toxicology endpoints.

- Dietary – EPA determines a reference dose (RfD) using the NOAEL for the most toxic endpoint divided by an uncertainty factor (UF) generally 100.

Example: if the endpoint is 1000mg/kg it is divided by 100 resulting in 10 mg/kg as the usable endpoint.

The risk is acceptable as long as the exposure does not exceed the RfD.

- Non dietary- EPA determines a level of concern (LOC) via addition of an UF.
 - A ratio of the toxicology endpoints of concern to exposure is calculated and compared to the LOC.
 - If it is less than or equal to the LOC the risk is acceptable.
- Carcinogenicity 1 in a million.

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■ Water

- Drinking Water Levels of Concern (DWLOC) are determined based on the remaining percent of RfD after food is taken into consideration.
- Exposure from drinking water levels are looked at from both an acute and chronic standpoint.
- Allowable water levels are compared to the DWLOC .

Studies Required for an Ecological Risk Assessment

- There are two categories of data required:
 - Environmental Fate and Transport Studies – looking at fate and transport of a pesticide and its degradates.
 - Ecological Toxicity Studies – looking at toxicity of the pesticide and its degradates.

Fate and Transport Assessments

- Tells us where and how the pesticide moves in the environment.
- How long a pesticide will persist.
- What degradation products are produced and in what quantities.
- How much is likely to reach ground water and/or surface water.

Chemical Degradation

- Hydrolysis
- Photolysis
 - Photodegradation in water
 - Photodegradation on soil
 - Photodegradation in air

Metabolism

Metabolism studies are used to determine the break down products from organisms metabolizing the parent pesticide product.

There are four types of fate metabolism studies:

- Aerobic Soil Metabolism
- Anaerobic Soil Metabolism
- Anaerobic Aquatic Metabolism
- Aerobic Aquatic Metabolism

Mobility and Bioaccumulation

- Volatility- looks at dissipation thru evaporation
- Dissipation studies - determine the extent of dissipation and mobility of pesticide residues under actual use conditions.
 - Aquatic field dissipation
 - Terrestrial field dissipation
 - Forest field dissipation
- Bioaccumulation in aquatic non-target organisms
- Leaching
- Accumulation in fish

Ecological Toxicity Studies

- Tests on avian species
- Tests on mammalian species
- Tests on aquatic species
 - Estuarine/marine fish
 - Estuarine/marine invertebrate
 - Warm water fish
 - Cold water acute fish
 - Freshwater invertebrate

Other Studies

Based on acute toxicity and if product is applied directly to water or will be transported to water at a given level

- Sub Chronic Testing of Fish
- Full Life Cycle Invertebrate
- Multi-generation Fish Study

Case-by-case basis based on outcome of other studies, fate characteristics and use pattern

PLANT TOXICITY TESTS

- Aquatic plants
- Terrestrial plants
 - Seedling emergence
 - Vegetative vigor

How do We Use These Risk Assessments?

- We use the data and risk assessments to develop labeling language.
 - User Safety Precautions
 - Environmental Safety warnings
 - Product Container Disposal
 - Directions for Use
 - Pesticide Classification

The label is the Law

WHAT DOES ALL THAT MEAN ?

You can use a pesticide labeled for aquatic use to control nuisance pests without causing unreasonable adverse effects on man or the environment, as long as you follow the label directions.

MCL

- The Office of Water is responsible for setting MCLs
 - A MCL is a maximum contaminant level
 - A MCL is set at a level at which there is no known or anticipated threat to a human
 - It is an enforceable level
 - There are MCL's for some aquatic pesticides
 - If a MCL exists for a chemical OPP uses it in its risk assessments

NPDES

- Short history NPDES and pesticides
 - Not required by regulation FR 11/27/2006
 - Court vacated EPA regulations – 1/7/2009
 - EPA proposed general permits 2010
 - Final Rule issued 10/31/2011 (handled in OW)
 - (1) mosquito and other flying insect pest control;
 - (2) weed and algae control;
 - (3) animal pest control; and
 - (4) forest canopy pest control.

Registration Review

- Registration Review
 - Applies to all pesticides
 - On a 15-year cycle
 - The process is set by rule
 - Science reviews are updated as needed
 - Adds to what we know about the chemicals

New Aquatic Herbicides for Invasive Weed Control

- Prior to 1986 -- 7 or 8 major aquatic herbicides registered
- From 1986 to 2003 no new aquatic herbicides registered
- Since 2003-- 7 new aquatic herbicides registered
 - Triclopry (Renovate) 2003
 - Imazapyr (Habitat) 2003
 - Carfentrazone-ethyl (Stingray) 2004
 - Penoxsulam in Florida 2007
 - Imazamox (Clearcast) 2008
 - Flumioxazin 2010
 - Bispyraibac-sodium 2011
 - Quinclorac ????????



Thank you!