Aquatic Herbicide Toxicology

Presentation for The Interface between Aquatic Herbicide Use and Salmonids: A Focus on Critical Habitat in the Pacific Northwest Region

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By Way of Introduction

• My career began in 1972
  – ESA enacted 1972
  – FIFRA data requirements modernized, October 21, 1972 and October 25, 1988
  – I began extensive work with aquatic herbicides in 1978

• I have been addressing pesticide risk since 1972 and risk mitigation with respect to the ESA since 1981

• Project Manager of the FIFRA Endangered Species Task Force since 1997
Outline

• Basic principles of discovery and development
• Aquatic herbicide registration requirements
• EPA review history
• Additional herbicide reviews and risk assessments
• Management of complexity and uncertainty in risk assessment and mitigation
Pesticides are not “externalities” of the market system, like air and water pollution, nor are they unfortunate byproducts of urban industrial society. We intentionally apply these chemicals for important agricultural and public health reasons. Pesticides are in many respects the key to America’s agricultural abundance, and have proved instrumental in eradicating such diseases as typhoid and malaria. Pesticides, as we shall see, might be characterized simply as “good things that can cause harm,” or, “bad things that can do good,” depending upon your perspective.

Bosso, 1990
Chinook Salmon, an endangered species. Photograph credit: Pat & Tom Lesson/Science Photo Library

Eurasian milfoil, an invasive species that destroys habitat. Photograph by John Kaprielian/Science Photo Library

Bluetongue virus particle, a Aquatic weed control research Photograph credit: USDA/Science Photo Library

Salmon spawning Photograph credit: David Nunuk/Science Photo Library
Bosso Goes on to Note:

Value conflict is accompanied by disputes over means and methods. Whose scientific data are more “correct?” Which analytical techniques do we accept as valid? Who decides? Values intrude mightily into every facet of science and technology.
Basic Principles of Discovery and Development

• All major invention companies now include selection criteria on environmental safety in their decision standards for new product development or for support of existing products

• Two distinct communities of conventional pesticide registrations have evolved: generic and original registrants

• Most aquatic uses are managed, from a technical and regulatory standpoint, by the data holders or “original registrant”
Understanding Data Development Components

1-2: Discover
   - Initial safety and delivery mechanism research

2-4: Develop
   - Testing in relevant field sites and lab

2-3: Define
   - Data compilation, risk assessment and peer review

2-3: Register
   - Continuous validation and reevaluation

2-3: Educate
   - Educate users on safe use; expand supporting data

Volume of Data Over Time
Potential Commercialization begins under an Experimental Use Permit

- An experimental use permit (EUP) is supported by a considerable amount of data, required before any significant environmental release of the product
- The EUP requires site-specific record-keeping and extensive field trial data collection
- Usually, only those products expected to be marketable reach the EUP stage, and some of these do not make it to commercial production
Full Registration

• Initial registration
  – Is typically *conditional*
  – Usually occurs after two or three years of EUP trials
  – Is reviewed
    • Whenever label directions change
    • Under Special Review if conditions warrant
    • Every 15 years

• Most aquatic herbicides remain in the “conditional registration” (as opposed to *full* or *unconditional* registration) phase for long periods or permanently
How Does Treatment Compare to Toxicity?

- Most aquatic herbicides are used at a water concentration level of less than 3 ppm.
- Three ppm is equivalent to 3 golf balls in a boxcar full of golf balls.
- The short term toxicity of these products to humans and animals is 10 to more than 1,000 times this amount.
What about Long Term Effects?

- Long term effects require long term exposure
- Long term exposure as defined by testing is continuous intake over a significant period of the life span
- Most commonly used aquatic herbicides last for short periods in water and long term exposure is therefore not expected (and is additionally mitigated by label restrictions)
Data requirements are initially determined by one of 12 use groups

(1) Terrestrial food crop use
(2) Terrestrial feed crop use
(3) Terrestrial nonfood crop use
(4) Aquatic food crop use
(5) Aquatic nonfood use
(6) Greenhouse food crop use
(7) Greenhouse nonfood crop use
(8) Forestry use
(9) Residential outdoor use
(10) Residential indoor use
(11) Indoor food use
(12) Indoor nonfood use
Basic Data Requirements

• Product Chemistry
  – Product composition
  – Nominal concentration and certified limits
  – Physical and chemical characteristics

• Product performance / Directions for Use

• Toxicology – Humans and Domestic Animals
  – Acute Studies
  – Subchronic studies
  – Chronic Studies
  – Developmental Toxicity and Reproduction Studies
  – Mutagenicity Studies
  – Metabolism Studies
Basic Data Requirements

• Hazards to Non-Target Organisms
  – Short Term Studies
    • Avian species
    • Freshwater, estuarine and marine aquatic vertebrates
    • Freshwater, estuarine and marine aquatic invertebrates
    • Terrestrial and aquatic plants
  – Long term Studies and Field Studies
    • Avian species
    • Freshwater, estuarine and marine aquatic vertebrates
    • Freshwater, estuarine and marine aquatic invertebrates
    • Terrestrial and aquatic plants
    • Ecosystem effects
  – Applicator and Post-Application Exposure
  – Pesticide Spray Drift Evaluation
Basic Data Requirements

• Environmental Fate
  – Degradation Studies
    • Hydrolysis
    • Photodegradation
  – Metabolism Studies
    • Aerobic soil, water and air
    • Anaerobic soil
  – Mobility
    • Leaching studies
    • Adsorption/desorption studies
    • Volatility
  – Dissipation
    • Movement through soil and water
    • Groundwater and run-off studies
    • Rotational crops
Basic Data Requirements

• Residue Chemistry
  – Nature of the Residue Studies in Foods
    • Plants (at least 3 studies in different species)
    • Animals (livestock, fish and shellfish)
  – Residue Studies in Edible Crops
    • Irrigated crop studies
  – Accumulation Studies
    • Rotational crop studies
    • Fish/shellfish studies
  – Residue Studies in Drinking Water
Flexibility of Data Requirements

FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review.

(40 CFR 158.30(a))
Typically with Aquatic Herbicides

• Multiple tiers of testing are required, due to the extreme sensitivity of releasing a chemical product into an aquatic ecosystem.
• Almost always, 40 CFR 158.30(b) applies to aquatic herbicides:

  The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.
Data Builds Over Time

• Most aquatic herbicides have been registered for long periods of time

• Data builds over time, for example
  – Endothall first registered for aquatic use in 1960
    • 1206 EPA data submissions
  – Diquat first registered for aquatic use in 1961
    • 1516 EPA data submissions
  – Floridone first registered for aquatic use in 1986
    • 330 EPA data submissions
Scientific Review

• Newer products, such as floridone, will undergo their first round of re-review under EPA’s Registration Review program
• Older products, such as 2,4-D, endothall, glyphosate, and diquat, have undergone numerous reviews
  – Of note: no product primarily devoted to aquatic use ever faced a “Rebuttable Presumption Against Registration,” a pre-1982 program wherein registration was challenged based on certain toxicity triggering points
Interesting Side Note

In the early 1980’s, this list of aquatic – ROW – Forestry herbicides was targeted for special review:

- Acrolien
- Amitrol
- Dichlorprop
- Diquat
- Fenac
- Karbutylate
- MAMA
- MSMA
- Prometon
- Triclopyr

Aquatic uses of acrolien, diquat and trichlopyr remain in place.
Special Review and Reregistration

• Special review grew out of the RPAR program and still exists and is used by EPA
  – Atrazine, for example, is under Special Review
• Reregistration was the first program to design EPA policy for complete review of all registrations having occurred prior to 1984
  – Focus was on human exposure and environmental concentrations (residues and fate in the environment)
Registration Review

- EPA’s current review requirements are for every registration to be reevaluated on a 15 year cycle
  - The focus of this first cycle is strongly on the assessment of pesticide risk to ESA-listed species
  - Review is more transparent, with more public docketing of information and data
    - Good source for summary information
    - Notes data update needs and risk assessment problem formulation
Risk Assessment is not a Static Process
Risk Assessment: FIFRA and Beyond

Hazard
- Product Chemistry
- Toxicology
- Hazards to Non-Target Organisms

Exposure
- Product Chemistry
- Residue Chemistry
- Environmental Fate

Mitigation
- Directions for Use
- Local restrictions
- State programs
Geospatial information is an extremely valuable tool, essential to establishing a screening level national assessment for which later risk mitigation measures, if necessary, can be informed by higher resolution data. However, neither the BiOps or EPA's effects determinations made effective use of geospatial data, but EPA is now incorporating it into their national level risk assessment process.

Map of the 8,438 HUC6 units in the Pacific Northwest (ISAB, 2011)
Uncertainty

• Because salmon ESUs typically consist of groups of populations that inhabit geographic areas ranging in size from less than ten to several thousand square miles (depending on the species), the analysis must be applied at a spatial resolution wherein the actual effects of the action upon the species can be determined (NOAA, 1999)

• Uncertainty and variability analysis should be planned and managed to reflect the needs for comparative evaluation of the risk management options (NRC, 2009)

• The capacity to disprove conclusively the possibility of Type II error events is not within reach of even rigorous scientific methods. Indeed, by discounting the value of science, these strong versions of the precautionary principle would reward ignorance. . . Precaution is a well-understood instinct, but in regulatory contexts such as ESA it lacks the structural decision-making framework that science supplies to the Scientific Method. [Ruhl, 2004]
Reducing Uncertainty for Aquatic Herbicide Use

• The logistics of considering species-use relationships at a national level can be managed at low resolutions, producing useful data for risk assessment purposes, in the manner EPA uses

• Implementation and understanding of mitigations must capture local data – thus many states have local risk assessment programs, particularly for aquatic herbicides

• Local permitting programs consider conditions, specific application windows, and special elements of concern

• Aquatic herbicides are “restricted use” requiring professional, licensed applicators
Thank you for this opportunity to share my thoughts and opinions.

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