US ERA ARCHIVE DOCUMENT

Aquatic Effects Assessment OW/OPP Harmonization

Purpose

- Develop a common effects characterization methodology for use in ecological assessment of chemicals by EPA to meet the mandates of the Clean Water Act and the Federal Insecticide, Fungicide, and Rodenticide Act.
- Enable EPA to communicate to stakeholders how the approaches used to characterize effects in aquatic ecosystems are integrated and implemented.
- Ensure tools and approaches are:
 - Based upon sound science and utilize available data,
 - Are legally defensible under the statutory mandates,
 - Are based upon methodologies that are as consistent as possible,
 - That are implementable at the federal and state level, and that
 - Can be developed as quickly and efficiently as possible.

Background

 Both OW and OPP have a statutory mandate to protect water quality.

 Both OW and OPP have established ecological assessment procedures that have been scientifically peer reviewed have been the basis for regulatory decisions for a number of years.

Existing Efforts: things that can be, are, or will be harmonized:

Data Sets:

- Generally, OW and OPP have similar basic data acceptability criteria.
- Current and future reliance on the ECOTOX database & holdings as the primary source of data in the public literature for effects assessment and criteria development.

Methods:

 OW and OPP have been working collaboratively to introduce state-ofthe-science methods into both OPP's and OW's risk assessments (e.g. species sensitivity distribution analyses used in both OW and OPP effect assessments).

Document Review:

 OW and OPP have been reviewing each other's ecological risk assessment/criteria documents, e.g., Atrazine, Acrolein, Diazinon, Copper

Milestones

- Stakeholder letter, January, 2009
- Scoping paper developed
 - Distributed in April 2009 (planned)
 - Articulates problem formulation.
 - Identify similarities and differences in current process.
 - Describes Stakeholder involvement
 - Identify potential paths forward
- White papers developed by Fall 2009,
 - Exploration of safety factors, including review of current GLI Tier II approach
 - Generation of dataset using synethetic data, e.g. SSD
 - Available methods for bridging data, e.g QSARs, relative sensitivity of species, or chemical mode of action
- Stakeholder Involvement
- Management review
- External peer review

Benchmarks

- Aquatic Life Criteria are available for currently registered pesticides (~16).
 - OST currently has the capacity to work on 3-4 chemicals/year, and must consider other National priorities (i.e., emerging contaminants).
- SFIREG encouraged collaboration between OW and OPP to agree on endpoints that states could use when Aquatic Life Criteria are not available.
- OPP has posted to its website 148 peer-reviewed aquatic life benchmarks available to the public
- OPP and OW issued a joint letter to SFIREG, indicating that States could use benchmarks for evaluating potential risks of pesticides when ALC not available.

Minnesota Community Benchmarks

(a key contribution to the harmonization effort)

- Evolution of the effects determination process toward a common method that harmonizes both approaches
 - Minnesota Pollution Control Agency
 "Development of Community-level Pesticide
 Aquatic Life and Plant Benchmarks Using Great
 Lakes Initiative Methodologies"
 - A cooperative effort between stakeholders
 - Exposure-based process for determining candidate pesticides.

Summary

- Both Office of Water and Office of Pesticide Programs recognize the value of developing a common methodology harmonizing approach for assessing aquatic ecological effects.
- Both Offices have been working to develop a plan for further harmonizing the effects assessment portions of their respective risk assessment methodologies.
- The two offices have initiated an internal issue scoping and problem definition process. OW and OPP, with assistance from ORD, are developing a problem statement of the science, policy and related programmatic issues.
- This will result in a balanced, transparent process that engages stakeholders, including ASIWPCA, SFIREG, nationally recognized technical experts, the environmental community, the regulated community, and state and local governments, and that assures substantial opportunity for stakeholder input and feedback.