OPP Standard Operating Procedure
Draft: October 25, 2006

Inclusion of Impaired Water Body & Other Water Quality Data in OPP's Registration Review Risk Assessment & Management Process

Goal: Establish a process for the voluntary submission of state & ttribal Clean Water Act (CWA) 303(d), 305(b), and other water quality data for consideration in exposure characterizations for ecological risk assessments and in risk management decisions for pesticide registration review.

Background: The Office of Pesticide Programs (OPP) published the final rule for pesticide registration review on August 9, 2006 with an effective date of October 10, 2006 (ref. www.epa.gov/oppsrrd1/registration_review/). This program ensures that all pesticides continue to meet current health and safety standards. The Congressional goal is to review all existing pesticides every 15 years.

Process for Identification & Submission of Water Quality Data for Registration Review:

1. Problem Formulation –begins well in advance of initiation of risk assessment

- Review schedule for opening registration review case dockets – with focus on the first two years (e.g., FY07 & FY08 in the first schedule). – *Regional water & pesticide staff with input from OPP*
- Identify Clean Water Act (CWA) 303(d) listed water bodies where the pesticide scheduled for review is the cause of impairment, and other State/Tribal water quality concerns associated with the scheduled pesticides based on CWA 305(b) biennial reports or other sources. - *Regional water and pesticide staff provide a single 'report' per region indicating pesticides for which data may be provided.*
- For registration review cases associated with 303(d) listings, mine existing data* that support the listing of each water body, and any other related data.***** Information on any current mitigation should also be submitted. - *Regional water and pesticide staff, working with states and tribes as appropriate.*
- Mine monitoring data* associated with CWA 305(b) or other water quality concerns – *EPA regional pesticide and water staff, working with states and tribes as appropriate*
- Submit all data, data links, or other information to OPP in advance of the docket opening that begins the registration review process, so that useful data can be cited and be available for public comment. Any data submitted later should be submitted during the

public comment period if possible. OPP would prefer to have the submissions in the last quarter of the fiscal year preceding the year in which the pesticide is scheduled to begin registration review. – *Regional water and pesticide staff, working with states, tribes and OPP as needed.*

* Data should conform to the quality standards in Appendix A to the extent possible to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

2. Risk Assessment

- Consider information on impaired water bodies or other water quality data of concern in characterization of predicted ecological risks when a revised risk assessment is needed. – *OPP, with OW and regional consultation/collaboration [Note: OPP's ecological risk assessment may identify additional issues beyond Clean Water Act 303(d) listings.]*
- Publish preliminary risk assessment for public comment along with supporting materials (generally 60 days) and ask for comment as well on possible/practical risk management options – *OPP*

3. Risk Management

- Develop risk management options to address impaired water bodies and other documented water quality issues, to the extent that the problem may be attributed to use of the pesticide. – *OPP, with OW and regional consultation/collaboration*
- Develop monitoring plan options as a condition of registration, based on a determination of risks-benefits, to establish the extent to which additional water bodies may be impaired by the chemical – *OPP, with OW and regional consultation/collaboration*.

4. Issue Risk Management Decision – *OPP*

- Issue an interim or final registration review decision for comment, stating whether the pesticide meets, or does not meet, the FIFRA standard for registration, including the basis for the proposed findings, proposed risk mitigation standards, additional data needs, proposed labeling changes, and deadlines to be set for completing required actions.
- Issue an interim or final registration review decision, including an explanation of any changes and responses to significant comments.
- Ensure risk mitigation measures are implemented, including label changes.

Attachment: Appendix A: Options for Providing Data or Data Locations to EPA/OPP

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There are several options for providing the data or data locations to EPA/OPP:

1. If the data are already in the new STORET database, then simply let OPP know where the dataset is located within the database.

2. If the data are in legacy versions of STORET, or in other data systems, then OPP would like to get the type of metadata and detailed data described in the following sections.

> (n.b., As a point of reference, ***The National Water Quality Monitoring Council***, a consortium of federal, tribal, state and local agencies, academia, and the private and public sector water supply industries, developed guidance on water quality data elements that enhance the evaluation and sharing of water quality data. The data elements identified below were derived from this guidance (http://acwi.gov/methods/data_projects/index.html, accessed 10/2/2006). In addition, detailed guidance on elements included in data quality standards may be found in the ***Environmental Sampling, Analysis and Results (ESAR)*** Data Standard issued by the Environmental Data Standards Council: http://www.envdatastandards.net/content/article/detail/649?PHPSESSID=f4d35d5d72960a91284c065c6ed71f9a)

Sample data must include at a minimum:

- Bibliographic reference
  Data included in an EPA risk assessment need to be citable. The reference would ideally be for a report on the study in which the data were collected. If the bibliographic citation is a website, it should reference the page containing the data in question (not the general site for the database), and must identify the date the page was accessed. A database that is on the web containing data from multiple studies is acceptable, as long as a lead contact (i.e. study director or collecting organization) for the study that collected the specific data in question is provided.
- Sample collection date (and time, if available)
- Sample ID
- Location description (Water body name in National Hydrography Dataset, and location descriptor such as: latitude/longitude, FIPS code, water body & segment)
- Sample media (e.g. water, filtered water, bed sediment, tissue, etc.)
- Concentration detected and measurement units

Other important information that aid in interpreting monitoring data are:

- What was the purpose of the study (i.e. study design rationale)? (a reconnaissance study, targeted to compounds of interest, TMDL plan, statistically designed)
- Analytical method
- Detection limit
- QA/QC for method & samples

- Time of sample (e.g. date, time, and duration (if a composite), or other relevant parameter (such as a flow weighted sample)
- Sample collection method (e.g. grab or composite)
- Toxicity benchmark, if available (e.g. state water quality criterion)

Metadata (ancillary data) are needed when using the data quantitatively, such as

- Land use, including cropping pattern, agriculture/urban, etc.
- Pesticide usage that could affect water quality at sampling location
- Did the sampling methodology & analytical methods go through a formal QA process
- Is the formal QA process documented (e.g. in a report or on a website address)
- For pesticides that adsorb to sediments: percent organic carbon, bulk density, etc.
- Relevant organism parameters (size or life stage)
- For some chemicals, environmental conditions may affect mobility and persistence (for example: temperature, pH, hardness, turbidity). If this is known to occur, information on the parameter would be helpful in interpreting the data.

OPP recognizes that raw data for all the parameters listed above may not be available in all monitoring studies, particularly for older studies, and that the types of water quality data collected might be different between monitoring programs. There is no need for states to create or reformat any data – OPP will attempt to use what is available, either qualitatively or quantitatively. In that spirit:

> If the supporting data were collected in a monitoring program conducted by the states themselves, OPP would like to receive the detailed monitoring data and a copy of any report describing the purpose and design of the monitoring study, or internet web address leading to this information.
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> If the data were collected by an outside party, such as university researchers, then citations of published reports or copies of the reports themselves would provide the needed context. (Note, please do not submit NAWQA data if it was used as the basis of a 303(d) listing or identification of a water body of concern, instead please reference the specific NAWQA dataset.)
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> If any 303(d) listings or other water quality concerns for pesticides were based on watershed characteristics or expected pesticide use, and not actual pesticide detections in surface water, such information could help inform OPP's risk assessment, as well.

In summary, OPP is interested in seeing all available data for a specific water body of concern to a State. If a monitoring study is already contained within the new STORET all that is required is its location within the database. For monitoring studies not contained with the new STORET, please submit data, or provide database locations, with associated documentation or references, as described above.