

AGENDA

FIFRA SCIENTIFIC ADVISORY PANEL (SAP) OPEN MEETING

October 28 – 31, 2008

FIFRA SAP WEB SITE <http://www.epa.gov/scipoly/sap/>

OPP Docket Telephone: (703) 305-5805

Docket Number: EPA-HQ- OPP-2008-0550

U.S. Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive, Arlington, VA 22202

Selected Issues Associated with the Risk Assessment Process for Pesticides
with Persistent, Bioaccumulative and Toxic Characteristics

Please note that all times are approximate
(See note at the end of the Agenda)

Tuesday, October 28, 2008

- 8:30 A.M.** **Opening of Meeting and Administrative Procedures by Designated Federal Official** – Myrta Christian, M.S., Designated Federal Official, Office of Science Coordination and Policy, EPA
- 8:35 A.M.** **Introduction and Identification of Panel Members** - Steven G. Heeringa, Ph.D., FIFRA Scientific Advisory Panel Chair
- 8:45 A.M.** **Welcome** – Frank Sanders, Director, Office of Science Coordination and Policy, EPA
- 8:50 A.M.** **Welcome and Opening Remarks** – Steven Bradbury, Ph.D., Division Director, Special Review and Reregistration Division, Office of Pesticide Programs, EPA
- 9:00 A.M.** **Goals and Objectives** – Donald Brady, Ph.D., Division Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 9:15 A.M.** **Background and Overview: Issues Associated with Assessing Ecological Risks of Pesticides with Persistence, Bioaccumulation, and Toxic Characteristics** - Keith Sappington, M.S., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 9:45 A.M.** **Background and Overview: Aquatic Ecological Exposure Assessments: Rapid Overview of Current Methods** - Ronald Parker, Ph.D., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 10:15 A.M.** **Break**

- 10:30 A.M. Environmental Persistence Issues** – Mohammed Ruhman, Ph.D., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 11:15 A.M. Introduction** - Donald Brady, Ph.D., Division Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 11:30 A.M. Current EFED Methods of Modeling Soil and Sediment Dynamics** – Ronald Parker, Ph.D., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 12:15 P.M. Lunch**
- 1:15 P.M. Overview of the AGRO Model for Pesticides** - Donald Mackay, Ph.D., Canadian Environmental Modeling Centre, Trent University
- 2:00 P.M. Application of Environmental Fate and Food Web Bioaccumulation Models for Assessing Ecological Risks of PBT-type Pesticides** - Frank Gobas, Ph.D., School of Resource and Environmental Management, Simon Fraser University
- 2:45 P.M. Sediment Transport Processes in Pesticide Models** – Robert B. Ambrose, Jr., P.E., Ecosystems Research Division, National Exposure Research Laboratory, Office of Research and Development, EPA
- 3:30 P.M. Break**
- 3:45 P.M. Conclusions: Simulating Sediment Dynamics for Pesticide Aquatic Ecological Exposure Assessments** - Ronald Parker, Ph.D., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 4:15 P.M. Assessing Pesticide Bioaccumulation in Aquatic Food Webs** - Keith Sappington, M.S., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 5:15 P.M. Adjourn**

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Selected Issues Associated with the Risk Assessment Process for Pesticides with Persistent, Bioaccumulative and Toxic Characteristics

Wednesday, October 29, 2008

- 8:30 A.M.** **Opening of Meeting - Administrative Procedures by Designated Federal Official** - Myrta Christian, M.S., Designated Federal Official, Office of Science Coordination and Policy, EPA
- 8:35 A.M.** **Introduction and Identification of Panel Members** - Steven G. Heeringa, Ph.D., FIFRA Scientific Advisory Panel Chair
- 8:50 A.M.** **Assessing Terrestrial Bioaccumulation** - Kristina Garber, M.S., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 9:30 A.M.** **Assessing Long-range Transport** – Faruque Khan, Ph.D., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 10:15 A.M.** **Break**
- 10:30 A.M.** **Evaluating Aquatic Toxicity of Persistent, Bioaccumulative Pesticides** - Brian Anderson, M.E.M., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 11:15 A.M.** **Conclusions and Path Forward** – Keith Sappington, M.S., Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 12:00 P.M.** **Lunch**
- 1:00 P.M.** **Public Comment**
- 3:30 P.M.** **Break**
- 3:45 P.M.** **Charge to Panel – Question 1**
Assessing Environmental Persistence

1. Assessing Exposure to Parent and Degradation Products. When assessing the potential ecological risks of proposed pesticide uses, the Agency is charged with considering both the parent compound and any degradation products of concern. In several of the case studies presented in this White Paper, the Agency has illustrated three approaches for assessing the PBT characteristics and exposure to parent and degradation products. When parent and degradates are considered sufficiently similar in their environmental fate and toxicological properties or when these properties were unknown for the degradates, the Agency has used the Total Residue (TR) method (i.e., the Agency modeled the combined parent and degradate using a common set of environmental fate and toxicological data). In situations where the environmental fate and toxicological properties of the parent and degradate are available and considered sufficiently dissimilar, the Agency has modeled the environmental fate separately using the Residue Summation (RS) or Formation/Degradation kinetics (FD) methods (i.e., modeling individual residues from the parent and degradation products).

- Please comment on the Agency's characterization of the strengths and limitations of these methods and the conditions under which each method should be applied.
- To what extent does the Agency's use of the total residue (TR) and individual residue methods (RS, FD) reflect the current state of the science for assessing exposure to combined parent and degradate compounds?
- Please identify any methods the SAP would recommend for addressing combined exposure to parent and degradate compounds based on the data typically available for pesticide ecological risk assessments as described in this White Paper.

4:45 P.M. Charge to Panel – Question 2

2. Interpretation of Aquatic Degradation Rates for Persistent Pesticides with High Sediment Sorption Coefficients. The environmental fate of persistent pesticides with high sediment sorption coefficients is often influenced by dissipation processes (*e.g.*, sorption on sediment) rather than degradation processes (*e.g.*, hydrolysis, metabolism, photolysis). In aquatic metabolism studies, the sorption process can be a most important process in removing pesticide from the water column. This removal process, however, is not considered as a degradation pathway because the pesticide is simply transferred from the water column to the sediment. Therefore, the total system half-life of the pesticide in aquatic metabolism studies is used to represent the most accurate degradation rate in aquatic environments.

- Considering the environmental fate data typically available to support pesticide registration decisions, please comment on the strengths and limitations of the Agency's approach of using total system half-life for assessing pesticide persistence in aquatic metabolism studies.

6:00 P.M. Adjournment

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Selected Issues Associated with the Risk Assessment Process for Pesticides with Persistent, Bioaccumulative and Toxic Characteristics

Thursday, October 30, 2008

- 8:30 A.M. Opening of Meeting - Administrative Procedures by Designated Federal Official** - Myrta Christian, M.S., Designated Federal Official, Office of Science Coordination and Policy, EPA
- 8:35 A.M. Introduction and Identification of Panel Members** - Steven G. Heeringa, Ph.D., FIFRA Scientific Advisory Panel Chair
- 8:50 A.M. Follow-up from Previous Day's Discussion** – Donald Brady, Ph.D., Division Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 9:15 A.M. Charge to Panel – Question 3**

- 3. Sediment Dynamics.** As part of its baseline ecological risk assessment process, OPP uses environmental fate and transport computer models to generate estimated environmental concentrations (EECs) of a pesticide in surface water, pore water and sediment. The EECs are generated using the EXAMS model parameterized to represent a static farm pond receiving pesticide mass in runoff from a treated agricultural field simulated by PRZM. It is assumed by OPP that EECs generated from this scenario are conservative representations of expected pesticide concentrations not only in this farm pond but also in small first and second order streams that receive runoff-containing pesticide residues from many fields. Currently, the OPP modeling approach accounts for movement of pesticide mass between the water column and benthic region using a set of “lumped” parameters (PRBEN) and a mass transfer coefficient. These parameters are intended to implicitly account for pesticide mass transfer due to processes such as diffusion, settling, resuspension and other processes that tend to mix the sediment layer with the water column. The current OPP modeling approach does not include inflow of sediment to the water body which could lead to burial of sediment containing pesticide through deposition.

- Please comment on the strengths and limitations of OPP's current approach for modeling pesticide transport between the water column and benthic region which relies on the use of lumped parameters to represent multiple transport mechanisms (e.g., diffusion, settling, resuspension) in static ponds.
- In the context of screening-level and refined assessments, please comment on the strengths and limitations of simulating pesticide burial by sediment in static ponds as a process that renders pesticide permanently unavailable for biological interaction (i.e., not bioavailable).
- Please comment on the strengths and limitations of models described in the White Paper with respect to modeling pesticide transport via sediment dynamics. Which processes associated with sediment-based pesticide transport (e.g., sediment enrichment, settling, re-suspension, burial, bioperturbation, pore water diffusion, scour, bank erosion) would be most important to consider in static ponds? Which processes would be most important in flowing water systems?

10:30 A.M. Break

10:45 A.M. Charge to Panel - Question 4

Assessing Bioaccumulation Potential

- 4. Aquatic Bioaccumulation Methods.** Traditionally, OPP's assessment of pesticide bioaccumulation potential in aquatic organisms has relied extensively on the use of bioconcentration factors (BCFs). BCFs consider direct chemical uptake through aqueous exposure routes only. For organic chemicals with PBT characteristics, bioaccumulation from non-aqueous exposure routes (e.g., diet and sediment) can be substantial. For these chemicals, risk assessments in other Agency programs (e.g., Office of Water ambient water quality criteria, Superfund site risk assessments, Office of Research and Development ecological risk assessments) have used a combination of laboratory-, field- and model-based methods for incorporating bioaccumulation via multiple exposure routes. In the pesticides program, a similar integrative approach is being considered for assessing the bioaccumulation potential of organic pesticides with PBT characteristics. This approach considers the type and quantity of data typically available for pesticide ecological risk assessments, relative strengths and limitations of each bioaccumulation assessment method, and uncertainty associated with bioaccumulation predictions using each method.
 - Please comment on the need to consider alternatives to the BCF method for assessing the bioaccumulation potential of organic pesticides with PBT characteristics.

- Please comment on the applicability of the Agency’s approach of using multiple methods (including laboratory-, field- and model-based methods) for assessing bioaccumulation potential of organic pesticides as illustrated in the White Paper.

12:00 P.M. Lunch

1:00 P.M. Charge to Panel – Question 5

5. Terrestrial Bioaccumulation in Terrestrial Food Webs. The Agency currently assesses risks to terrestrial vertebrates that result from direct deposition of pesticides on food items that inhabit the treatment area. In general, this assessment is considered to provide relatively “high end” estimates of acute exposure through the ingestion pathway. At this time, however, the Agency does not routinely assess pesticide bioaccumulation in terrestrial food webs in non-target sites, in part, because the methods and tools for assessing bioaccumulation in terrestrial food webs are not as developed compared to those for aquatic food webs.

- Please comment on factors (e.g., physico-chemical properties) the Agency can consider to identify when bioaccumulation potential in terrestrial food webs may be important to consider in its pesticide ecological risk assessments?
- Please comment on the current state of the science underlying existing terrestrial food web bioaccumulation models and their relative strengths and limitations.

2:00 P.M. Charge to Panel – Question 6

Assessing Toxicity

6. Incorporating Multiple Exposure Routes. For a number of organic chemicals with PBT profiles, aquatic organism exposure via non-aqueous routes (diet, sediment) can be important relative to direct exposure from water. Most standard aquatic toxicity test studies submitted to the Agency for pesticide registration do not incorporate realistic chemical exposure through the diet (e.g., water only exposures). Therefore, toxicity reference values (TRVs) from these studies may underestimate actual environmental effects. To address this concern, other Programs within the Agency have proposed using a tissue residue approach (TRA) for quantifying chemical toxicity (e.g., Office of Water, Office of Research and Development). For quantifying toxicity of organic pesticides with PBT characteristics, the Agency is also considering the use of the TRA.

- Please comment on the strengths and limitations of the tissue residue approach for addressing pesticide toxicity from multiple exposure routes and other methods the SAP deems appropriate.

- In the context of the tissue residue approach, please comment on the strengths and limitations of using measured and predicted tissue residue-effect relationships that are derived from water-only exposures in laboratory toxicity tests.

3:00 P.M. Break

3:15 P.M. Charge to Panel – Question 7

Assessing Long-Range Transport

7. Screening for Long-Range Transport Potential. For some pesticides with PBT characteristics, long-range transport (i.e., transcontinental and intercontinental transport) has been well documented. Currently, OPP's ecological risk assessment process relies heavily on monitoring data for assessing long-range transport concerns. However, this process does not *a priori* screen for long-range transport potential prior to pesticide release in the environment. Difficulties in linking local use patterns of pesticides to far-field (e.g., intercontinental) deposition and exposure in a modeling framework is considered a major challenge in screening and assessing long-range transport potential.

- Please comment on the strengths and limitations of available tools for screening the long-range transport potential of pesticides (e.g., the OECD screening tool for long-range transport).

4:15 P.M. Charge to Panel – Question 8

Cross-Cutting Questions

8. PBT Risk Assessment Issues: In this White Paper, the Agency describes a number of issues associated it has encountered when assessing persistence, bioaccumulation, toxicity and long-range transport in its aquatic and terrestrial ecological risk assessments involving pesticides with PBT profiles. In addition, the Agency has identified various methods and approaches that it is considering for refining its ecological risk assessment process specifically to address these PBT and LRT-related issues. Please comment on:

- The extent to which the Agency has identified and characterized the unique or problematic issues associated with assessing ecological risks of pesticides with PBT characteristics,
- The need for the Agency to incorporate refinements in the tools and methods it uses to assess ecological risks of these compounds

5:30 P.M. Adjournment

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- 8:50 A.M. Follow-up from Previous Day's Discussion** – Donald Brady, Ph.D., Division Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA
- 9:15 A.M. Charge to Panel – Question 9**

9. Example Pesticide Assessments. In this White Paper, the Agency provides examples of how it has assessed the environmental persistence, bioaccumulation, toxicity and long-range transport of several unidentified pesticides using refinements to its ecological risk assessment methods. Given the data available, as illustrated in the pesticide examples provided in the White Paper, please comment on:

- Whether the Agency has used these data appropriately to the fullest extent possible in assessing ecological risks of pesticides with PBT characteristics
- Methods it has used to characterize environmental persistence, bioaccumulation, toxicity and long-range transport potential of the example pesticides.

10:15 A.M. Break

10:30 A.M. Charge to Panel - Question 10

Future PBT-Related Refinements

10. The Agency is considering refinements to its problem formulation process to improve the ecological risk assessment of pesticides with PBT characteristics, as outlined in Chapter 8 of the White Paper. In particular, please comment on:

- The Agency's proposed process for identifying (screening) pesticides for potential PBT risk assessment issues that need to be addressed
- The priority for developing new models, methods, and information for addressing PBT issues.

11:30 A.M. Adjournment

Please be advised that agenda times are approximate; when the discussion for one topic is completed, discussions for the next topic will begin. For further information, please contact the Designated Federal Official for this meeting, Myrta R. Christian, M.S., via telephone: (202) 564-8498; fax: (202) 564-8382; or email: christian.myrta@epa.gov