

US EPA ARCHIVE DOCUMENT

AGENDA

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING
February 25 – 27, 2009

FIFRA SAP WEB SITE <http://www.epa.gov/scipoly/sap/>
OPP Docket Telephone: (703) 305-5805
Docket Number: EPA-HQ-OPP-2008-0835

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

Scientific Issues Associated with the Data Required to Register Plant-Incorporated Protectants.

Please note that all times are approximate (see note at end of Agenda).

Wednesday, February 25, 2009

- 1:30 P.M. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
- 1:40 P.M. **Introduction and Identification of Panel Members** – Steven Heeringa, Ph.D., FIFRA Scientific Advisory Panel Chair
- 1:50 P.M. **Welcome and Opening Remarks** – Steven Bradbury, Deputy Office Director for Programs, Office of Pesticide Programs, EPA
- 1:55 P.M. **Welcome and Introductions** – Janet Andersen, Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
- 2:00 P.M. **Introduction of Topics** – Chris Wozniak, Ph.D., Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
- 2:05 P.M. **Overview of bioinformatics assessment of novel proteins and gene/protein nomenclature issues** - John Kough, Ph.D., Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
- 2:30 P.M. **Overview of issues associated with synergistic effects of multiple PIPs in a plant** - Annabel Waggoner, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
- 2:45 P.M. **Overview of issues associated with soil microbial community effects** - Zig Vaituzis, Ph.D., Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
- 3:00 P.M. **Break**
- 3:15 P.M. **Overview of issues associated with environmental assessment of gene flow** - Chris Wozniak, Ph.D., Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
- 3:45 P.M. **Public Comment**
- 5:30 P.M. **ADJOURN**

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Thursday, February 26, 2009

- 8:30 A.M. Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
- 8:35 A.M. Introduction and Identification of Panel Members** – Steven Heeringa, Ph.D., FIFRA Scientific Advisory Panel Chair
- 8:45 A.M. Charge to Panel**

Charge Question A.1 – Please comment on this approach to identification of proteins found in PIPs to describe the active ingredient and its function as a pesticide. Please comment on the use of the gene name or phenotype in PIPs developed using RNAi. Is there another more systematized naming system that could be employed for either proteins or RNAi ? Please provide a basis for your answer.

10:00 A.M. BREAK

10:15 A.M. Charge to Panel (continued)

Charge Question B.1 – Given the negative results of specific serum screening of novel proteins triggered by identification of six to eight segment searches for allergenic epitopes to date, please comment on whether the six to eight amino acid epitope search provides a statistically significant and biologically meaningful approach for addressing allergenicity risk in the absence of the 35 percent identity trigger? Please provide recommendations on criteria for judging databases for their validity and completeness to address allergen, toxin, anti-nutrient and other hazardous protein similarities. Please provide a basis for your answer.

11:15 A.M. Charge to Panel (continued)

Charge Question C.1 – EPA has developed a draft test guideline [See OPPTS Guideline 890.3800-Synergistic Activity Test] for determining the potential for synergism for combination PIP products, specifically for registration applications that intend on citing existing toxicological data from previously registered PIP event lines. Please comment on the methodology to support the analysis for synergistic

effects for combination PIP products and any additional comments on this approach- including identifying instances where the Agency would be justified to require additional testing with a combination test substance containing a mixture of two or more active ingredients for data development on human health and non-target organism effects.

12:00 P.M. LUNCH

1:15 P.M. Charge to Panel (continued)

Charge Question C.2 – EPA has developed soil microbial community toxicity tests for plants that are modified to inhibit microbial growth (e.g., a gene is inserted into a plant that exhibits a microbiocidal mode of action against a plant pathogen) [See OPPTS Guideline 890.3850 Soil Microbial Community Toxicity Test]. Considering the natural fluctuation of microbial populations in the soil ecosystem and the inherent variability in extracting representative soil samples, please comment on limiting testing to examining effects on activity of beneficial soil microbes, specifically carbon and nitrogen cycling at the soil microbial community level (soil is analyzed for NH₃ and NO₃ content to establish ammonification and nitrification values, respectively, and for CO₂ efflux, in the presence and absence of the stressor). Please provide a basis for your answer.

2:15 P.M. Charge to Panel (continued)

Charge Question D.1 – Gene flow has been distributing various naturally occurring genes between sexually compatible species for millions of years and some of these genes encode traits for plant disease and insect resistance mechanisms. Various methods have been used to study the impacts of natural gene flow. Assuming a case wherein hybridization and introgression of a transgene expressing a pesticidal substance occurs between crop and wild species:

a.) The EPA asks the Panel to discuss whether it is possible to evaluate, in part, impacts of a gene flow event by gathering data on target (pest) species which are associated with the wild species (transgene recipient).

b.) The EPA asks the Panel to discuss whether the gathered data will allow estimating the degree to which resistance to these target species may influence the population dynamics or invasiveness of the wild relative.

c.) The EPA asks the Panel to discuss whether empirical data regarding the target species (e.g., fungi, insects, etc) and non-target species (e.g., pollinators, detritivores) associated with the sexually compatible wild relative have the potential to inform about risks to the SCWR population and the associated community. d.) The EPA asks the Panel to discuss whether an understanding of the potential effect(s) of introgressed transgenes on basic plant habit, phenology and physiology provide a basis for a assessing potential impacts following a gene flow event.

d.) The EPA asks the Panel to discuss whether an understanding of the potential effect(s) of introgressed transgenes on basic plant habit, phenology and physiology provide a basis for a assessing potential impacts following a gene flow event.

3:15 P.M. Break

3:30 P.M. Charge to Panel (continued)

5:00 P.M. Adjourn

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Friday, February 27, 2009

- 8:30 A.M. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
- 8:35 A.M. **Introduction and Identification of Panel Members** – Steven Heeringa, Ph.D., Scientific Advisory Panel Chair
- 8:45 A.M. **Charge to Panel (continued as needed)**
- 10:00 A.M. **Break**
- 10:15 A.M. **Charge to Panel (continued as needed)**
- 12:00 P.M. **Adjourn**

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, Joseph Bailey, via telephone: (202) 564-0130; fax: (202) 564-8382; or email: bailey.joseph@epa.gov.