AGENDA

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING

March 31 - April 1, 2009

FIFRA SAP WEB SITE http://www.epa.gov/scipoly/sap/
OPP Docket Telephone: (703) 305-5805
Docket Number: EPA-HQ- OPP-2008-0859

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 Designating a Prion as a "Pest" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and Related Efficacy Test Methods

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

Tuesday, March 31, 2009

8:30 A.M. **Opening of Meeting and Administrative Procedures by Designated Federal Official –** Myrta R. 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. **Welcome and Opening Remarks** – Steven Bradbury, Ph.D., Deputy Director, Office of Pesticide Programs, EPA

9:00 A.M **Background and Overview -** Jeff Kempter, Senior Advisor, Antimicrobials Division, Office of Pesticide Programs, EPA

9:20 A.M. **A Regulatory Approach to C&D for CWD and EPA's Role in the Process** – Dean Goeldner, D.V.M., Chronic Wasting Disease Program Manager, USDA-APHIS-VS-NCAHP-RHP, Riverdale, MD

9:40 A.M. **FDA Approach to Claims for Reducing TSE Infectivity on Medical Devices** - Sheila Murphey, M.D., Chief, Infection Control Devices Branch; Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation; Center for Devices and Radiologic Health; FDA, Rockville, MD

10:15 A.M. **Break**

10:30 A.M. **EPA's "White Paper" –** Richard Wiggins, Ph.D., National Health and Environmental Effects Research Laboratory, Office of Research and Development, EPA, Research Triangle Park, NC

10:50 A.M. **EPA's Guidance for Efficacy Test Methods for Products Bearing**

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Prion-Related Claims – Richard Wiggins, Ph.D., National Health and Environmental Effects Research Laboratory, Office of Research and Development, EPA, Research Triangle Park, NC

11:15 A.M. **Prion Infectivity Assays** – Christopher J. Silva, Research Chemist, Foodborne contaminants Research Unit, Western Regional Research Center, Albany, CA

11:40 A.M. **Transmissible Spongiform Encephalopathies (TSEs/Prion Diseases): Target Criteria for Assessing Agent Clearance** – David M. Asher, MD, Chief, Laboratory of Bacterial, Parasitic and Unconventional Agents; Division of Emerging and Transfusion-Transmitted Diseases; Office of Blood Research and Review; Center for Biologics Evaluation and Research; FDA, Rockville, Maryland

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**

1. White Paper Issue: Whether EPA's draft review paper, "Scientific Information Concerning the Issue of Whether Prions Are a 'Pest' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)," adequately identifies and summarizes available, relevant scientific studies.

In 2005, EPA established a Work Group to develop a Notice of Proposed Rulemaking (NPRM) that defines a prion as a "pest" under FIFRA. To assure that it considers key available scientific studies that are relevant to the issue of whether a prion is a "pest" under FIFRA, the Work Group drafted a review paper. While the paper received intra-Agency review, it was not subjected to peer review outside of EPA. Accordingly, EPA seeks the SAP's peer review of the attached, draft review paper (USEPA 2008). Some of the key references cited in the review paper have been provided to the SAP.

EPA wishes to point out that the NPRM will also focus on legal and policy matters that are not addressed in depth in the "white paper." EPA is presenting this paper to the SAP solely for review as to its characterization of the <u>scientific</u> issues, and is <u>not</u> asking the SAP to interpret legal/policy issues such as Congress' intent in drafting FIFRA.

- **Please comment on the accuracy of the characterization of the nature of prions, and the adequacy of the review of the relevant scientific information to support that characterization, as presented in EPA's draft paper, "Scientific Information Concerning the Issue of Whether Prions Are a 'Pest' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)."**

5:00 P.M. **Adjournment**

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Wednesday, April 1, 2009

8:30 A.M. **Opening of Meeting - Administrative Procedures by Designated Federal Official** - Myrta R. 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** – Jeff Kempter, Senior Advisor, Antimicrobial Division, Office of Pesticide Programs, EPA

9:15 A.M. **Charge to Panel – Question 2**

2. Efficacy Guidance Test Method Issue: Whether the specific test systems recommended in the draft guidance document are scientifically appropriate to support the registration of pesticide products with prion-related claims.

The draft efficacy guidance document (USEPA 2009) recommends a carrier-based, animal infectivity test method, if the intended use of a product is for treating environmental surfaces, and a suspension-based, animal infectivity test method if the intended use of a product is for treating liquids. The draft efficacy guidance document also states that the test methods may either be end-point titration or incubation time interval assays. EPA is interested in knowing the SAP's opinion on whether these recommended test systems are scientifically sound and appropriate approaches to evaluating the efficacy of pesticide products with prion-related claims. EPA would also like to know whether the SAP recommends that other test methods be considered to evaluate the efficacy of pesticide products used either on

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environmental surfaces or in liquid media.

- **Please comment on the scientific appropriateness of:**

  a. **Carrier-based, animal infectivity assays recommended by EPA's guidance for evaluating the efficacy of pesticide products used on environmental surfaces (e.g., hard, nonporous surfaces).**

  b. **Suspension-based, animal infectivity assays recommended by EPA's guidance for evaluating the efficacy of pesticide products used in liquid media (e.g., wastewater).**

  Any other known test methods for evaluating the efficacy of pesticide products used on either environmental surfaces or in liquid media.

10:30 A.M. Break
10:45 A.M. Charge to Panel - Question 3

3. Efficacy Guidance Performance Criterion Issue: Whether the product performance criterion specified in the draft guidance document to support the registration of pesticide products with prion-related claims is scientifically sound.

The draft efficacy guidance document recommends a target efficacy criterion of six (6) logs of reduction of infectivity in the treated versus untreated (control) groups. This criterion is widely used in the current scientific literature. EPA would like the SAP's comment on this proposed product performance criterion.

- **Please comment on the scientific soundness of the product performance criterion recommended in the draft guidance document to support the registration of pesticide products with a prion claim.**

12:00 P.M. Lunch
1:00 P.M. Charge to Panel – Question 4

4. Efficacy Guidance Labeling Claim Issue: Whether the labeling claim described in the draft guidance document is scientifically appropriate based on the recommended test systems and product performance standard.

The draft efficacy guidance document recommends a carefully worded labeling claim statement: "Has been demonstrated to reduce infectivity of prions (TSE agents) based on testing using (insert type of organism in which the prions were raised) (insert prion type)." EPA believes that claims that may normally be applied to microorganisms (e.g., "destroy," "mitigate," "eliminate," "control") may be misleading when applied to prions. Because currently available test methods can only measure a reduction in infectivity, and the total elimination or destruction of prions cannot be

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measured, EPA believes that “reduce infectivity” is the only appropriate claim.

- **Please comment on the scientific appropriateness of the term “reduce infectivity” in a label claim to reflect the action of a pesticide on prions.**

3:00 P.M. Break
3:15 P.M. Charge to Panel – Question 5

5. Efficacy Guidance Hierarchy Issue: Whether different prion types exhibit variation in the degree of resistance to inactivation by pesticide chemicals and whether a hierarchy of resistance by prion type can be reliably determined at this time.

Comparisons of different types of prions in a common animal infectivity assay indicate there may be significant differences with regard to their ability to resist inactivation by pesticide chemicals. For example, Peretz et al. (2006) compared the resistance of hamster scrapie and human CJD prions in transgenic mice expressing either hamster PrP or a chimeric mouse-human PrP transgene and found that human sCJD prion tested was 100,000 fold more difficult to inactivate than hamster Sc237 prion. Preliminary additional studies indicate that the cow BSE prion may be even more resistant to inactivation than the human CJD prion (Giles et al. 2006; 2008 in press).

- **Please comment on whether a hierarchy of resistance among prion types can be reliably demonstrated for different pesticide chemicals based on the available data.**

5:00 P.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