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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

December 7, 2009

MEMORANDUM

SUBJECT: Transmittal of Meeting Minutes of the FIFRA Scientific Advisory

Panel Meeting held November 3, 2009 on the Presentation of the

Approach to Reevaluate Atrazine

TO:

Debbie Edwards, Ph. D.

Director

Office of Pesticide Programs

FROM:

Joseph E. Bailey, Designated Federal Official

FIFRA Scientific Advisory Panel

Office of Science Coordination and Policy

THRU:

Laura Bailey, Executive Secretary Laura

FIFRA Scientific Advisory Panel

Office of Science Coordination and Policy

Frank Sanders, Director

Office of Science Coordination and Policy

Attached, please find the meeting minutes of the FIFRA Scientific Advisory Panel open meeting held in Arlington, Virginia on November 3, 2009. This report addresses the informational meeting held on the Presentation of the Approach to Reevaluate Atrazine.

Attachment

cc:

Stephen Owens James J. Jones Steven Bradbury Vicki Dellarco William Jordan Margie Fehrenbach Keith Matthews Donald Brady William Diamond Jack Housenger Tina Levine Jack Fowle Joan Harrigan-Farrelly Lois Rossi Richard Keigwin Anna Lowit **Edward Ohanian** Elaine Francis Carol Christensen Elizabeth Mendez **Enesta Jones Douglas Parsons** Vanessa Vu **OPP Docket**

FQPA Science Review Board Members

Steven G. Heeringa, Ph.D. (FIFRA SAP Chair)
John R. Bucher, Ph.D., DABT
Janice E. Chambers, Ph.D., DABT, Fellow ATS
Carey N. Pope, Ph.D.
Kenneth M. Portier, Ph.D.
Daniel Schlenk, Ph.D.

SAP Minutes No. 2009-09

Federal Insecticide, Fungicide and Rodenticide Act Scientific Advisory Panel Informational Meeting

Presentation of the Approach to Reevaluate Atrazine

November 3, 2009
FIFRA Scientific Advisory Panel Meeting
held at the Environmental Protection Agency
Conference Center
Arlington, VA

NOTICE

These meeting minutes have been written as part of the activities of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP). The meeting minutes represent the views and recommendations of the FIFRA SAP, not the United States Environmental Protection Agency (Agency). The content of the meeting minutes does not represent information approved or disseminated by the Agency. The meeting minutes have not been reviewed for approval by the Agency and, hence, the contents of these meeting minutes do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the Federal Government, nor does mention of trade names or commercial products constitute a recommendation for use.

The FIFRA SAP is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act and established under the provisions of FIFRA as amended by the Food Quality Protection Act (FQPA) of 1996. The FIFRA SAP provides advice, information, and recommendations to the Agency Administrator on pesticides and pesticide-related issues regarding the impact of regulatory actions on health and the environment. The Panel serves as the primary scientific peer review mechanism of the Environmental Protection Agency, Office of Pesticide Programs (OPP), and is structured to provide balanced expert assessment of pesticide and pesticide-related matters facing the Agency. FQPA Science Review Board members serve the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP. Further information about FIFRA SAP reports and activities can be obtained from its website at http://www.epa.gov/scipoly/sap/ or the OPP Docket at (703) 305-5805. Interested persons are invited to contact Joseph E. Bailey, SAP Designated Federal Official, via e-mail at bailey.joseph@epa.gov.

In preparing these meeting minutes, the Panel carefully considered all information provided and presented by EPA, as well as information presented by public commenters.

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SAP Minutes No. 2009-09

FIFRA Scientific Advisory Panel Informational Meeting Regarding:

Presentation of the Approach to Reevaluate Atrazine

November 3, 2009 FIFRA Scientific Advisory Panel Meeting Held at the Environmental Protection Agency Conference Center Arlington, VA

Steven G. Heeringa, Ph.D.

FIFRA SAP Chair

FIFRA Scientific Advisory Panel

Date: December 1, 2009

Joseph E. Bailey

Designated Federal Official

FIFRA Scientific Advisory Panel

Date: December 1, 2009

Federal Insecticide Fungicide and Rodenticide Act Scientific Advisory Panel Meeting November 3, 2009

PARTICIPANTS

FIFRA SAP Chair

Steven G. Heeringa, Ph.D., Research Scientist & Director for Statistical Design, University of Michigan, Institute for Social Research, Ann Arbor, MI

Designated Federal Official

Joseph E. Bailey, FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, EPA

FIFRA Scientific Advisory Panel Members

John Bucher, Ph.D., DABT, Associate Director, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC

Janice Chambers, Ph.D., DABT, Fellow ATS, Director, Center for Environmental Health Sciences, College of Veterinary Medicine, Mississippi State University, Mississippi State, MS

Carey N. Pope, Ph.D., Professor, Head & Sitlington Chair of Toxicology, Department of Physiological Sciences, Oklahoma State University, College of Veterinary Medicine, Stillwater, OK

Kenneth Portier, Ph.D., Program Director, Statistics, American Cancer Society, National Home Office, Atlanta, GA

Daniel Schlenk, Ph.D., Professor of Aquatic Ecotoxicology and Environmental Toxicology, Department of Environmental Sciences, University of California, Riverside, CA

INTRODUCTION

An informational meeting of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP) was held to consider a presentation of the approach to reevaluate atrazine. Advance notice of the meeting was published in the *Federal Register* on October 7, 2009. The open meeting was held in Arlington, Virginia, on November 3, 2009. Dr. Steven G. Heeringa chaired the meeting and Joseph E. Bailey served as the Designated Federal Official.

The purpose of the informational meeting was to present to the Panel and the public, EPA's approach to reevaluate atrazine in light of new science available since 2003. EPA is reevaluating the atrazine's potential human health impacts by using information about atrazine's mode of action and by carefully considering the potential for cancer and non-cancer effects based on the available data from laboratory animal and human epidemiology studies. Through a series of three SAP meetings to be held in 2010, EPA's evaluation of the new scientific evidence available since 2003 will be described in the context of how it is similar to or differs from evidence available for the last atrazine assessment, and how this new evidence does or does not affect the Agency's human health risk assessment of atrazine.

Steven Bradbury, Ph.D., Deputy Office Director for Programs, Office of Pesticide Programs, and Tina Levine, Ph.D., Director, Health Effects Division, Office of Pesticide Programs, provided an overview of the planned approach for reevaluation of atrazine.

PUBLIC COMMENTS

Oral Statements were presented as follows:

Scott Slaughter, Center for Regulatory Effectiveness

Janis McFarland, Ph.D., Peter Hertl, Ph.D. and Charles Breckenridge, Ph.D., Syngenta Crop Protection

Jennifer Sass, Ph.D., Natural Resources Defense Council

Joel Nelson, California Citrus Mutual

Gary Marshall, Missouri Corn Growers' Association .

Jere White, Triazine Network

Rod Snyder, National Corn Growers' Association

Alex Avery, Hudson Institute, Center for Global Food Issues

Ray McCallister, CropLife America

Approximately 98 written statements were submitted to the Public Docket (EPA-HQ-OPP-2009-0759) at www.regulations.gov by individuals either representing themselves or various organizations.

SUMMARY OF PANEL DISCUSSION

EPA explained that the purpose of this informational meeting was to provide the members of the permanent Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) and the public with the Agency's approach to a comprehensive scientific reevaluation of the human health and ecological effects of atrazine. This effort will initially focus on human health issues and include three SAP meetings to be held in 2010 (see Table 1). The Panel recognized that each of these meetings will involve a complex set of issues which will be demanding to review. Therefore, the Panel emphasized the need for as much time as possible to review the background materials and prepare for each meeting. As a consequence, the Panel strongly recommended that EPA provide the Panel with the charge questions and all supporting background materials as early as possible in advance of each meeting. One panelist commented that if background materials are not ready significantly in advance of the meeting, perhaps the meeting should be postponed.

The Panel provided EPA with the following specific comments on the proposed approach:

- 1. For the February 2010 meeting, it is the Panel's understanding that the Agency will be primarily interested in exploring the generic importance and role of epidemiology studies as an integral part of human health risk assessments, with illustration of this approach through case studies, one of which will represent atrazine. EPA clarified that this would be the case. One Panel member requested that the Agency provide information on the value and power of each epidemiology study, an element that was missing from a previous SAP meeting held earlier in 2009 at which epidemiology studies were the primary focus of the meeting.
- 2. For the April 2010 meeting, it is the Panel's understanding that the Agency will explore the roles of current and future in *vitro* and *in vivo* animal toxicology studies in human health risk assessments, *e.g.*, Tox21TM and ToxCastTM programs, again with the atrazine human health risk assessment being used as a case study. The Panel expressed concern with linking the data from the ToxCastTM phase 1 pesticide evaluation to the atrazine review. The concern is that the broader understanding and implications of the ToxCastTM data might be hindered by consideration specifically in the context of the atrazine risk assessment. EPA clarified that the primary focus of this meeting will be on atrazine and, in particular, how these studies inform the mode of action and toxicity pathways of atrazine. General applicability of these studies will also be discussed.

3. For the September 2010 meeting, the focus will be a review of the results of the Agricultural Health Study sponsored by EPA and the National Institutes of Health, and in particular, the study results related to cancer outcomes. These results are expected to be available in the spring of 2010. The Panel requested that the results of the Agricultural Health Study be made available to them as soon as possible to allow adequate time for thorough review and evaluation.

Table 1. Major Topics for Future Atrazine SAP Meetings

February 2010	April 2010	September 2010
Incorporating epidemiology studies and human health incident data in risk assessment Case study using recent atrazine hypothesis generating epidemiology studies	Preliminary evaluation of in vitro & in vivo laboratory studies	Epidemiology studies: cancer & non-cancer
	Preliminary identification of critical effect(s) and dose-response assessment	Integrated weight of the evidence & hazard characterization
	Frequency of atrazine monitoring in drinking water sources	Frequency of atrazine monitoring in drinking water sources in context of new integrated weight of the evidence analysis