

US EPA ARCHIVE DOCUMENT

October 17, 2000

**FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING
OCTOBER 18-20, 2000
FIFRA SAP WEB SITE <http://www.epa.gov/scipoly/sap/>
OPP Docket Telephone: (703)305-5805**

**WEDNESDAY, OCTOBER 18, 2000
MARRIOTT CRYSTAL CITY HOTEL
1999 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202
(703)413-5500**

- 8:30 AM Introduction of Panel Members** - Christopher Portier, Ph.D. (FIFRA SAP Session Chair)
- 8:45 AM Administrative Procedures by Designated Federal Official** - Mr. Paul Lewis
- 8:50 AM Welcome** - Steven K. Galson, M.D. M.P.H. (Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, EPA)
- 9:00 AM Introductory Remarks** - Ms. Susan B. Hazen (Deputy Director, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, EPA)

SESSION 1: Bt Plant-Pesticides Risk and Benefit Assessments

- 9:10 AM Introduction** - Janet Andersen, Ph.D. (EPA, Office of Pesticide Programs)
- 9:20 AM Overview** - Mr. Michael Mendelsohn (EPA, Office of Pesticide Programs)
- 9:30 AM Insect Resistance Management** - Sharlene Matten, Ph.D. (EPA, Office of Pesticide Programs) and Ms. Robyn Rose (EPA, Office of Pesticide Programs)
- 10:15 AM Review of Agency Questions** - Mr. Alan Reynolds (EPA, Office of Pesticide Programs)
- 10:20 AM BREAK**
- 10:35 AM Public Comments**
Mr. Dan Moellenbeck, on behalf of ABS Technical Committee
Mr. David Guyer, on behalf of Novartis Seeds
Mr. Hollis Isbell, on behalf of the American Cotton Producers
Jane Rissler, Ph.D., on behalf of the Union of Concerned Scientists
Gary Herzog, Ph.D., on behalf of the University of Georgia
Mr. Larry Antilla, on behalf of the Arizona Cotton Growers Association
Mr. Jesse Young, on behalf of Young and Young
- 11:30 AM LUNCH**
- 12:30 PM Public Comments (continued)**

Susan MacIntosh, Ph.D. on behalf of Aventis CropScience
Michael Phillips, Ph.D. on behalf of the Biotechnology Industry Organization
Harold Coble, Ph.D. on behalf of the Council for Agricultural Science and Technology
Galen Dively, Ph.D. on behalf of the University of Maryland
Mr. Jere White, on behalf of the Kansas Corn Growers Association and the Kansas Corn Commission
Mr. Paul Bertels, on behalf of the National Corn Growers Association
Mr. Graham Head, on behalf on Monsanto
Leah Porter, Ph.D. on behalf of the American Crop Protection Association
David Hawthorne, Ph.D. on behalf of the University of Maryland

2:00 PM Panel Discussion

1. What improvements, if any, should be made to the 1998 SAP definition of high dose and its verification?

Lead Discussants: Fred Gould, Ph.D. and Mike Caprio, Ph.D.

Bt Cotton

2. What impact does differential expression in different *Bt* cotton cultivars have on resistance management for TBW, CBW, and PBW? What data can be collected to investigate the impact of differential expression in different *Bt* cotton cultivars on refuge strategies?

Lead Discussants: Tim Dennehy, Ph.D. and Ralph Bagwell, Ph.D.

3. How does CBW north to south movement (and potential gene flow) affect refuge design and deployment for *Bt* cotton? *Bt* corn?

Lead Discussants: Fred Gould, Ph.D. and Tim Dennehy, Ph.D., and Michael Caprio, Ph.D.

4. EPA believes models are an important tool in its weight of evidence approach to determine which IRM strategy will be most effective in reducing the risk of resistance development. How should the *Bt* cotton insect resistance management models (Gould, Caprio, Peck, Livingston) be used to evaluate the effectiveness (i.e. years to resistance) of potential refuge options? How can these models be verified? How can these models (or others) be improved to more accurately predict when (or if) resistance is likely to occur?

Lead Discussants: Ralph Bagwell, Ph.D., Michael Caprio, Ph.D., Fred Gould, Ph.D. and Brian Federici, Ph.D.

5. Compare and contrast the technical effectiveness (including refuge proximity and structure), grower feasibility, and likelihood of adoption for each refuge option: 95:5 or 90:10 embedded

refuge, 95:5 or 90:10 external unsprayed refuge, and 70:30 or 80:20 external sprayed for each of the three primary target pests: TBW, CBW, and PBW? What if any additional refuge strategies that should be considered, e.g. 20% seed mix for PBW?

Lead Discussants: Richard Hardee, Ph.D. and Tim Dennehy, Ph.D.

6. What is the minimum size and structure of a refuge needed to mitigate TBW and CBW resistance if there are multiple small fields (<25A each) grouped to represent an “embedded area” refuge?

Lead Discussants: Tim Dennehy, Ph.D., Richard Hardee, Ph.D., and Michael Caprio, Ph.D.

3:00 PM BREAK

3:15 PM Panel Discussion (continued)

7. What is the effect on the production of susceptible lepidopteran insects in the “unsprayed” refuge from the use of a ½ pound rate of acephate and methyl parathion for control of stink bugs or plant bugs? Does the use of pyrethroid oversprays (on the Bt fields) effectively provide a “high dose” for control of CBW? What is the impact of these oversprays on control of CBW in Bt cotton fields? How can management of the refuge be improved with use of appropriate economic thresholds to minimize insecticide treatment, good agronomic practices, economic incentives, and other incentives?

Lead Discussants: Michael Caprio, Ph.D., Fred Gould, Ph.D., Ralph Bagwell, Ph.D. and Terrance Hurley, Ph.D.

Bt Corn

8. How should the following resistance management models be used to evaluate the effectiveness of these refuge options (e.g., years to resistance): Gould and Onstad, Onstad and Gould, Onstad and Guse, Hurley et al.? How can the models be verified? How can these models (or others) be improved to more accurately predict when (or if) resistance is likely to occur? How does the lack of a high dose for control of CEW affect the predictions of the models? Should CEW and SWCB be included in the models? Why or why not?

Lead Discussants: Richard Hellmich, Ph.D., Randy Higgins, Ph.D., and David Andow, Ph.D.

9. What is the optimal deployment of a 20% refuge to mitigate ECB resistance: 1) in-field, 2) external unsprayed, and 3) external sprayed (i.e., blocks near or adjacent to fields, perimeter strips around fields, blocks or strips within fields)? How will deployment change for areas coinfecting with SWCB? CEW? What is the optimal deployment for an in-field refuge, e.g. number of rows (>2 rows v. >6 rows), in the context of what is known about ECB, CEW, and

SWCB larval movement data? What deployment method(s) works best for growers on large acreage? Small acreage?

Lead Discussants: Blair Siegfried, Ph.D., Richard Hellmich, Ph.D., and Mark Sears, Ph.D.

10. Given differences in biology of the target insect pests (ECB, CEW, SWCB, CSB), can pest specific regional plans be defined, especially where there two or more pests? If so, how?

Lead Discussants: Fred Gould, Ph.D., Tony Shelton, Ph.D., Randy Higgins, Ph.D. and David Andow, Ph.D.

11. What refuge strategies (or other insect control strategies) should be used to best manage insect resistance in areas with frequent insecticide treatment?

Lead Discussants: Blair Siegfried, Ph.D, Randy Higgins, Ph.D., Richard Hellmich, Ph.D. and Brian Federici, Ph.D.

Bt Sweet Corn

12. What are the strengths and weaknesses of the Agency's analysis of the resistance management plan for *Bt* sweet corn? Is crop destruction of residues necessary and how should it be accomplished? What crop destruct techniques (e.g., rotary mowing, discing, plowdown) are the most effective? When should crop destruction occur, immediately after harvest, or is within 30 days adequate?

Lead Discussants: Richard Hellmich, Ph.D., Randy Higgins, Ph.D., and Tony Shelton, Ph.D.

Bt Corn and *Bt* Cotton

13. What if any improvements are needed to the *Bt* corn and *Bt* cotton monitoring plans (e.g., number of regions, sampling strategy, consistency of sampling, number of populations sampled and bioassayed, monitoring techniques)? What is the sensitivity of the discriminating or diagnostic dose assays currently in use and what is their utility? What is the relevance of the CBW "tolerance" described by Sumerford et. al. and how should it be examined?"

Lead Discussants: Michael Caprio, Ph.D. David Andow, Ph.D., Blair Siegfried, Ph.D. and Fred Gould, Ph.D.

14. What improvements are needed to the remedial action plans for *Bt* corn and *Bt* cotton? What measures should be employed if resistance is determined to exist? Taking into consideration the need to work with farmers who will be affected (both with resistance and without resistance), how quickly can remedial action measures be implemented? How should the affected area be defined? What level of susceptibility or reduction in resistance allele frequency would one need

to achieve before *Bt* corn and/or *Bt* cotton products could return to the market and resistance would be considered mitigated? What other methods might be used to measure the success of a remedial action strategy?

Lead Discussants: Ralph Bagwell, Randy Higgins, Ph.D., Richard Hardee, Ph.D. and Tony Shelton, Ph.D.

15. Are grower surveys an effective measurement tool of grower adoption of IRM plans? What other measurement tools are available to measure grower adoption (e.g., Global Positioning System)? What compliance mechanisms (e.g., grower contracts, sales incentives, insurance) does the SAP believe will maximize compliance?

Lead Discussants: Richard Hellmich, Ph.D., Brian Federici, Ph.D., Terrance Hurley, Ph.D. and Blair Siegfried, Ph.D.

6:00 PM **ADJOURNMENT**

NOTE: THERE ARE TWO MARRIOTT HOTELS IN CRYSTAL CITY. THE HOTEL MEETING LOCATION WAS CHANGED TO THE CRYSTAL CITY MARRIOTT HOTEL, 1999 JEFFERSON DAVIS HIGHWAY, ARLINGTON, VA. THE HOTEL PHONE NUMBER IS (703) 413-5500.

THURSDAY, OCTOBER 19, 2000
MARRIOTT CRYSTAL CITY HOTEL
1999 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202
(703)413-5500

- 8:30 AM Introduction** - Christopher Portier, Ph.D. (FIFRA SAP Session Chair)
- 8:45 AM Administrative Procedures by Designated Federal Official** - Mr. Paul Lewis
- 8:50 AM Welcome** - Steven K. Galson, M.D. M.P.H. (Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, EPA)
- 9:00 AM Introductory Remarks** - Ms. Susan B. Hazen (Deputy Director, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, EPA)

SESSION 1: Bt Plant-Pesticides Risk and Benefit Assessments (continued)

- 9:10 AM Gene Flow and Outcrossing** - Christopher Wozniak, Ph.D. (EPA, Office of Pesticide Programs)
- 9:40 AM Environmental Fate in the Soil** - Douglas Gurian-Sherman, Ph.D. (EPA, Office of Pesticide Programs)
- 10:10 AM BREAK**
- 10:25 AM Non-Target Organism Effects** - Zigfridas Vaituzis, Ph.D. (EPA, Office of Pesticide Programs)
- 11:25 AM Public Comments**

Mr. Graham Head, on behalf of Monsanto

Ms. Janet Carpenter, on behalf of the National Center for Food and Agricultural Policy

Ms. Demetra Vlachos, on behalf of Novartis Seeds

Jane Rissler, Ph.D., on behalf of the Union of Concerned Scientists

Val Giddings, Ph.D. on behalf of the Biotechnology Industry Organization

Mr. Eric Sachs, on behalf of ABS Technical Committee

Dennis Calvin, Ph.D., on behalf of Pennsylvania State University

Rebecca Goldberg, Ph.D., on behalf of Environmental Defense

Lincoln Brower, Ph.D., on behalf of Sweet Briar College

12:30 PM LUNCH

1:30 PM Panel Discussion

Gene flow/Outcrossing Questions

1. Does quantifying risk (*e.g.*, hybridization rates, gene introgression) provide adequate

means to assess potential environmental impact and determine approval of a plant-pesticide which has wild or feral relatives in the U.S.? If yes, what further risk assessment is warranted to evaluate the risk of outcrossing?

Lead Discussants: Charles Neal Stewart, Ph.D. and Mitch Cruzan, Ph.D.

2. Are isolation distances as proposed for certified or registered seed considered as sufficient to mitigate gene flow between Bt-crops and wild or feral populations of sexually compatible species? If not, what distances or measures should be imposed to mitigate outcrossing?

Lead Discussants: Alison Power, Ph.D. and John Willis, Ph.D.

3. Does the panel agree that the gene flow and outcrossing assessment contained in the background document are adequate for the currently registered Bt crops? If not, what additional data or issues should be considered to assess gene flow and outcrossing risks from Bt-expressing plant products?

Lead Discussants: Alison Power, Ph.D. and Charles Neal Stewart, Ph.D.

Bt Soil/Fate Questions

1. Considering that EPA now requires toxicity studies for Collembola and earthworms, what are the appropriate indicator species that should be tested to assess risks of *Bt* Cry proteins on soil invertebrates? In particular, which if any, soil dwelling non-pest Coleoptera could be tested in laboratory conditions that would provide valuable information for assessing risks from Cry3A?

Lead Discussants: Mark Sears, Ph.D. and Brian Federici, Ph.D.

2. The Panel is requested to address whether the studies determining rates of degradation of Cry proteins in soil have been of sufficient duration, and were performed under adequate conditions (typically soil microcosms). Comment on whether available experimental results and EPA's evaluation of this data adequately address the question of persistence of Cry proteins in Bt crop soil.

Lead Discussants: Robert Miller, Ph.D., Guenther Stotzky, Ph.D. and David Andow, Ph.D.

3. Please comment on what would be appropriate methods to examine secretion of Cry proteins from roots and the merits of such tests for risk assessment (e.g., tests could include examining the protein sequence of Cry proteins for putative endoplasmic reticulum signal peptides or actual experiments to test for secretion). If the Panel believes that testing for secretion is needed, should current Bt crops be tested?

Lead Discussants: Guenther Stotzky, Ph.D., Eliot Herman, Ph.D., Ian Pepper, Ph.D., and Robert Miller, Ph.D.

4. Comment on the available data concerning the possibility that Cry protein could accumulate in crop soil and what, if any, additional testing of field soil is needed to adequately address this question for the purpose of hazard assessment.

Lead Discussants: Brian Federici, Ph.D., Eliot Herman, Ph.D. and Ian Pepper, Ph.D.

5. Please provide comment on whether the environmental fate data and horizontal gene transfer assessment is an adequate evaluation of the fate of *Bt* proteins and assessment of horizontal gene transfer? Also, are there additional data, such as that listed by EPA in the preliminary assessment, that should be obtained for the current *Bt* plant-pesticides?

Lead Discussants: Robert Miller, Ph.D., Guenther Stotzky, Ph.D. and Ian Pepper, Ph.D.

3:00 PM **BREAK**

3:15 PM **Panel Discussion (continued)**

Non-target Organism Effects Assessment Questions

1. The Panel is requested to provide comments on the Agency's weight of evidence assessment and its conclusion that *Bt* crops would not threaten the long-term survival of a substantial number of individuals in the populations of wild mammals, birds, invertebrates, and aquatic species.

Lead Discussants: Richard Hellmich, Ph.D., and Rosalind James, Ph.D.,

2. The Panel is requested to comment on the Agency's analysis of the currently available data on the potential impacts of MON810, Bt 11, and CBH351 on monarch butterflies.

Lead Discussants: Richard Hellmich, Ph.D., Karen Oberhauser, Ph.D. and Chip Taylor, Ph.D.

3. The Panel is requested to comment on the Agency's assessment that Karner blue butterflies are not at risk from the current *Bt* plant-pesticides and to provide EPA advice on any further considerations that should be made for this or other endangered species.

Lead Discussants: David Andow, Ph.D., Stephen Malcolm, Ph.D, and Randy Higgins, Ph.D.

4. Please comment on additional studies which might be needed to strengthen the database identified at the end of the environmental assessment including the future on-going

research on non-target Lepidoptera and other non-target invertebrate species.

Lead Discussants: Mark Sears, Ph.D., Brian Federici, Ph.D. and John Pleasants, Ph.D.

***5:00 PM* ADJOURNMENT**

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FRIDAY, OCTOBER 20, 2000
MARRIOTT CRYSTAL CITY HOTEL
1999 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202
(703)413-5500

- 8:30 AM Introduction** - Stephen Roberts, Ph.D. (FIFRA SAP Session Chair)
- 8:45 AM Administrative Procedures by Designated Federal Official** - Mr. Paul Lewis
- 8:50 AM Welcome** - Steven K. Galson, M.D. M.P.H. (Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, EPA)

SESSION 1: Bt Plant-Pesticides Risk and Benefit Assessments (continued)

- 9:00 AM Benefits and Economic Analysis** - Mr. Edward Brandt (EPA, Office of Pesticide Programs)
- 9:30 AM Human Health Effects** - John Kough, Ph.D. (EPA, Office of Pesticide Programs)
- 10:00 AM Product Characterization** - John Kough, Ph.D. (EPA, Office of Pesticide Programs)
- 10:15 AM BREAK**

10:30 AM Public Comments

Mr. Carl Casale, on behalf of Monsanto
Mr. Leonard Gianessi, on behalf of the National Center for Food and Agricultural Policy
Ms. Demetra Vlachos, on behalf of Novartis Seeds
Mr. Mark Lange, on behalf of the National Cotton Council
Jane Rissler, Ph.D., on behalf of the Union of Concerned Scientists
Gary Munkvold, Ph.D., on behalf of Iowa State University, Department of Plant Pathology
Shelby Fleisher, Ph.D., on behalf of Penn State University
Mr. Clyde Sharp, Arizona cotton grower
Barbara Henry, Ph.D., on behalf of Aventis Crop Science

12:00 PM LUNCH

1:00 PM Public Comments (continued)

Michael Phillips, Ph.D., on behalf of the Biotechnology Industry Organization
Mr. Bill Freese, on behalf of Friends of the Earth
Galen Dively, Ph.D., on behalf of the University of Maryland
Greg Nuessly, Ph.D., on behalf of the University of Florida
Mr. Dee Vaughn, on behalf of the National Corn Growers Association
Mr. Michael Hansen, on behalf of Consumers Union
Marlin Rice, Ph.D. on behalf of Iowa State University, Department of Entomology

2:30 PM Panel Discussion

Benefits and Economic Analysis Questions

1. Discuss whether there are improvements in the model or methods for estimating benefits and costs? What methods would you suggest to improve estimation of the mean and variance of grower demand (willingness-to-pay)? Would dividing the analysis into more homogeneous geographical units (i.e. infestation, weather, geography, acres planted) be appropriate? Why or why not?

Lead Discussants: Terrance Hurley, Ph.D.

2. Is there a better methodology to incorporate all the NASS data than EPA used in its assessment? Discuss whether the data support more rigorous statistical tests on significant differences.

Lead Discussants: Margriet Caswell, Ph.D.

3. Please provide comments on other approaches which might better characterize and/or quantify environmental and health benefits?

Lead Discussants: Frederick Buttel, Ph.D.

4. Is the benefits assessment contained in the background document an adequate assessment of the benefits from *Bt* plant-pesticides? If not, what additional data are necessary to assess the benefits from *Bt* plant-pesticides?

Lead Discussants: Terrance Hurley, Ph.D.

3:30 PM BREAK

3:45 PM Panel Discussion (continued)

Product Characterization and Human Health Questions

1. Please provide advice on whether there is a threshold amount of protein below which concern for risk from exposure/consumption of proteins expressed in plants will be eliminated/reduced? If so, how should this threshold be determined?

Lead Discussants: Steven Gendel, Ph.D. and Ricki Helm, Ph.D.

2. Please provide comment on the quality and thoroughness of the product characterization review. What additional data, if any, should be evaluated in order to adequately characterize the Bt-expressing plant-pesticide products?

Lead Discussants: Hubert Noteborn, Ph.D., and Brian Federici, Ph.D.

3. Please provide comment on whether the human health data is an adequate evaluation of the risk from the Bt proteins. What, if any, additional data is necessary to assess the risk from the Bt-expressing plant-pesticide products?

Lead Discussants: Hubert Noteborn, Ph.D. and Ricki Helm, Ph.D.

5:30 PM ADJOURNMENT

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Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Official for this meeting, Mr. Paul Lewis, via telephone: (703) 305-5369; fax: (703) 605-0656; or email: lewis.paul@epa.gov.