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FIFRA Scientific Advisory Panel

October 24-26, 2006 Meeting Agenda

Agenda: October 24-26, 2006

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN MEETING
OCTOBER 24 - 26, 2006
FIFRA SAP WEB SITE http://www.epa.gov/scipoly/sap/
OPP Docket Telephone: (703) 305-5805
Docket Number: EPA-HQ-OPP-2006-0657

TUESDAY, OCTOBER 24, 2006
Holiday Inn Rosslyn at Key Bridge
1900 North Fort Myer Drive
Arlington, VA 22209
(703) 807-2000

EVALUATION OF THE RESISTANCE RISKS FROM USING 100% BOLLGARD AND BOLLGARD II COTTON AS PART OF A PINK BOLLWORM ERADICATION PROGRAM IN THE STATE OF ARIZONA

8:30 A.M. **Introduction and Identification of Panel Members** - Steven Heeringa, Ph.D., FIFRA SAP Chair
8:40 A.M. **Administrative Procedures by Designated Federal Official** – Myrta R. Christian
8:45 A.M. **Opening Remarks** – Janet Andersen, Ph.D., Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
8:55 A.M. **Pink Bollworm Eradication Program in the United States and Mexico** – Osama A. El-Lissy, Ph.D., Director, Invasive Species and Pest Management, U.S. Department of Agriculture - Animal and Plant Health Inspection Service - Plant Protection and Quarantine - Pest Detection and Management Programs
9:40 A.M. **Overview of the State of Arizona FIFRA Section 24(c) Registrations in the Pink Bollworm Eradication Program** – Alan Reynolds, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA

10:00 A.M. **BREAK**

10:15 A.M. **Review of Likelihood of Bt Resistance During Arizona's Pink Bollworm Eradication Program** – Sharlene Matten, Ph.D., Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, EPA
11:15 A.M. **Public Comments**

12:00 P.M. **LUNCH**

1:00 P.M. **Public Comments (continued)**

3:00 P.M. BREAK

3:15 P.M. Questions to the Panel

- **Estimations of Pink Bollworm Populations Using Pheromone Trapping and Spatial Analysis**

Geospatial maps of the *Bt* and non-*Bt* cotton fields were provided by the Arizona Cotton Research and Protection Council (**Appendix 4**). There were 4,626 total fields (approx. 156,000 acres) in the eradication zone. There were 334 non-*Bt* fields (6.92%) and 4,292 *Bt* fields (93.08%) **(Table 2).** Each field is numbered. These fields are the target areas for the sterile moth releases, pheromone, and insecticide treatments. There were a total of 4,541 pheromone traps placed in all fields with 3,541 pheromone traps placed in *Bt* fields and 1,000 pheromone traps placed in non-*Bt* fields. The protocol for the sterile moth releases is found on **p. 11** of EPA's technical assessment. The actual sterile moth release rates through August 25, 2006 are found in **Table 4.** The number of traps per field ranged from 0 to 14. The scheme for using the trapping and map data is shown in **Figure 5**.

To present the trapping data as a predicted surface of PBW numbers, the Kriging method was used to calculate a predicted value for areas between the known values of each field. Kriging is a regression technique used in geostatistics to estimate the optimal interpolation of these points across the spatial domain.This method handles spatial autocorrelation and is not sensitive to uneven sampling in specific areas, such as the distribution of cotton fields in the eradication program. Ordinary Kriging using a spherical model was applied to trap counts for each week (see Volume 2, Table 1 of the submission, MRID# 469048-02 for the data) to develop a predictive surface model encompassing the cotton fields. Kriging constructs a weighted moving average that estimates the value of a spatially distributed variable from adjacent values while considering the interdependence.Kriging results in a smoothing effect in which high original values are underestimated and low original values are overestimated. It is a best linear unbiased estimator because it minimizes the variance of the estimation errors.

The Kriging maps of native and sterile PBW populations in Arizona's eradication program from June 25 through July 22, 2006 are found in **Figures 6A-H**. This analysis indicates that the sterile PBW adult populations are more abundant, consistent and more widely distributed than the native population. The native populations are limited to 1-5 moths per trap with 3-5 areas as "hot spots" (PBW captures > 25) during this four week sampling period. The sterile PBW populations are more abundant with captures > 50 in many areas. Early results from the eradication program indicate that the sterile releases have been quite successful in reducing native PBW populations.

a) The Panel is asked to comment on the accuracy and precision of the estimates of native and sterile pink bollworm population levels in the eradication zone in Arizona in 2006 using the described pheromone trapping and boll sampling methods, and spatial analysis (Kriging method). Factors that may affect the native and sterile pink bollworm populations estimates include, but are not limited to:

- Number and location of *Bt* and non-*Bt* fields
- Size of fields (e.g., 15 ha)
- Use of pheromone traps, only males sampled, to estimate overall population size (and therefore population suppression estimates)
- Number and placement of traps within a field
- Number of traps in *Bt* vs. non-*Bt* fields
- Use of the centroid of the field to estimate trap location within a field vs. exact location of the field using GPS

coordinates for the spatial analysis (Kriging method), e.g., to address "hot spots" within a field or set of small fields
- Sterile release rates (*Bt* vs. non-*Bt*)
- Frequency of sterile releases
- Predictions about the ratios of sterile: native moths
- Estimations of overwintering larvae per field
- Boll sampling data (not available for these analyses, too early in the season)

Please identify major sources of uncertainty in the estimates of PBW population levels and comment on whether the estimates tend to overstate or understate actual levels of native and sterile PBW.

5:00 P.M. ADJOURNMENT

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WEDNESDAY, OCTOBER 25, 2006
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8:30 A.M. Introduction and Identification of Panel Members - Steven Heeringa, Ph.D., FIFRA SAP Chair
8:35 A.M. Administrative Procedures by Designated Federal Official – Myrta R. Christian
8:40 A.M. Follow-up from Previous Day's Discussion – Alan Reynolds and Sharlene Matten, Ph.D., Biopesticides and Pollution Prevention Division (Office of Pesticide Programs)
9:00 A.M. Panel Discussion Question 1 (continued)

1) Estimations of Pink Bollworm Populations Using Pheromone Trapping and Spatial Analysis

b) Given the discussion in a) above, what suggestions does the Panel have to strengthen the accuracy and precision of the native and sterile pink bollworm population estimates?

10:00 A.M. BREAK

10:15 A.M. Panel Discussion (continued)

- **Simulation Modeling**

The Agency required that simulation modeling be used to compare the impact of pink bollworm population suppression vs. resistance risk over the four-year period of the

eradication program. The simulation model used was a revised version of the spatially-explicit, stochastic model discussed in Sisterson *et al.* (2004). The simulations examined population suppression (number of pink bollworm per ha) and risk of resistance to *Bt* cotton (rate of increase of resistance allele frequency). This model assumes that resistance is controlled by a single, recessive gene. This model is based on PBW resistance to Cry1Ac. Modifications to the model include the release of sterile moths. A variety of scenarios were simulated using the best estimates of the parameter values as well as more optimistic and more pessimistic scenarios.

Preliminary modeling, even using more "worst-case/pessimistic" parameter assumptions, predict that the four-year eradication program in Arizona will suppress pink bollworm without creating a problem with Cry1Ac resistance to *Bt* cotton. In 11 of 12 sets of assumptions examined, the simulated eradication program eliminated the PBW from the 4096 fields modeled in two years or less without causing a resistance problem. In the one exception, PBW was not removed from the region when the model simulation assumed no release of sterile moths in *Bt* fields, 90% *Bt* cotton, and r = 0.01 in all five replications. In this case, the population density declined by 98% (460 final overwintering larvae per field/29,000 starting overwintering larvae per field) and the resistance allele frequency increased from 0.01 to 0.02 after four years, but was still far lower than the 0.50 value typically used as a criterion for a resistance problem. The model assumes that population suppression will occur if the mean PBW density in the region is equal to or less than 0.1 overwintering larvae per 15 ha (=0.0067 larvae per ha).

a) The Panel is asked to comment on the certainty of the preliminary outcomes of the modeling simulations using worst-case assumptions, in many cases, that pink bollworm populations will be suppressed and there will be no resistance to Cry1Ac during the four years of the eradication program simulations.

12:00 P.M. LUNCH

1:00 P.M. Panel Discussion Question 2 (continued)

2) Simulation Modeling

Dr. Bruce Tabashnik (University of Arizona) plans to conduct additional simulations using field data collected in 2006 as model inputs in place of certain assumptions used in the 2005 simulations.

- b) The Panel is asked to comment on whether there is any reason to expect these additional simulations of pink bollworm resistance over the four-year period of the eradication program will change the predicted outcome to indicate a greater risk of the development of resistance than seen in the 12 other simulations in which no resistance was seen.

PBW resistance to the Cry2Ab2 toxin was not considered in either the simulation modeling or DNA screening analyses. Additional consideration of PBW resistance to the Cry2Ab2 toxin would only be important if the selection pressure dramatically increases in the next three years, i.e., much more Bollgard II planted in the eradication zone. If some or all of Arizona's *Bt* cotton had two toxins, Cry1Ac + Cry2Ab, evolution of resistance would be much less likely than it is with only Cry1Ac. Modeling resistance to cotton that produces only Cry1Ac is the more pessimistic scenario. The modeling predictions (using only Cry1Ac resistance), therefore, are conservative, i.e., they tend to overestimate resistance risk. Based on simulation models examining the likelihood of insect resistance to pyramided toxins in *Bt* crops (e.g., Roush, 1998; Zhao *et al.*, 2005), even if Bollgard II acreage substantially increases, the likelihood of PBW resistance to both the Cry1Ac and Cry2Ab2 toxins would remain low during the four-year PBW eradication program in Arizona.

c) The Agency asks the Panel to comment on the likelihood of Cry2Ab2 resistance

given that percentage of Bollgard II planted in Arizona has been <5% of the total *Bt* cotton acreage, and simulation modeling predicts that the likelihood of insect resistance to pyramided toxins in *Bt* cotton would be extremely low.

3:00 P.M. BREAK

3:15 P.M. Panel Discussion (continued)

- **Likelihood of Pink Bollworm Resistance in Future Years of the Eradication Program in Arizona**

The Panel is asked to comment on the scientific validity of whether the preliminary field data, spatial analysis, and simulation modeling are adequate to provide reasonable certainty that the likelihood of pink bollworm resistance to the Cry1Ac and Cry2Ab2 toxins will be extremely low during the four years of Arizona's eradication program.

5:00 P.M. ADJOURNMENT

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9:00 A.M. Panel Discussion continued (as needed)

10:00 A.M. BREAK

10:15 A.M. Panel Discussion continued (as needed)

11:00 A.M. ADJOURNMENT

Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Official for this meeting, Ms. Myrta Christian, via telephone: (202) 564-8450; fax: (202) 564-8382; or email: christian.myrta@epa.gov