APPENDIX 3 – AGENDA

Plant-Incorporated Protectant Experimental Use Permit: Process and Compliance

Crystal City Hilton, Arlington, Virginia
February 10 and 11, 2004
8:30 am - 5:00 pm

WORKSHOP PROGRAM - DAY ONE

8:30 - 9:00 **Welcome and Purpose of the Workshop**

- Background on scope, purpose, and desired outcomes of the workshop
- Agenda review and ground rules for the meeting

9:00 - 10:30 **Panel Session: Goals related to activities under EUP**

Panel speakers will discuss their goals and mandates with regard to biotechnology research conducted under experimental use permits. The session will illuminate commonalities and differences between the Panel members
Janet Andersen, USEPA
Susan Koehler, USDA
Doug Gurian-Sherman, Agriculture and Biotechnology Consultant
Russell P. Schneider, Monsanto Company
L. LaReesa Wolfenbarger, University of Nebraska at Omaha

10:00 - 10:15 **Break**

10:15 - 11:30 **Regulatory Review Process of Field Testing**

- USDA APHIS Notification and Permit Process – Susan Koehler, USDA
- US EPA Experimental Use Permit Process - Mike Mendelsohn, USEPA

11:30 - 12:00 **Introduction to brainstorming session on PIP EUP Issues**

Explanation of goals and format for the afternoon break-out sessions. Workshop participants will divide into four groups and consider each category in turn. The goal of these groups is to identify PIP EUP issues to be addressed in each category. During the Day 2 breakouts, participants will develop recommendations to address issues identified in this session. The categories are:

- EUP application and decision process; content and data requirements
- Regulatory terminology; definitions and standards
- Containment and confinement; clarification of standards and strategies to achieve
- Ensuring clear permit conditions and compliance with permit conditions

12:00 - 1:00 **Lunch**

1:00 - 2:20 **Breakout sessions (40 minutes per session)**

2:20 - 2:40 **Break**

2:40 - 4:00 **Breakout sessions (40 minutes per session)**

4:00 - 5:00 **Summary of Day One, Preparation for Day Two**

- Facilitators from the break-out sessions will report back on the issues identified in each category.
- Explanation of goals and format for Day 2 break-out sessions to identify remedies for issues identified in each category.

WORKSHOP PROGRAM - DAY TWO

8:30 - 8:45 **Introduction - Day 2**

- Recap of goals and format for break-out sessions, and goals of afternoon panel discussions.
- Concurrent sessions will be held on the four issue categories from Day 1. Participants will be assigned to two topics total.

8:45 - 10:15 **Breakout Sessions: Remedies and Recommendations**
Rotation 1: Brainstorm possible approaches and recommendations to address the issues identified on Day 1.

10:15 - 10:30 **Break**

10:30 - 12:00 **Breakout Sessions Remedies and Recommendations Continued**
Rotation 2: Brainstorm possible approaches and recommendations to address the issues identified on Day 1.

12:00 - 1:00 **Lunch**

1:00 - 2:00 **Recap of Morning Remedies and Recommendations**
Representatives of each breakout group will summarize key recommendations

2:00 - 2:45 **Panel Discussion: Coordination of USDA and EPA field testing programs**
Panel speakers will include:
Phil Hutton, USEPA
Susan Koehler, USDA
Natalie Hubbard, DuPont
Keith Pitts, Pew Initiative of Food and Biotechnology

2:45 - 3:00 **Break**

3:00 - 3:45 **Panel Discussion: Balancing protection of proprietary information and public disclosure**
Panel speakers will include:
Stan Abramson, Arent Fox
Peter Jenkins, Center for Food Safety

3:45 - 4:30 **Panel Discussion: Compliance, why it matters and how it can be supported**
Panel speakers will include:
Morven McLean, AgBios
Greg Jaffe, Center for Science in the Public Interest
Terry Mitchell, Texas Department of Agriculture

4:30 - 5:00 **Workshop Summary and Next Steps**

- Process by which EPA will move forward and future challenges and opportunities
- USDA statement on future challenges and opportunities

Participant reflections on