



**AEIC 1999 Fall Meeting  
September 30—October 1, 1999  
Des Moines, Iowa**

**Secretary's Minutes**

**P.L. Hunst (AgrEvo USA)**

The AEIC Fall Meeting was hosted by Pioneer Hi-Bred in Des Moines, Iowa. There were 21 attendees representing 15 companies. The meeting was opened with welcoming remarks from Dr. Bruce Orman, Director of Analytical Biochemistry, Pioneer Hi-Bred.

Following the opening remarks, Steve Tanner from GIPSA-USDA presented a talk on GIPSA (Grain Inspection, Packers and Stockyards Administration). GIPSA was created in 1916. There are approximately 650 employees nationwide. GIPSA receives 75% of its funding from user fees and only 25% from tax dollars. GIPSA services include: grain grading; grain standards; grain testing methods; permissive third party domestic grain inspection; and mandatory third party export grain inspection. The primary role of the agency is to facilitate the marketing of U.S. grain. Under the Grain Standards Act, GIPSA sets grades and standards for 12 grains. Rice, beans, peas and lentils are not graded by GIPSA because they fall under the Agriculture Marketing Act. GIPSA is responsible for validation of reference methods, i.e., does a method directly measure the parameter of interest; what is required to evaluate and calibrate instrumentation/kits used for objective testing in the field. GIPSA also works to gain international acceptance of the methods and preferentially uses rapid methods, i.e., tests are conducted in seconds to minutes of time. GIPSA also is responsible for calibration development and monitoring (NIRT, protein, oil, moisture, NMR, etc.) as well as the development of visual reference materials/aids. This includes developing a uniform understanding of subjective interpretations to promote consistent application of them. They have a national training program for their grain inspectors on these visual reference methods. GIPSA also performs research and method development to continually improve the cost, accuracy and relevancy of test. They do use immunoassay kits due to their ease of use and rapid turnaround time for results as approved methods. These kits are usually from the commercial marketplace (such as the DON kit by Neogen). GIPSA evaluates the kit based on identified commodities to be test; acceptable accuracy limit (fortified samples); acceptable precision limits (samples containing naturally occurring analyte such as DON); LOD; does not contain toxic or hazardous substances; temperature sensitivity, stability (shelf life) and performance verification. GIPSA also performs check testing which aligns official system labs with national standards. The agency also has technical training/support to facilitate system-wide standardization of test methods and procedures. GIPSA also offers third party domestic testing services through 59 delegated or designated agencies which are certified for testing. GIPSA contracts with 300 service labs, however, the agency has 15 field offices and 92 service labs of its own. The GIPSA labs are the only ones that test grain at export points—no contract labs are used. GIPSA also offers services for reference samples, QC and check samples. The agency holds foreign trade group seminars and briefings to build confidence in the U.S. grain quality and

testing procedures. Steve pointed out that questions on testing for genetically modified grain has rarely come up in these seminars or briefings. The agency has an international reputation as an independent provider of testing services. GIPSA is currently working with life science businesses in order to be prepared for the testing of genetically modified grain. The agency has proposed the creation of a lab, in Kansas City, for this testing. They have approached the life science businesses in regards to access to reference materials, special analytical tools/techniques used and information on specific genetic sequences for the evaluation in DNA-based analytical methods. The timetable for this PCR lab is to be open in late August, 2000. Currently, PCR is not conducive to point of origin testing (testing at elevators, barges, etc.) so the agency is leaning towards immunoassays. They have just started talking to kit manufacturers. The benefits of GIPSA taking on this effort includes standardized testing, decreased time for starting up a national lab, and increased credibility of testing. Steve also noted that GIPSA does have the authority to set tolerances for what is genetically modified corn. However, the agency has no plans to do this at the moment. The agency does not want the testing level (sensitivity) to drive what the threshold should be set at, however.

Dave Grothaus (Pioneer) presented the talk he gave at the SFAI conference in September on the overview of transgene analysis. This talk presented what is done at Pioneer for testing of transgenic plants and how immunoassays are used. The Protein Analysis Group at Pioneer consists of 5 areas: Protein Core Facility, Immunoassay Development, Applications Group, Kit Development Group and the Regulatory Science Group. The Protein Core Facility produces proteins for antibody production. The Immunoassay Development Group develops ELISAs, arranges for peptide synthesis and antibody production, maintains a reagent inventory for the immunoassays and provides technical support. The Applications Group run the routine immunoassays and other tests on submitted samples. The group ran one million samples for protein analysis last year. The group uses ELISA (quantitative/qualitative), PAGE, westerns, dot blots and enzyme assays. The Kit Development Group transfers the immunoassays to the field for use in areas such as winter nurseries, seed quality labs, etc. The Regulatory Science Group analyzes samples via immunoassays for regulatory studies for the transgenic products. The work is done according to GLP protocols and methods.

Chuck Mihaliak (Dow Agro) gave a brief overview of trade industry activities. ACPA (American Crop Protection Association) has a diagnostic working group. This group has an active dialog with the USDA, NGFA (National Grain & Feed Association), ASA (American Soybean Association), NCGA (National Corn Growers Association) and the corn refiners association. The group has issued a technical brief on current diagnostic testing technology (can be found on ACPA website). ASTA (American Seed Trade Association) is developing a seed testing/certification program for GM-free seed. The program is being designed for ASTA member companies. SDI's Trait Check<sup>®</sup> kits for detecting Roundup-Ready<sup>®</sup> soybeans will be used since this is the only GM trait in soybeans to date. For corn, event specific PCR testing is necessary and there are numerous issues to resolve prior to its implementation. These issues include cross licensing event specific PCR primers: how to share information but protect confidential information; what threshold to accept—different companies have different tolerances. The NGFA (National Grain & Feed Association) has an active dialog with technology providers. The association is currently working on a white paper on ag. biotech which will include a lengthy discussion of diagnostic testing. Other trade industry efforts include:

- a) the International Seed Industry Initiative for the Transboundary Movement of Seed and Biotech (aligned with ASTA effort);
- b) AOSCA (Association for Official Seed Certifying Agents): has a long history in seed certification; writes general standards for the Identity Preserved Program;
- c) CEN (Committee on European Norms): writing standards for all validated methods associated with genetically modified foodstuffs (mainly a European focus).

Penny Hunst (AgrEvo) gave a presentation on the Agricultural Biotechnology Stewardship Working Group (ABSWG). This is a group of companies brought together by the publication of

the work by John Losey on the hazards of Bt pollen to monarch butterflies. The group operates from ACPA and its goals are:

- 1) address scientific issues central to responsible stewardship of agricultural ecosystems;
- 2) develop practical solutions that offer a balanced approach to managing risk while optimizing the opportunities for farmers and consumers worldwide;
- 3) provide broad-based expertise and educational resources to inform policymakers, interest groups, media and public audiences.

In response to the Losey article, the ABSWG asserted that a comprehensive assessment of Bt pollen effects must exposure as wells as hazard to monarchs; questions arising from the monarch issue must be answered by independent and reputable scientists; and swift responsible action by the biotechnology providers will demonstrate our commitment to environmental stewardship. The ABSWG enlisted the support of third party expert advisors which includes Rick Hellmich (USDA-ARS), Alex Martin (Univ. of Nebraska), Mark Scriber (Michigan State Univ.) and Joe Yenish (Washington State Univ.). These experts worked with industry to a) understand the potential for Bt pollen effects on monarch butterflies and other non-target spp., b) identify critical research needs and objectives, and c) review and critique submitted research proposals. The research areas which were identified were 1) milkweed distribution, 2) pollen movement and 3) monarch biology. The ABSWG funded 10 researchers in these areas for work which was conducted during the summer of 1999. The results will be reviewed in November at a symposium sponsored by the USDA-ARS in Chicago. A second symposium will be held at the National ESA Conference in Atlanta in December.

After the lunch break, the Biotech Subcommittees presented updates of their activities. These subcommittees were formed at the Spring AEIC Meeting which was held in Princeton, NJ.

Validation Subcommittee: Cindy Lipton (Zeneca) presented an overview of a paper that is being prepared by the subcommittee on validation guidelines for immunoassays used for detection of genetically modified plants and products. The subcommittee has met several times to discuss the paper and Cindy has written several drafts based upon these discussions. A fourth draft of the paper will be sent out to the authors the week of October 4. After receiving comments back from the authors, a final draft will be written and distributed to the AEIC membership for comments. Following this distribution, the AEIC Board will review the document for final approval for submission for publication. The goal is to complete the process by early November and then submit to a peer reviewed journal such as the Journal of Agriculture and Food Immunology (journal of SFAI). Jim Rittenburg (Biocode) is an editor of this journal. Steve Tanner (GIPSA) commented that GIPSA would like to review the paper and give some thought internally as to how the paper could be used. He suggested that GIPSA may be able to ultimately endorse the paper which would lend their credibility to it as a guideline document.

Recruiting Subcommittee: Dave Grothaus (Pioneer) gave an update on the discussions of this group. The major consideration has been expanding membership by inviting other ag. chem companies to join. However, due to consolidations in the industry, there are not any companies who have not been contacted or who are not currently members. After some discussion, it was decided that the Recruiting Subcommittee would have the following initiatives:

- a) membership drive to contact grain, food processing and food manufacturing companies (ADM, Cargill, Consolidated Grain & Barge, Nestle, General Mills, etc.). It was also suggested that AEIC may want to consider inviting these companies to the next meeting to give short informational talks on their business and needs for diagnostic testing;
- b) invite PCR researchers from ag. biotech companies (member companies) and contract labs conducting PCR for customers to next meeting to discuss the technology and validation.

Further discussion of the agenda for the Spring 2000 AEIC Meeting was tabled until the business meeting.

SFAI Update: Jim Rittenburg (Biocode) gave an update on the recent meeting of the Society for Food and Agriculture Immunology (SFAI) Meeting which was held in the UK. The meeting consisted of three days of presentations and posters. The topics were mostly technical and the participants were largely from academia and research institutes. The topics focused on the detection of chemicals, antibiotics, mycotoxins and allergens. There was a small section on GMO detection. Most scientists attending the meeting did not feel that GM food was harmful but they were big proponents of consumers having choice in what they buy and eat. The scientists also do not buy the argument for world food need and also stated that GM food products were not cheaper than those containing conventional ingredients. There were questions about and requests for more information on the AEIC. There is interest in trying to establish a similar group in Europe.

Sampling and QA/QC : Joe Dautlick (SDI) indicated that this subcommittee has not met since the members have been actively out trying to learn about the grain business. The subcommittee will not concentrate on writing a paper on sampling and QA/QC.

Since the meeting was ahead of schedule, it was decided to start on some of the business meeting agenda items. The secretary's minutes of the 1999 Spring Meeting were accepted by the membership. Yelena Dudin (Monsanto), substituting for Kim Magin, gave the treasurer's report. AEIC currently has a balance of \$9240.19 and is expecting to receive \$12,000 from membership dues. To date, Kim has received only one check for dues and asks that each member company send in their dues ASAP. There was a brief discussion on how to spend the AEIC funds. Several suggestions were made:

- a) allocate funds for the next meeting based on the suggestion that it would be a larger meeting due to the invitations to other companies;
- b) allocate funds for AEIC members to attend other professional meetings to AEIC and its activities, i.e., Pacific Basin Meeting (Honolulu, HI), ACS Spring Meeting (CA), SFAI Meeting (Prague), etc.
- c) update trifold to have as handouts at other meetings such as the IBC GM Food Conference which is being held in November in Washington, DC.

Chuck Mihaliak (Dow Agro) indicated that the AEIC website needs to be revamped, i.e, the biotech initiative needs to be added and the current links do not reflect any biotech. He also suggested that we may want to give the site a "new look" than its current format. He has asked that anyone who has any ideas contact him.

The Business Meeting was continued on Friday morning. Jim Brady (Novartis) indicated that Brian Skoczinski (Beacon Analytical) has offered to host the Fall 2000 Meeting in Portland, Maine.

A discussion then ensued concerning the Spring 2000 Meeting which will be hosted by Ricerca, Inc. in Painesville, Ohio. The dates for the meeting are April 6-7, 2000. It was suggested that the theme of the meeting be GM Diagnostic Methods and incorporate both immunoassays and PCR. The intention would be to learn how immunoassays and PCR fit together for GM testing. It was decided that a planning committee should plan the logistics and agenda of this meeting with Ricerca. Also, AEIC will assist in the funding of the meeting. The planning committee members are: Cynthia Lipton (Zeneca), Jim Brady (Novartis), Stuart Reeves (Diamond V Mills), Kim Magin (Monsanto), Joe Dautlick (SDI), Chuck Mihaliak (Dow Agro) and Fernando Rubio (Abraxis). Suzan Woodhead and Larry Powers of Ricerca will work with this committee in arranging accommodations, etc.

The last item discussed was the annual election of officers. For this year, the office of President, Vice President and Secretary were up for nominations. The nominations for these offices are:

President: Dave Grothaus (Pioneer); Chuck Mihaliak (Dow Agro)  
Vice President: Jan Sharp (Elf Atochem), Cynthia Lipton (Zeneca), Joe Dautlick (SDI)

Secretary: Penny Hunst (AgrEvo)

It was decided to hold the elections via e-mail and fax. Ballots will be sent out and received back by the Secretary. The election is to be finished by the middle of October.

Jim Brady (Novartis) closed the meeting with a thank you to all participants for all the hard work that has gone on since the last meeting.