

**AEIC 2001 Spring Meeting Minutes**  
**May 2-3, 2001**  
**Indianapolis, Indiana**  
**P.L. Hunst, Secretary\***

The Spring Meeting was held at the Dow AgroSciences' site in Indianapolis, IN on May 2-3, 2001. There were 38 attendees, representing 23 companies, government and industry associations.

The meeting began with a talk by **Garry Hamlin** (Dow AgroSciences) on the activities of the Council for Biotechnology Information (CBI). CBI was founded by the agbiotech technology provider companies and trade associations in 2000 with the intent to improve people's understanding and acceptance of biotechnology. Scientists, dignitaries, farmers, researchers and medical professionals are also important members of CBI. CBI is not a lobby group but instead, works through alliances with other organizations, etc. CBI currently has a television ad, called Promise II, airing on cable and local stations. The group also utilizes ads in magazines to expand their message. The targets of these ads are the primary shoppers (usually the wives who do most of the food shopping for the family) and opinion leaders (have some college education; mid to high income). CBI has conducted surveys over the last year to determine the effectiveness of their efforts. Trends have shown an improvement in attitudes about biotech, however, there are problems. There is still concern about safety to the environment, long term effects of agbiotech and concern over safer food. Due to several events in the past year, there has been no overall change in support for agbiotech from a year ago.

**Dave Grothaus** (Pioneer), President of AEIC, gave a short presentation of suggested goals for AEIC in 2001. The AEIC Board, during its February meeting, developed a list of possible goals for 2001. From this list, the Board made the following recommendations for goals:

- a) Update the AEIC PowerPoint presentation;
  - b) Sponsor a workshop targeted toward regulators (EPA, USDA, FDA) and food/grain customers to discuss detection methods for GM crops/ingredients;
  - c) Develop and publish papers on appropriate applications of detection methods for DNA and protein in biotech materials and a paper on the validation guidelines for PCR methods for detection of biotech DNA.
- These suggestions were discussed further in a later session of the meeting.

**Kim Magin** (Monsanto) and **Richard Cantrill** (AOCS) presented the ANSI/ISO initiative and AEIC's role. The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity. The Center for European Norms (CEN) has been working on standards for GM crop detection for the past couple of years. CEN and ISO are bound by the Vienna Agreement in which the two organizations have agreed to accept the guidelines and recommendations that have been made by each other. This avoids duplication of effort on the part of the two organizations. Since CEN has developed some guidelines for GM crop detection, ISO will adapt these and thus, the US will be bound by European standards. The concern is that the US needs to have some voice in the ISO standards. The voice would be provided through participation in the American National Standards Institute (ANSI). In order to do this, several things must be implemented: 1) ANSI status must be changed from "observer" to "participant" to ISO; 2) a technical advisory group (TAG) on detection methods must be established in the US (3 year commitment); and 3) a member of ANSI must sponsor the TAG. Each of these requires people and monetary support. AEIC, AACC and ACPA have all agreed to support the initiative. AEIC will contribute ~\$2500/year for 3 years.

---

\*The AEIC Secretary would like to thank April Ernest and Laura Tagliani of Dow AgroSciences for taking excellent notes while the secretary had to step out of the meeting and contributing to the minutes.

**Don Kendall** (USDA/GIPSA [www.usda.gov/gipsa](http://www.usda.gov/gipsa)) gave an update on the recent activities within USDA/GIPSA. The biotech lab in Kansas City has been operational since January. The facility includes sample prep, ELISA testing, DNA isolation, amplification, and PCR labs. Directive 9181.2 on rapid test performance verification is in place, and directive 9181.3 on DNA based laboratory accreditation is in draft form. Draft directive 9181.3 includes requirements for 1) documentation on management structure, facilities, SOPs, and staff qualifications, 2) performance of analysis on 50 “challenge” samples, 3) on-site evaluation by USDA/GIPSA, and 4) a monitoring program to be put into place. A test monitoring program for grain exported to Japan has been put into place. The program consists of weekly testing of five samples (samples consist of three 800 kernel sets) using a lateral flow strip test. Five 1000 g samples and the results from the lateral flow test are then sent to Japan. There were some problems initially with conflicting results from USDA and Japan. A Starlink performance monitoring study was performed conducted by USDA/GIPSA. The study consisted of twelve participants, including ten official agencies, one field office, and biotech lab. Two sets of samples (3 kg sample broken down and a 720 g sample) with Starlink levels of 0, 0.1, 0.5, and 1% were analyzed in triplicate by lateral flow tests. The results were 100 % correct except in the 3 kg sample set at 0.1% (75% correct) and 1% (95% correct) levels. These results will be published.

**Leah Porter** (ACPA) gave a brief update on the activities within ACPA. Two summits have taken place including key organizations and companies. She emphasized that these were NOT Starlink briefings. General areas of consensus coming out of the summits are the need for the market to drive legislation and regulation and the improved communication and stewardship. ACPA filed comments to the USDA/GIPSA rulemaking. The comments included 1) let the market determine the grading and IP system, 2) zero presence of GM not realistic, and 3) ACPA supports the laboratory accreditation program. Comments to the FDA pre-market biotech notification (PBN) were submitted jointly by ACPA and ASTA, and were generally supportive. Support for biotech was reaffirmed at the ACPA strategic planning retreat that was held November 31<sup>st</sup> through December 1<sup>st</sup>.

**Anne Bridges** (Medallion Labs) represented AACC with a presentation describing the validation process for AACC methods, and gave an update on the progress of on-going AACC collaborative studies. The first ELISA collaborative study including AACC, SDI, Monsanto, JRC, and Medallion Labs was completed on schedule. The method, “Bt Modified Corn in Corn Flour – ELISA Method”, has been approved and published. Two additional collaborative studies are planned this year. One is an ELISA method for Cry 9C, which includes twenty-six international labs using ELISA kits from two companies. This study is underway with results expected mid-summer. The other collaborative study is the FDA’s PCR method for *cry 9c*. This collaborative study is in the planning stages. A list of AACC accomplishments was given including 1) facilitated an international web site discussion, 2) represented CAST at the EPA’s SAP meetings, 3) represented AACC at other professional societies meetings, 4) took part in writing CAST issue papers.

Following the lunch break, **Mary Trucksess** (FDA) presented a talk on some of the agency’s work on StarLink corn detection. Due to the sensitive nature of the StarLink issue, Mary was unable to present much of the detail on her work. Therefore, she gave an overview of the methods and some of the problems encountered. Mary has been working with immunoassays for 10 years in her lab. Her group is composed mainly of chemists and they supply all the analytical data for food. The techniques used include thin layer chromatography, liquid chromatography, gas chromatography, mass spectrometry and immunoassays. When they use liquid chromatography to determine if a food is contaminated, they must confirm the identity of a peak (using mass spectrometry) before they can say a contaminant is present. For immunoassays, they use ELISA, immunoaffinity columns and immunosensor on food samples. For StarLink, they used a sandwich format ELISA for testing corn based food products because of the need for sensitivity. The FDA also conducted interlab evaluations of the ELISA on the food products as well as their own intralab evaluation. In the interlab evaluations, they were testing for cross-reactivity, recovery and comparison of standard deviations between labs. Food is a very heterogeneous matrix and protein denaturation in sample processing will give rise to different antibody binding responses. Also, different

sources of food materials may result in different antibody responses and the food may also be of variable composition. Overall, food testing is a complex process.

**Jupiter Yeung** (NFPA) described the work his group has done on the EnviroLogix ELISA kit to analyze for Cry9C in corn food and processed products. The EnviroLogix ELISA was chosen for this work because it met the criteria they had established, including polyclonal Abs, quantifiable, ability to be validated, and fit into their general sample prep criteria. A range of Cry9C protein levels was spiked into a variety of matrices to develop the protocol. From their results, they concluded that the method can be used to analyze corn products. During the discussion the point was raised that care needs to be taken in drawing conclusions about samples with low Cry9C protein values (like chips or tortillas). One cannot conclude that the protein is gone, but only that the antibody can no longer detect the protein. In addition, even though antibody binding may change with grain or food processing, those changes may not be related to potential allergenicity of the protein.

**Keith Lampel** (FDA) gave a brief description of the FDA's safety assessment approach. He spoke about new initiatives within FDA, and discussed research projects that have taken place at FDA. FDA's general approach to safety assessment is the evaluation of new varieties relative to traditional counterparts. Keith described getting his lab set up to do PCR work on a very short Starlink timetable and their positive results just one week later. Since then they have analyzed 63 food products for Cry9C. They set up lab conditions (separate rooms, forward flow) and sample prep methods (crush samples in double layer plastic bags) to address PCR contamination concerns and developed a nested PCR method for positive confirmation of the PCR product.

In the late afternoon, a discussion of 2001 AEIC goals occurred. The first discussion centered around the proposed workshop. It was suggested that we need to understand what other organizations are doing this year, i.e., the efforts of ABSTC and ILSI, what they are focusing on. Beyond this, suggested topics for the workshop were compiled. These included: regulatory status, sampling issues, detection methods 101, protein/DNA methods and methods for testing grain, food and seed for GM content. Other suggestions included validation criteria for protein/DNA methods, zero tolerance—why this is not possible, detection of experimental GM events and unapproved events, detection of stacked gene products, detection of GM in mixed products (corn in soybeans). Kim Magin and Chuck Mihaliak are going to determine what ILSI has planned for this year. (Who is going to follow up on the workshop for AEIC?)

Dean Layton (Envirologix) will coordinate the updating of the AEIC PowerPoint presentation. Penny Hunst (Dow AgroSciences) will assist Dean.

To assist Kim Magin with the ANSI/ISO initiative, the following people volunteered: Dave Grothaus (Pioneer), Randy Giroux (Cargill), Chuck Mihaliak (Dow AgroSciences), Kevin Worden (Michigan Dept. of Ag.) and Anne Bridges (AACC).

There was also a discussion of AEIC participation, i.e., who else we might want to bring into the organization as either invited guests or active member participants. Suggestions included a) persons with alternate points of view on biotech; b) statisticians; c) persons involved in allergen research and allergenicity testing; d) more participation and presentations on mycotoxins; e) more academic and government participation; and e) outreach to other industry associations to speak and/or participate. It was suggested that allergenicity and mycotoxins be possible topics at the fall meeting in New Orleans.

On the morning of May 3, the AEIC Business Meeting was held. Approximately 15 members were present. The Secretary's minutes of the AEIC Board Meeting and the 2000 Fall Meeting were approved. Dean Layton gave the Treasurer's report (see attached).

Jim Stave lead a short discussion of the AEIC mission statement. The mission statement will be updated on the website to change "immunoanalytical" to "bioanalytical". It was also decided and approved to add "food" to the first statement (insert after "agricultural"). This would expand our focus to issues of allergenicity.

Chuck Mihaliak will head up the nominations committee for the fall meeting. Nominations will be needed for the President, Vice President and Secretary. Penny Hunst was asked to run again for the secretary position and she acknowledged that she would.

The agenda for the fall meeting was then discussed. The meeting will be held in New Orleans, LA on September 27-28 and will be hosted by GeneScan, USA. Possible topics for the meeting included a) food allergy/mycotoxin testing, b) talk by Barb Henry (Aventis) on Cry9C, c) talk from other technology providers on food allergy (Monsanto & Dow), d) discussion of the FAO/WHO food allergy initiative (Steve Taylor?—Nebraska). Along with the possible talks, the agenda should also include updates on the AEIC PowerPoint presentation progress, update on the ILSI workshops and further discussion of an AEIC workshop. It was also decided to continue with updates from other organizations such as GIPSA, AACC and ACPA as well as others. Due to the low attendance of members at the business meetings, it was suggested that we may want to rethink the format of the meeting to encourage more members to participate. A suggestion was made to have the business meeting in the afternoon of the first day and continue with talks/discussions on the second day. Further proposals will be generated for alternative formats and will be presented at the fall meeting (J. Stave).

The 2002 Spring Meeting will be hosted by Aventis in North Carolina.

The business meeting ended with a final discussion of the AEIC goals/initiatives. The PCR paper will be placed on the website since it is not publishable in its current form. Randy G. will talk with Kim M. to discuss her issues with the paper and will then forward to the secretary for web posting. Dave G. will continue to work on the protein/DNA paper and keep it a very applied type of paper. The Board will check with EPA, USDA and FDA concerning their interest in a workshop on detection methods for protein/DNA.

The meeting was then adjourned by the president.

# AEIC Treasurers Statement -- May 3, 2001

## Summary 2000

### 2000 Expenditures

Sidewinder	\$1,786.05
USDA AEIC Workshop	1,622.34
Reprints	545.40
Pacific Basin Chem	500.00
Fall Meeting	1,644.00
State of DE	20.00
Trophy	65.62
<b>TOTAL</b>	<b>\$6,183.41</b>

### 2000 Income

Membership	\$5,950.00
Interest	151.00
<b>TOTAL</b>	<b>\$6,101.00</b>

**Outstanding dues** **\$5,300.00**

**Account Balance as of January 29, 2001** **\$11,504.13**

## 2001 AEIC Spring Meeting Attendees

Name	Affiliation
Brady, Jim	Syngenta
Bridges, Anne	Medallion Labs
Bryan, Willye	Agdia
Cantrill, Richard	AOCS
DeLisle, Alice	Individual
Ernest, April	DAS
Giroux, Randy	Cargill
Glancy, Todd	DAS
Grace, Tom	Biacore
Grothaus, Dave	Pioneer/DuPont
Hefle, Sue	U. of NE
Hernandez, Rafael	Monsanto
Hindman, Sarah	Agdia
Hunst, Penny	DAS
Jenkins, George	USDA GIPSA
Jennings, James	Monsanto
Kahler, Alex	Biogenetic Services
Kendall, Don	USDA GIPSA
Klein, Frank	Neogen
Lampel, Keith	FDA
Layton, Dean	Envirologix
Magin, Kim	Monsanto
Mihaliak, Chuck	DAS
Porter, Leah	ACPA
Rittenburg, Jim	Biocode
Scussel, Vildes	Federal University of Santa Catarina - Brazil
Shillito, Ray	Aventis
Skoczinski, Brian	Beacon Analytical
Song, Ping	DAS
Spiegelhalter, Frank	GeneScan
Stave, Jim	SDI
Tagliani, Laura	DAS
Trucksess, Mary	FDA
Worden, Kevin	Michigan Ag.
Xia, John	Agdia
Yeung, Jupiter	NFPA