AEIC Fall 2005 Meeting Minutes

P.L. Hunst, AEIC Secretary

The AEIC 2005 Fall Meeting was held at Notre Dame University in South Bend, Indiana and was hosted by Agdia, Inc. (Elkhart, IN) on October 5-6, 2005.

AEIC Business Meeting (October 5):

Minutes of 2005 Spring Meeting: A motion was made and seconded to approve the Secretary minutes. The motion was carried by a positive vote.

Treasurer Report: D. Layton (Envirologix) presented the financial details of the AEIC:

•	Starting balance		$26038
•	Collected dues		$ 6350
•	Outstanding dues		$ 2250
•	Expenditures		
o	Budgeted	$ 5773	
o	Actual	$11412	
o	Total	$17186	
•	Total (current)		$21629
•	Total (by end of 2005)		$18122

A motion was made and seconded to approved the Treasurer's report. The motion was carried by a positive vote.

Membership: D. Layton also presented a breakdown of the membership which is split about equally (14 large, 13 small) between large and small companies. Suggestions were given as to companies that may possibly be interested in joining AEIC. These included:

- Large Scale Biology
- Ventria
- Valent
- Riceland
- Biolex
- Phyton
- Phillip Morris
- ADM, Bunge
- Scott's
- Chlorogen
- Silliker, Inc.

A discussion was held on whether government agencies should be allowed to be voting members. The consensus of the group is that it may become too political for agencies to

join since some of them regulate the products that the companies produce. Agencies are always welcome to attend the meetings and provide updates.

AEIC – Change of Words behind the Letters: The AEIC Board announced a contest at the 2005 Spring Meeting to formulate new words for the acronym "AEIC" that would more accurately represent what the organization has evolved into. A $100 prize was offered. The following candidates were presented to the group:

--Agbiotech Excellence through Industry Collaboration
- --Agbiotech Evaluation through Industry Collaboration
- --Agbiotech Examination through Industry Collaboration
- --Analytical Excellence through Intelligent Collaboration
- --Agbiotech Exchange through Industry Collaboration
- --Agbiotech analytical Exchange through Industry Collaboration
- --Analytical Excellence through Agbiotech Industry Collaboration
- --Analytical agbiotech Excellence through Industry Collaboration
- --Analytical Excellence through Industry Collaboration
- --Analytical Exchange of Information Consortium

The membership voted and winner is:

Analytical Excellence through Industry Collaboration

The suggestion was submitted by Virginia Pantella of VIP Consulting and she will be awarded the $100 which will go towards VIP Consulting's dues for 2006.

AEIC Mission Statement: It was decided that the mission statement needs updating. R. Shillito (Bayer) will draft a new statement which will be sent out to the membership for editing/comments. The AEIC Board will then review edits/comments and send out to the membership prior to the statement being posted on the website.

AEIC Board Election: A motion was made and seconded that P. Hunst (Secretary) and D. Layton (Treasurer) remain in these positions until such time as they choose to retire. Both accepted the assignment. Therefore, the election will be held for the positions of President and Vice President. Nominations were accepted from the floor during the meeting. Members also were asked to send any further nominations to the Secretary prior to Nov. 1. The ballot will be distributed electronically on or after Nov. 1 and the electronic voting will conclude before the Thanksgiving holiday.

2006 Spring Meeting Venue: USDA GIPSA will host the Spring Meeting in Kansas City, MO in April. Date will be announced later this year.

2006 Fall Meeting Venue: Envirologix will host the Fall Meeting in Portland, ME. Date to be announced later (hopefully will coincide with the fall foliage).

2005 Goals/Activities: R. Giroux (President) asked for suggestions/comments on any other activities AEIC could engage in. A suggestion was made to further support the ISO TAG possibly by helping to fund travel/research on the infrastructure of commodities through the channel such as sponsoring a researcher from the U. of MO who is working on sampling. Another suggestion was made by G. Clapper to sponsor a symposium at the 2006 AOCS meeting in St. Louis. The last suggestion was AEIC engaging in an inter-laboratory study to generate correlation data between immunoassays and PCR methods.

2006 initiatives: Paper on lateral flow strip test validation (M. Bandla).

2006 Spring Meeting Suggested Topics:

- Cotton/canola value chain
- Adventitious presence testing
- PMPs – animal health products
- Identity preservation on output traits
- Preparation by testing companies for emergency situations, i.e., hurricanes, tornadoes, floods, etc.
- New detection technology other than PCR
- Stacked biotech events, i.e., how to apply testing; how will regulatory agencies view %GM content > R. Jenkins volunteered to present
- Where are we with certified reference materials, i.e., do we have more; are there agreements between countries; intentions of technology providers
- Presentation of standards (ISO, CEN, etc.) > G. Clapper volunteered to put presentation together
- New member and old member presentations (Biodiagnostics? Dow AgroSciences?)

The Business Meeting was adjourned by R. Giroux.

Invited Speaker Presentations:

Systems for Tracking Rice (J. Wells, Horizon Ag) –

Horizon Ag was formed in 1997 as a joint venture of six rice seed companies located in Missouri, Arkansas, Louisiana, Mississippi, Texas and California. Horizon Ag provides a bridge between technology providers and the public breeding programs by providing foundation and registered seed increases, seed testing, marketing, planning, education and royalty management. Horizon uses authorized producer-processors to do certified seed increases, processing inventory, logistics, wholesale/retail sales, seed treatments. The Orygen Seed Management System developed by Horizon Ag is a computer system to track all sales, inventory, etc. via the website (www.orygen.net). Currently the system is being used to track Clearfield rice (developed by BASF). Services for the Clearfield rice are provided by Horizon Ag and include foundation/registered/certified seed production, winter nursery production in Puerto Rico, identity preservation/royalty tracking, certification of growers, authorization of seed companies/retailers, production/processing protocols and monitoring, auditing of sales/inventory and piracy prevention. There is an

online grower agreement for grower certification to buy and grow the seed. Each grower must sign a technology agreement prior to purchasing the seed. Horizon Ag has two other systems. The iCon reporting allows tracking of pesticide and environmental programs. The iPedigree is a seed tracking program which was developed using seed producers as a model. The program tracks seed through the life cycle starting with breeder seed. The program will integrate all production, harvesting, processing, storage and sales and provides a concise pedigree of the crop being purchased or sold. User groups of the system are seed producer/grower; seed company/technology provider; seed testing entity, mill/broker. All information on fields is GPS-based. For example, the type of information that a seed producer/grower may want to access is the planting report, harvest report (storage/combining), processing report (where it goes) and the sales report. The "value" of the system is defined by each user group. The iPedigree system will be fee-based, i.e., users will be segregated based on needs.

Rice Supply Chain—Traceability Requirements (D. McCaskill, Riceland) –

Riceland is a farmer-owned co-operative which processes rice and soybeans. Riceland actually engages in the crushing of soybean which makes them unique. They also handle some corn, wheat and milo.

Rice as crop is large on a global basis with 401 million metric tons being produced. In the US, rice is small with about 7.4 million metric tons produced. Rice is predominantly produced in 6 states of the US: Arkansas leads in production and is followed by California, Louisiana, Mississippi, Texas and Missouri. Rice consumption has steadily increased in the US which has been affected by the increase in the rice-eating populations in the country. There are 3 types of rice: long-grain, medium-grain and short-grain (grown in California predominantly). Classification of rice grain is based on the length to width ratio of the grain. Certain properties of the grain are maintained through breeding Such as starch pasting properties, starch gelatinization temperature and cooked texture. The specialty types of rice grown include aromatic (Basmati), waxy (<1% amylase) and "canner's" or "soup" rice (holds up well through additional processing). Specialty rice is usually not blended with other rice types since the grower is tracked and the rice is milled separately. Other rice types are kept separate but also have allowances in grade standards. Varieties of rice are kept separate within a commodity framework. The major markets for US rice is domestic (60%) and export (40%). The domestic market includes food processors, foodservice and consumer/retail. The US is the third largest rice exporter after Thailand and Viet Nam. The countries exported to include Japan, European Union, Africa, South and Central America. The US is a net exporter rather than an importer since on average the US imports only about 5% of their rice. The imported rice is usually specialty types not grown in the US. The rice supply has many variations such as

- Grower>export
- Grower>distributor>export
- Grower>miller>export
- Grower>miller>distributor>consumer
- Grower>miller>distributor>foodservice

The rice milling industry in the US consists of about 30 mills which are a mix of co-operatives and proprietary mills. A grower has two options at harves: on-farm drying/storage or send to a mill or export terminal. Commercial elevators will place the rice in a temperature bin, then dry and store and then send it to a mill or export terminal. The majority of the rice grown is for commodity and the majority goes to commercial elevators. California has more on-farm storage than other states. Millers may parboil or shell to produce brown rice. Brown rice is then milled/polished, graded and stored. Parboiling is performed for certain consumer markets since it improves kernel resistance to damage/breakdown in further processing. Stored rice may also be bagged/packaged and then sent to distributors/exporters. Rice may also be bulk loaded for food processors or exporters. There are logistical constraints in rice production. For rough rice, there is a narrow harvest window (30-40 days), drying capacity is limited, multitude of varieties (>25 long-grain varieties alone), finite number of long-storage bins and transport logistics to mills. For drying, moisture of the grain must be reduced from 18% down to 13% which requires multiple passes (each pass reduces moisture by 3%). Tempering is performed between each pass to prevent stress cracking of the grain. Drying capacity is now up to 10,000 bushels/hour, however, there are a finite number of working bins. For milling, the throughput is 300 – 1000 cwt/hour. There are multiple processing steps and storage is required between steps. Other constraints are milled rice storage capacity and packaging/transport. Identity preservation and traceability are required in some markets. Some markets require certain varieties. For GM rice, the EU and Japan would require labeling which becomes a testing vs. a paper trail.

Rice Quality Testing (E. Poling, USDA GIPSA FGIS) –

FGIS facilitates the marketing of rice, grain and processed commodities. FGIS' purpose is to maintain official US standards, establish methods/procedures, and manage the national inspection system. FGIS operates under the Ag Marketing Act (AMA) of 1946. Inspections are conducted under AMA and are performed only upon request. Fees are charged for service and most FGIS inspections are required by purchase contract. FGIS personnel are located in the field at export ports and at headquarters in Washington, DC and Kansas City, MO. Kansas City is the technical center for FGIS. FGIS ensures quality by reporting what is there and this is done by equipment accuracy, QA specialist in all field offices. A Board of Appeals/Review is the final authority for any disputed decisions. FGIS works with APHIS (insect contaminations, etc.) and FDA (additives, enrichments, mycotoxins, etc.).

Sampling of a load of rice is accomplished by the use of an Ellis cup, a probe or a mechanical sampler. A representative sample is obtained in a random manner and of sufficient size to permit the required tests to be conducted and still allow a retention sample. The retention sample is maintained in its original condition in case of any disputes. The original sample (1500g) is cut down to two 750g samples. One is the file sample and the other is used for moisture and grade testing. Recently, the 750g samples have been increased to 1250g. Retained samples are kept 60-120 days to allow repeals of any decisions. In 2004, the Board of Appeals had 35 submitted. Standards are in place for rice types (long, medium and short grain), rough or paddy rice and brown rice for

processing. There is no standard for edible brown rice. Visual image references are used to ensure consistent and uniform application of grading lines. Each illustrates the type of damage for each grade. Rough rice grading factors include: total seeds/heat damage; objectionable seeds (any other seeds in the rice); heat damaged kernels (usually caused by storage); red rice and damaged kernels (volunteer rice, insect damage, etc.); chalky kernels (starch is soft in kernel); other types of rice (different grain lengths); and color (no. 1 grade needs to be white or creamy; no. 2 may be slightly gray). Whole kernels give the profit in rice. The special grades of rough rice include parboiled light, parboiled, parboiled dark, glutinous (98% chalky), aromatic, smutty and infested. Brown rice classes include long grain for processing, medium grain, short grain and mixed. The grading factors for brown rice include paddy kernels, objectionable seeds, heat-damaged, well-milled kernels, red rice/damaged kernels, chalky kernels. Milled rice classes include second-head rice, screenings rice, brewers rice, long grain, medium grain, short grain, and mixed rough. The grading factors include other seeds, heat-damaged/paddy kernels, heat-damaged/objectionable seds, red rice/damaged kernels, chalky kernels and total broken kernels, other types of rice, color and degree of milling. The degree of milling refers to the amount of bran that is taken off from the rice kernels. Special types of milled rice include coated, granulated, parboiled, etc.

LibertyLink Rice (D. Mitten, Bayer CropScience) –

New technology in rice is coming. In China, Bt rice is already in advanced testing and Xa21 disease resistance was registered in 2005 for commercial production. Golden rice 2 breeding is underway in local lines in the Philippines and India and seed may be available in 2007. In the US, pharma rice (Ventria) is in confined production for clinical testing since 2001. Press releases from Iran indicate that Bt rice is being grown there. Also, LibertyLink rice is in advanced testing in the US and Brazil with a limited introduction being planned for Brazil (about 2 years away). Bayer has been working on herbicide tolerant rice (via acquisitions of AgrEvo and Aventis) since 1997. LibertyLink (LL) rice is designed for weed control of red rice and other weeds (water grass) resistant to other herbicides. Red rice is a serious problem for rice farmers since an intense infestation causes the farmer to take the land out of production which is the case in Brazil. LL rice carries the bar gene which expresses the BAR (PAT) protein which confers tolerance to Liberty (glufosinate-ammonium) herbicide. The gene promoter is 35s. The event, LLRICE62 locus has been bred into varieties adapted for the southern US. LL rice has not yet been commercialized even though it has full US approval (USDA, FDA and EPA (chemical label approval to use on LL rice)). Submissions have been made globally and expected timing of approvals are as follows:

- Brazil – 2007
- Argentina – 2006
- Canada – 2005
- Mexico – 2005
- EU – 2007
- Uruguay – 2006

Submissions are also being planned for Central America (2005-06), South Africa (2005) and Colombia (2006). Bayer has produced a controlled amount of certified foundation

grade seed and has an extensive seed quality program to assure purity of the registered event and meet seed trade standards. Bayer can also offer technical support and methods as appropriate. Quantitative ELISA for PAT detects 12-13 ug PAT/g FW in the rice as compared to PAT in corn which is in the ng range. Most Bayer products now use the bar gene rather than the pat gene. A commercial lateral flow test strip is available from SDI which detects both PAT and BAR. Envirologix has a lateral flow test strip which detects BAR. The strip test detects 1 seed/3000 seeds. The test will be validated by GIPSA for use by the rice industry. A PCR test has also been developed with detects in the 0.1% range (1 grain/1000 grains).

Plant-Made Pharmaceuticals (PMPs) (M. Horn, Phyton) –

Mike Horn is now employed by Phyton. Previously he was employed by ProdiGene and he spoke of several projects that he was involved with at ProdiGene.

Molecular "pharming" is the production of commercially important compounds using recombinant plants and animals. These are high value/high volume products, usually proteins and usually purified or semi-purified. PMPs include pharmaceutical proteins, pharmaceutical intermediates, monoclonal antibodies, industrial enzymes and edible vaccines. The existing production systems include goats (milk), cows (milk), rabbits, mice, eggs and plants (corn, rice, barley, tobacco, potato, alfalfa, Lemna). The advantages of PMPs include: rapid scale-up and no limitation to scale of production; low cost of goods; low capital requirements; mammalian virus-free and prion-free; flexibility and continuity of supply; glycosylation is similar to mammalian sources; and ease of storage, handling, transportation and purification. Products currently on the market include Paclitaxel (Phyton), Trypzean (ProdiGene), Aprolizean (ProdiGene), Avidin (ProdiGene), GUS (ProdiGene), Lactoferrin (Ventria), Lysozyme (Ventria). ProdiGene's compliance program included the following:

- All personnel trained on procedures
- Everything is under USDA permits
- Growers are under contract for a minimum of 2 years
- Dedicated equipment
- Chain of custody maintained throughout production, storage, processing
- Isolation from other corn exceeds USDA minimum standards
- Three levels of monitoring: grower/crop consultant; internal audit and 3rd party audit.

TrypZean is a serine protease originally isolated from bovine or porcine pancreas. The market driver for producing this in plants was the need for a non-animal source. TrypZean is used in bioprocessing, commercial cell culture, foods, as a digestive aid, wound care, eye care, fine chemicals and leather processing. The gene put into plants is of bovine origin and the protein is trypsinogen. Constructs were made to try to produce sufficient quantities. These constructs included:

- Constitutive promoter>cell wall target>trypsinogen
- Constitutive promoter>cell wall target>trypsin
- Seed-directed promoter>amyloplast>trypsinogen

- Seed-directed promoter>cell wall target>trypsinogen (10% of total soluble protein)

Edible vaccines have been shown to be efficacious in animals and humans. The advantages to the vaccines are no refrigeration is required, no needles are required for administering the dose, accurate dosing is possible with a dry grain fraction, humoral responses are well established and cell-mediated responses are possible. An oral vaccine for swine transmissible gastroenteritis virus (TGEV) was produced in corn. The disease is a highly contagious disease with a high mortality in piglets. Outbreaks occur every 3-4 years with losses totaling about $9 million/year in Iowa alone. Through testing, it was found that the plant-produced vaccine actually worked better than the commercial vaccine. Lactogenic immunity was also shown.

Paclitaxel is made by Phyton which is a division of DFB Pharmaceuticals of Texas. It is also known as taxol and was isolated from Yew bark in 1964. The compound was developed by Bristol Myers Squibb for treatment of ovarian cancer and was approved by the FDA in 1992. Sourcing has been a major problem for the drug. Removing bark from Yew trees kills the trees. In vitro production has numerous technical challenges including low yield of secondary compounds, slow growing to Yew and scale-up production. Phyton screened over 1 million clones for the optimum expressors and used these to optimize cultures. All promising strains were cryo-preserved (up to 10 years in storage with no effect on expression). Productivity enhancers such as plant growth regulators, by-product formation inhibitor, inducers, etc. have been used. Phyton produced over 250 kg in 2004. Production is carried out in bioreators (with custom propellers) in Ahrensburg, Germany.

PCR Testing in Food (B. Levin, University of Massachusetts – Amherst) –

The application of PCR to food systems is rapidly evolving. One goal is to be able to distinguish DNA form live bacterial cells from DNA from dead bacterial cells. One method to do this is to use ethidium bromide monazide. This dye penetrates dead cells with damaged membranes. It is a bifunctional agent which forms divalent bonds when activated. Photo-activation forms crosslinks in DNA from dead cells not allowing denaturation to occur in the PCR reaction. The level of ethidium bromide monazide must be optimized for every organism.

PCR inhibitor compounds in food products are a problem in using PCR for testing. Inhibitor compounds include Haem (hemoglobin, myoglobin), polysaccharides, pigments, products of bacterial metabolism (amines), DNase activity (from tissue or microorganisms) and insoluble protein fibers. The problem to solve is how to clean up PCR samples prior to running the test. Activated charcoal was considered, however, the problem was that charcoal binds bacterial cells and thus, food pathogens would be bound rendering no identification possible. In order to get around this, Dr. Levin's lab has employed the use of a blocking agent. In this case Pseudomonas fluorescens, a bacterium. The P. fluorescens cells do not penetrate the pores of the activated carbon and only bind to the surface, thus preventing the binding of other bacterial cells in the food extract. This technique has been tried on oyster homogenate is which contains a notorious amount

of PCR inhibitors. The procedure is "basic bucket chemistry". First, activated carbon is "blocked" with the P. fluorescens. The blocked activated carbon is washed and then incubated with the food extract. The solution is placed in a column (50ml syringe barrel) and the food extract is drained off leaving the activated carbon in the column. The column is then washed with saline to remove the target test bacterium. The eluate is centrifuged and the pellet is washed, re-pelleted and then lysed. The lysate is centrifuged to pellet insoluble protein fibers and the clear solution then contains the bacterial DNA which can be used in a PCR reaction. The system still needs to be optimized for food homogenates.

Lateral Flow Strip Validation (M. Bandla, Envirologix) –

Validation of lateral flow strips (LFS) is the validation of the device, not the method. The objective is for the LFS to perform as per the specification within the state shelf-life. The specifications refer to the sensitivity claim, specificity claim, reproducibility, robustness, matrix, temperature, humidity. Factors to consider when marketing globally include geographical, economical, cultural, political, matrix, temperature and humidity. For geographical, there are 4 zones in world:

- Zone 1 = temperate
- Zone 2 = subtropical with possible high relative humidity
- Zone 3 = hot/dry
- Zone 4 = hot/humid

Manufacturers of LFS devices need to focus on Zone 4 since it is the extreme for humidity. Manufacturers must also consider the shipping conditions, i.e., how the devices are shipped, how long they are held in customs, etc. Shelf-life can either be estimated or real-time. Most manufacturers do estimations via accelerated stability studies using the modified Arrhenius equation (rate of reaction increases with increased temperature). Most manufacturers also do real-time stability studies in-house. For matrix considerations, the extraction medium is important. If it is water, it needs to be defined as to what water is since it will differ in different geographies. A lot of countries accept the validation of LFS devices if the validation is performed according to 510K guidelines. However, there may be additional requirements. Therefore, AEIC should consider working to develop an ISO item for guidelines for devices or convince ICH (International Committee of Harmonization) to define acceptable guidelines for LFS for agricultural use. After discussion by the meeting participants, it was suggested that AEIC should draft a paper on LFS guidelines and publish in a journal just as has been done for ELISA and PCR validation. This paper then could be taken to ISO or ICH. M. Bandla will lead this effort.

UPDATES:

Tunisia Meeting (D. Dixon, Monsanto) –

Meeting was sponsored by JRC and Tunisia. The JRC shared the EU perspective of enforcement of GM products in order to do capacity building. Industry had an opportunity to provide input for one hour during the meeting. This was provided by

EuropaBIO and basically was summarized by the following: 10 years of commercial products, regulation perspective on a global level, experience with EU regulations by an EU seed company. The meeting was in large part an "infomercial" from the EU regulators. The topics that were covered included reference materials, sampling, impact of adopting CEN sampling protocol, validation of methods, DNA and protein methods for detection (key message was to use only DNA methods), Biosafety Protocol implementation (UN had contingency at meeting). The technical information was biased to the JRC view. Summary from meeting:

- Willingness to work with JRC
- Recognized need for training for testing, sampling, risk assessment
- Some countries expressed concern over chemicals vs. GMOs
- Some countries were not convinced for the need for traceability.

AEIC Protein Paper (D. Grothaus/V. Pantella) –

The title of the paper is "Immunoassay as an Analytical Tool in Agricultural Biotechnology" and is authored by AEIC members (D. Grothaus, M. Bandla, T. Currier, R. Giroux, R. Jenkins, G. Shan, J. Stave, V. Pantella). The paper will be submitted to the Jouranl of AOAC within the next few weeks for review/publication. D. Grothaus will follow up on the strategy for publishing short summary articles in the trade journals pointing back to this paper.

USDA AMS Update (R. Jenkins substituting for M. Sussman) –

USDA AMS is focusing on bio-molecular testing such as AFLP and SSR. AMS is working with the Plant Variety Protection Office to fast track PVP applications based exclusively on molecular data. M. Sussman would like feedback on this proposal.

USDA GIPSA Update (R. Jenkins) –

R. Jenkins gave an overview of GIPSA's proficiency testing program. 119 organizations were contacted to participate. Bi-annual dissemination of samples has been conducted with the first samples going out in February, 2002 (20 organizations participated). The last set of samples sent out was October, 2005 (60-70 organizations participated). The samples sent included 6 corn samples and 3 soybean samples. The corn samples included TC1507 and Mon863—new events in the market. Participants were allowed to do quantitative or qualitative testing using either protein or DNA methods. Results will be posted on the GIPSA website by the end of October. The geographical distribution of the participants were: EU labs (42%), US labs (26%), South American labs (10%), Asia labs (10%), other labs (3%). Sixty organization participated in total. Twenty-five labs provided qualitative results only—7 of these reported results for all events and 3 of these were 100% correct. Twelve labs reported quantitative results only—4 reported results for all events and 2 of these provided acceptable Z scores. Twenty-three labs reported both quantitative and qualitative results—8 labs reported results for all events. Basic statistics were done on the quantitative PCR results such as Z score, mean, standard deviation, coefficient of variation, range (min/max values) and % relative error. There was much

discussion of the results presented and attendees were encouraged to look over the results once they are posted on GIPSA's web page and then ask questions of Ron.

ILSI/AEIC Workshop in China (R. Shillito) –

AEIC is collaborating with the International Life Sciences Institute (ILSI) to sponsor a workshop on detection methods for Chinese regulators the first of December, 2005. Speakers for the workshop are from AEIC member companies and are funding their own way to China.

European Testing Workshop (R. Shillito) –

There was a proposal for ILSI to conduct a workshop on reference materials/detection methods in January, 2006. However, ILSI Europe is not really interested due to costs and logistics.

ILSI Harmonization (R. Giroux) –

ILSI Harmonization is not for harmonizing methods but to harmonize around performance and reference materials. The idea is to get governments engaged around how PCR is validated and what reference materials really are. NAFTA governments not engaged since activities for validation and reference materials are occurring outside of the US, Canada and Mexico. Therefore, in order for these governments to influence internationally, they must have their own positions. These governments want more information. There is a three-part initiative to supply the information: collate the information first; follow up with government regulators; organize a meeting to bring regulators together and come to consensus on a position. Current work is on collating the information and the group has solicited proposals and the document is currently under preparation. Expect to finish this within the next 60 days.

ISO TC34 New and Testing SC (G. Clapper) –

There is a need for testing guidelines for seed. The proposal was taken to the technical management board who said that it is up to the US and French scientists to resolve. Industry is all for a new committee, however, the current secretary and convenor are not willing to relinquish current roles. Therefore, the French must be convinced to relinquish the WG. One compromise to suggest to them to keep the secretariat position and make them realize there is no shame in the TC ending. USDA has offered to contribute $45,000 for each of next 10 years to fund seed subcommittee. According the rules, a government cannot be the only one to contribute funds for a subcommittee, therefore, industry needs to think about adding the additional $35,000 for each of the next 10 years.

ISO TC 34/WG 7 and TS21098 (R. Shillito) –

Working group was set up 3-4 years ago in response to EU initiative to develop standards for testing in food. TS21098 is a technical specification for how methods are submitted

and proposes a fast process. The group met in New Orleans earlier in 2005 (hosted by GeneScan) and participants had a chance to view the sampling of a large barge which helped to give an understanding of how long it really takes to get one sample from a barge and put some context around the EU proposal for taking 100 samples/barge. Twelve countries participated in the meeting. ISO sent letter to CEN to stop development of standards. ISO needs 12 votes of the TC 34 members and thinks they have these votes but they are still working with the countries.