2008 AEIC Spring Meeting Minutes

April 2-3, 2008

New Orleans, LA

As recorded by
P.L. Hunst, AEIC Secretary

There were thirty-five attendees from 15 companies, USDA GIPSA, USDA AMS, AOCS, FASMAC and INRA. Eurofins GeneScan hosted the meeting. Mike Russell, Eurofins GeneScan, welcomed the group to New Orleans.

AEIC Business Meeting

Secretary's Minutes of 2007 Fall Meeting:

A motion was made, seconded and positively voted to approve the minutes.

Treasurer's Report:

	Planned	Actual
Beginning Balance as of January 1, 2008	**$12,399**	**$12,399**
2007 Additional Membership Dues Projected	8,200	1,250
TOTAL PROJECTED REVENUE	**8,200**	1,250
Expenditures		
Scientific Paper	4,000	
Wire Transfer Fee		11
DE Fanchise Tax Report	25	25
ANSI/ISO Initiative (AOCS – ISO TAG)	2,750	
Board Meeting Expenses	100	
Spring Meeting Expenses	1,000	
Hostway (Website – now Mandy Stockstad)	500	96
Bank Service Charges		
Fall Meeting Expenses	1,000	
New Brochure		
Brochure Reprints	300	263
Subscriptions – Conferences	100	
Miscellaneous	100	
TOTAL PROJECTED EXPENSES	**9,875**	**384 (to date)**
PROJECTED BALANCE (Checking Account)	**10,524**	**13,265**
CD Account	10,000	10,000
Interest on CD Account	500	604
TOTAL ACCOUNTS BALANCE	**21,224**	**23,869**

Motion was made, seconded and positively voted to accept the report.

AEIC Membership Update:

Large Corporate Members	14
Small Corporate Members	10
Associate Members	2
Individual Members	2

One small company member was lost since SGS bought Mid-West Seeds. Also, Beacon Analytical has decided not to participate in AEIC in 2008.

2008 Fall Meeting:

The 2008 Fall Meeting will be hosted by BioDiagnostics (River Falls, WI). Since BioDiagnostics is located very close to St. Paul, MN, the meeting venue will be in St. Paul. The membership suggested the following possible topics for the meeting:

- Possible theme might be seed production
- ISO 101 talk
- Canola topics> speakers from CGC, CFIA, Canadian Canola Council
- Update on reference genes
- Talk from Chromatin or other new technology company (i.e., Cibus)?
- Hybrid canola production
- Visit to seed conditioning facility
- Seed chipping technology (Monsanto)>allows the examination of populations and choosing the appropriate ones
- Representative from Latin America to talk on production of seeds (A. Galvez)
- Update on GMO Detection Meeting in Como, Italy
- Member presentation>ABI, SGS Mid-West Seeds?

The suggested potential dates are October 1-2, 2008.

Spring Meeting 2009:

Monsanto will host the meeting in St. Louis.

GMO Detection Conference:

The first World Conference on GMO Detection will be held in Como, Italy in June, 2008. D. Grothaus has submitted an abstract for a presentation on the AEIC protein paper. R. Giroux (Cargill) is a keynote speaker. The question was proposed to the membership as to whether AEIC would like to share the cost of an exhibit space with AOCS and/or present a poster in one of the sessions. The cost for an exhibit booth is 3400 euros (~$5370). Another alternative is the “Point of Presence” which costs 1200 euros (~$1895) and could be shared with AOCS. The Point of Presence allows enough space

for two poster displays (one from AOCS and one from AEIC). AEIC will spend approximately $1000 for the Point of Presence fee and about $100 for poster preparation. A motion was made, seconded and voted positively to do both a poster in a poster session as well as display a poster (based on the AEIC brochure) in the Point of Presence. Ray Shillito will put together an abstract based on the PCR paper and Gina Clapper will prepare an abstract for a poster on AEIC. R. Jenkins (USDA GIPSA), member of the GMO Conference Planning Committee, commented that only 10 vendors have paid to exhibit at the conference and currently only 300 people have registered to attend (maximum of 600 allowed). There is currently a speaker from Greenpeace and GeneticID has two oral presentations and one poster. It was also mentioned that the JRC may be providing transportation to the venue. There are also some early discussions on the possibility of a 2nd World GMO Conference, with the U.S. as a possible site. The website for the 2008 conference can be found at http://gmoglobalconference.jrc.it.

AEIC 2008 Goals/Activities:

The following topics were discussed as possible goals/activities for AEIC in 2008:

Seed Technologists Workshop (to be held at the SCST AOSA Meeting): AEIC will participate in the workshop to be held on Saturday (June 7, 2008). The meeting is June 7-14 and vendors will be present for 3 days of the meeting.

Leonardo Academy: The group is a support group for sustainable farming and they believe that no GMOs should be allowed in sustainable agriculture. They have written a standard which will be filed as ANSI standard for trial use. Any standard filed with ANSI must go through a public comment process. The Farm Bureau and Wheat Growers are concerned about the influence of the Leonardo Academy on ISO, however, this is not currently being worked on in ISO. Also, this is out of AEIC's area of expertise so as a group, AEIC will not comment but encourages the members to feel free to submit comments.

Challenges that stacking traits presents: Challenges that were mentioned include detection, sampling, etc. which are within AEIC's expertise to comment on but there was no conclusion as to whether AEIC would or not.

Thresholds for seeds: AEIC can comment on how to sample, detect, etc. but the actual threshold is a regulatory decision. Therefore, threshold setting would not be an activity for AEIC.

New member recruiting: The following were suggested to be contacted and invited to join to AEIC:

- ABI (M. Thompson will contact)
- Cargill (G. Clapper will contact)
- Nestle (R. Shillito will contact)
- Proctor & Gamble (R. Shillito will contact)

- State Crop Improvement Associations (F. Spiegelhalter will contact Illinois/Indiana)
- Illinois Official Grain Inspection (D. Layton will contact)
- Companies that participate in USDA GIPSA verification program (R. Jenkins will distribute AEIC brochure PDF to them)
- Invitation will be offered at the SCST workshop

UPDATES

ISO TC34 SC16 (M. Sussman, USDA AMS):

The title for this technical committee was originally "Horizontal methods for the detection of molecular biomarkers in foods, seed and propagules of food crops, commodity food crops, fruits, vegetables and derived foods". The proposal was shortened to "Biomarkers". The scope is the standardization of biomolecular testing methods applied to foods, seeds and propagules of food crops. This would include methods that test nucleic acids (i.e., PCR, real-time PCR), genotypic analysis and sequencing, or protein (i.e., ELISA) and other suitable methods. The SC is envisioned as being horizontal in scope, i.e., applicable to other SCs. The SC Oversight Group will meet in plenary. The SC WG will meet separately (in parallel) and report in the plenary. There are 3 WGs: WG1>detection of specific molecular biomarkers in seeds/food plants (formerly ISO/TC 34/WG 7) and foodstuffs; WG2> varietal identification; WG3>detection of potential pathogens of seeds/plants. WG1 is involved in the implementation of ISO TS21098 and the review of:

- ISO 21572>foodstuffs – detection of GMO and derived products
- ISO 21569>foodstuffs – methods of analysis for detection of GMOs – qualitative PCR
- ISO 21570>foodstuffs – methods of analysis for detection of GMOs – quantitative PCR
- ISO 21571>food stuffs – methods of analysis for detection of GMOs – nucleic acid extraction
- ISO 21276>general requirements and definitions
- ISO/TC 34/N1081 Foodstuffs – Detection of GMO in oleaginous seeds added work program of SC
- Performance standards for methods used to determine gene technology derived content of seed lots

WG2 is involved in the determination of performance criteria for use of microsatellites and other DNA- and protein-based molecular markers for cultivar identification, germplasm screening; determination of molecular markers for wheat gluten strength; and determination of a standard marker set for tomatoes.

WG3 is involved in the performance criteria for use of biomolecular marker methods to detection and identify plant pathogens.

CropLife International Detection Team (R. Shillito, Bayer CropScience):

CropLife International (CLI) is a trade organization composed of the 6 major multi-national agricultural companies. The CLI Detection Team has members from all 6 companies, some of whom also happen to be represent their companies at AEIC. The CLI Detection Team supported the ILSI Workshop in Singapore. It also works on harmonization of methods and certified reference materials through coordinated industry communication with government agencies. CLI is also supporting the NIST activities on 35S and NOS screening methods. It also funds activities and provides participants to workshops.

ISTA/ASTA (D. Dixon, Monsanto Company):

ISTA is holding their meeting in Como, Italy right before the World GMO Conference and they will also discuss some GMO topics. Seedcalc 8.0 version is now available on the ISTA website (http://www.seedtest.org/en/content---1--1143.html).

Codex (R. Shillito, Bayer CropScience):

CCMAS met March 9-12 in Budapest. Going into the meeting, it was thought that the U.S. would have a positive opinion on "Methods of Analysis and Sampling", however, the U.S. support was reversed at the last minute, apparently due to a last minute decision. The document has however been proposed by CCMAS to the meeting of the CAC in June to go forward as a guidance document. If the U.S. opposes again, the document may be stopped. In the meantime, the document will be reviewed for further necessary changes.

ILSI Workshops (R. Shillito, Bayer CropScience):

A Workshop was recently held in Singapore (March 27-29, 2008) where 7 countries from the region participated. It was held at the Ngee-An Polytechnic Institution in Singapore which provided great lab facilities. The intent of the workshop was to train technical/regulatory people on issues of sampling/detection. The plenary session was 1½ days of talks given by Anne Bridges (Australia – Victoria Govt.), Dave Grothaus (Monsanto), Marco Mazzara (JRC, EU), Etienne Jaccaud (Nestle), Paul Chiew (AVA), Ray Shillito (Bayer), Paul Teng (U.Singapore), and Dabing Zhang (China). There were 28 participants in the lab portion of the workshop which followed. The next workshop will be held in Santiago, Chile in August 2008. There will be plenary and breakout sessions but no lab sessions. There has also been a request from Colombia to have a workshop with labs. It is possible that this could be scheduled with the Seed Congress in Cartegena in order to have the maximum participation.

Chinese Detection Method Database (R. Shillito, Bayer CropScience):

The GMO Detection Laboratory in Shanghai Jiaotong University has signed a memorandum of understanding with RIKILT (Netherlands) to establish a database of detection methods (GMDD), together with Chinese Government inspection agencies. The

database includes information on existing methods, gene elements and characterization information which includes sequences. The factors for standardization include validation information, comprehensive reference information, open access for users. The GMDD can be found at: http://gmdd.shgmo.org. The structure of the database is by event and the basic information included is the OECD identifier, the trade name, species, introduced trait, transformation method, transformation vector, developer, introduced elements, sequence (from EU submission) and molecular characterization. Detailed information of the detection method includes the primers, the method, some validation information according to CRL and ISO and references. There is no cost to use the database. Currently, there 133 GM events, 350 pairs of primers, 30 protein methods, 30 endogenous genes, 90 certified reference materials, 9 reference molecules and 42 inserted sequences in the database. GMDD plans to organize the project of sequencing GM insert border sequences (including sequencing full inserts). GMDD will continue to cooperate with their EU partner, the Institute of Food Safety in the Netherlands, as well as with AgBIOS and the JRC.

INVITED TALKS

Eurofins GeneScan Introduction (M. Russell, Eurofins GeneScan):

Eurofins had $750 million in revenue in 2007 and has 150 labs worldwide. Eurofins has the capability to conduct 25000 different analytical methods. The main markets for Eurofins are food, pharma and environmental testing. The mission of Eurofins is to be the world leader in bioanalytical testing market by contributing to global health and safety by providing customers with high quality lab and advisory services whilst creating opportunities for employees and generating sustainable shareholder value. Currently, Eurofins has 20,000 customers globally and is projecting $1 billion in revenues by 2011. The food market drivers include globalization, product safety and process integration-process verification. Quality is the bottom line to meet the customer's needs. In the U.S., Eurofins provides the traditional analytical services for pharma, food, feed and seed industries.

Regulations and Standard Detection Methods for GM Foods in Japan (S. Futo, FASMAC):

FASMAC (Food Assessment and Management Center) was established in 2001 to provide a wide range of testing for food. The primary shareholders are Nippon Flour and Eurofins Japan K.K. FASMAC is a NFRI official venture company and is located in Kanagawa, Japan. The business units include DNA synthesis, food testing and R&D. FASMAC has government relationships with Japan, Korea and China as well as industry relationships.

Japan produces approximately 5% of the soybean used in the country, 0.001% of the maize and 0.1% of the canola. It ranks at the bottom for the self-support ratio of rice. Therefore, much of the food is imported. The general public in Japan is concerned about

new technologies for food production due to lack of scientific information, the mass media reporting alarming news concerning food, and the anxiety created by real health issues due to the detection of pollutants, including natural toxins, etc. The general public does not really feed that there is a necessity for new technology for food production.

Two government agencies are involved in food regulation in Japan: the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF). Food is regulated under the Food Sanitation Law (in MHLW), the Japan Agriculture Standards Law (MAFF), the Safety Assurance and Quality Improvement of Feeds (MAFF) and the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of LMOs (MHLW and MAFF; Biosafety Protocol). The safety of foods is assessed via MHLW through the Food Safety Committee (FSC). Labeling of food is governed by MHLW and MAFF. The safety of feed is governed by MAFF via the FSC and the Agriculture Material Council assessments. Monitoring of unapproved GMOs is governed by MHLW and the monitoring of feed is conducted by FAMIC via MAFF.

Approximately 35 foods are subject to labeling with the following exceptions: a) DNA/protein removed or highly degraded; b) the 3 major ingredients (weight/proportion) do not exceed >5% in the food. If GM materials are intentionally used in the food, then the food is labeled as "GM materials used". If the biotech content is uncertain, the food is labeled "GM ingredient not segregated". A food which is labeled "non-GM" must be identity-preserved.

Standard detection methods for GM foods are found in the JAS Testing and Analysis Handbook which is issued by FAMIC (Food and Agricultural Materials Inspection Centre). Monitoring of labeling of GM foods in the domestic Japan market (approved GMOs) is carried out by the use of qualitative PCR (construct or event-specific) for processed food and quantitative PCR (construct or event-specific using plasmids as calibrators) for raw materials. There are guidelines for testing food produced by rDNA techniques which are published by MHLW. These guidelines cover monitoring for unapproved GMO, monitoring of labeling for GM foods (imported grains/feeds), sampling method, testing for approved and unapproved GM events. Sampling methods are detailed for corn, soybean, papaya, ground corn/soybean and processed foods. These methods are similar to U.S. methods. Unapproved GM events that are tested for include CBH351 (StarLink), 55-1 papaya, Bt10, Bt63 rice, LLRICE601 and Event 32. Approved GM events such as Roundup Ready soybean and corn events are tested by quantitative PCR using 35S + GA21 to screen. If the screening results are higher than 4.5%, the construct-specific PCR is performed.

Japan agencies perform quantitative and qualitative PCR method development and validate the tests. A quantitative PCR method has been developed for J101 and J163 alfalfa and qualitative PCR for Event 32. Current work is focused on developing quantitative screening methods for GM maize (including stacked traits) and quantitative PCR for MIR604. Stacked maize traits present a detection challenge. Current methods

are single kernel-based PCR (Akiyama et al., 2005 – Multiplex PCR). The multi-bead shocker is used for grinding since 48 kernels can be ground within 1 min.

Common Endogenous Reference Genes in quantitative PCR (D. Mittanck, Monsanto):

Endogenous reference systems are used to give a relative measurement of the quantity of GM in a sample, i.e., % GM = GM DNA/species DNA with the GM DNA coming from the trait such as Roundup Ready or B.t. and the species-specific DNA coming from the endogenous reference genes such as hmg, lec, etc.

Currently in maize, the endogenous reference systems are:

- Hmg (MON 810, TC1507, DAS-59122-7)
- Adh1-70bp (NK603, MON 863, GA21-m, MON 88017)
- zSspIIb
- Zein
- Invertase

In cotton, the reference systems include SAH7 (WideStrike), Adh (LL25), Acp (MON 1445, MON 531, MON 15985) and Sad1. Cruciferin and others have been used in canola.

The factors that affect the use of the species-specific genes include difference in copy number between end targets, stability of the reference gene, PCR efficiency/inhibition. The effects of using numerous endogenous reference genes included increased analysis (increased testing, mixed samples) and the potential for conflicting quantitative results. Standardization refers to the use of the same endogenous reference system for all products of the same species. Harmonization refers to not necessarily using the same endogenous reference system but to ensure all systems produce comparable results. For standardization, EuropaBIO has efforts underway to identify 1-2 endogenous systems per species and then obtain agreement from participating companies to use exclusively. The proposed effort is large and may be scaled back due to cost and legal issues under EU law due to cross-company collaboration. The experimental plan is to use a third party lab, reference materials and JRC validated DNA extractions. The quantity of each transgene is measured with each reference system by performing 3 PCR runs within 3-5 days with verification of linearity, accuracy and precision. The results would then be compared. For harmonization, EuropaBIO and CLI (CropLife International) have a proposal for maize, soybean and cotton and USDA GIPSA is working on maize reference systems. In the USDA study, hmg, adh1, zein, invertase, SspIIb are being used with certified reference materials. Statistical analysis is conducted on the end Ct-values. The objective was to understand the variability and determine which endogenous gene to push forward. The results will be published. Some countries such as Japan, Korea, Taiwan and possibly the EU are moving to plasmid calibrators. The questions relate to how harmonized are plasmids and can criteria be set? Reference material is complex with stacked traits and negative control source is still needed.

MEMBER COMPANY PROFILE: Agilent (M. Jensen, Agilent):

Agilent is a test and measurement company with a third of its business in the life sciences testing. The making of gene arrays constitutes one-sixth of the business. In 2003, Agilent had an interest in GM testing but decided not to pursue at the time due to a) lack of standardized methods/reference materials and b) no real-time PCR instrument capability. In 2007, Agilent acquired Stratagene which has given them the real-time PCR instrumentation. Stratagene has two quantitative PCR systems—the mx3000 and the mx3005. The mx3005 allows the use of five filters and they can be mismatched. Light is filtered going in and out which results in less signal noise. There is a single excitation source which improves reproducibility. The software is comparable to ABI and others and software updates are free. Web seminars are available on their website.

Grain Trade at the Mississippi River (L. Vanderbrook, Russell Marine):

Russell Marine is an inspection company which executes between buyers and sellers. Successful execution for the seller might be the logistics of moving a product from origin to destination in the most efficient and the most cost effective manner. For the buyer, successful execution might be the delivery of a problem-free product. The logistics for successful execution include:

U.S. river system → barge loading → product inspection → product analysis → IP handling →vessel loading

The U.S. river system provides a continuous flow of product via water by allowing U.S. grain and grain by-products originating in the Midwest to move economically in large quantities. There are approximately two dozen barge lines operating 12,000 covered hopper barges. Barges are owned by grain companies or independent barge lines. Each barge holds 58 large semi-truckloads or 15 jumbo railroad hopper cars. A panamax boat (which crosses the ocean) holds 37 barges or 35-50 MMT. New Orleans is the largest port for export grain. Amsterdam and Rotterdam are world's largest ports. Barges are sampled and sampling also occurs during the loading of the ships. Grain must be officially sampled by USDA GIPSA. Farmer's silos and country elevators connect to river barge loading terminals and river elevators. The barges connect river terminals to 10 export elevators and 3 floating elevators on the lower end of the Mississippi River. Floating elevators load directly onto ships so there is no storage of the grain in silos.

Trucks and rail cars are the typical means of grain transport to the river. Shippers contract barge lines to freight the product from inland river terminals to export terminals. It typically takes 8 hours to load a barge from trucks. Products under the U.S. Grain Standards Act are sampled by the Federal Grain Inspection Service. Other products (meal and by-products) are inspected by private labs. Five samples per truck are taken, usually via a pneumatic probe. Within the river barge trade, the FGIS origin grade is final. Origin analysis of non-regulated by-products by independent labs is final. The origin grade follows the barge to point of export. The export buyer is protected because

all product is re-sampled and re-graded at the point of export. Barges are consolidated into larger tows and pushed down river to the export port.

A visual inspection of the commodity is conducted prior to sampling. The surveyor walks through the cargo, checking the condition and looking for cargo damaged due to barge deficiences. The barge line incurs costs due to deficiences. Barges are classified as A (newest), B (5-10 years old) and C (>10 years old). Damaged grain is often bought by salvage companies as well as elevators which use it to blend with other grain. Barges are sampled with a 12 foot probe via every barge inspection door (18 doors per barge). A temperature probe and meter are used to determine the cargo temperature. Barges are also checked for clogged rain gutters on steel roll-top barges. Gutters that are clogged with cargo can cause damage to remaining cargo. On ships, if the moisture within the hold is at 11% or lower, there is no problem. Infestation by grain pests is a much larger problem on ocean voyages. If a ship is not allowed to unload at destination point for some reason (called demurrage), the grain owner pays the ship owner $25,000/day.

Grain and by-products are tested for GM events, heavy metal residues, for contract settlement and for meeting government regulations. Typical tests that are performed include GM events, proximates, mycotoxin content, pesticides/herbicides, nutritional profiles, feed supplements, animal drugs, vitamins and heavy metals. Sampling is conducted before the cargo is loaded on the ship. Export elevators and floating elevators are equipped with automatic diverter type of samplers. These sample every 17 seconds and diverts across the whole flow of grain. A composite sample is made for every barge. FGIS mandates that the sampler must be located at the highest point before grain descends into the ship. Identity-preserved (IP) cargo is loaded directly from the floating elevator onto the ship to avoid any admixture. The future trend is toward traceability and IP for grain and food products. FDA and Homeland Security currently discussing and would be a major problem for shippers.

Dealing with Heterogeneity in Ship Sampling (K. Remund, Monsanto):

The objective of grain testing is to estimate/test bulk characteristics of a lot. Spatial pattern testing requires a large amount of sampling and testing resources. Spatial/random sampling variability is due to the difference in samples. The goal is to try and minimize so that the results are right 95% of the time. Using probe sampling is reasonable if the heterogeneity occurs as horizontal or inverted cone layers. Systematic sampling is sampling of the flow of seed/grain on regular time intervals by sampling the flow from a hopper bottom truck or from a silo or from a vessel during loading/unloading. More samples are needed as heterogeneity increases. Samples need to be collected from cut through entire flow. Sample pools are obtained to evaluate bulk characteristics. A Monte Carlo simulation was run for an example. The simulation results indicate that proper systematic sampling schemes can yield reasonable estimates for seed/grain testing. Sampling schemes do not generally require excessive numbers of primary samples.

Theory and Practice of EU Traceability Regulations for GM Food (J. Davison, INRA):

The EU has many food safety concerns due to reports of mad cow disease, foot/mouth contamination, Listeria, dioxin, radioactivity from Chernobyl, PEG-contamination of wine, bird flu, dioxin in mozzarella cheese from Italy, etc. This causes a lack of confidence in food safety and government administrations. This lack of confidence extends to GM food/feed and encouraged by anti-GM groups but also by EU politicians. For example, Stavros Dimas, Minister of Environment, would halt GM authorizations and reject Syngenta and Pioneer/Dow cultivation approvals. On the other hand, the EU Ag. Commissioner and the EU Trade Commissioner wish to speed up authorizations and have warned of economic consequences if this is not done, i.e., rising food/feed prices.

Safety assessments of GM products by EFSA (European Food Safety Authority) have very little effect on the EU public. GM products are never approved via a qualified majority vote of the Member States since there are always split votes. This results in the decision going to the EU Commission for approval. EU supermarkets have decided not to stock GM food and EU consumers are confused about the safety of GM products. The results of the Eurobarometer, a survey conducted very year of 25,000 citizens, indicates that consumers see more risk than benefits.

Labeling of new foods/ingredients is governed by directive 258/97 and is not specific to GM products. The deliberate release of a GMO is governed by 2001/18 EC and must be transposed into national law by each Member State. Member States often delay transposition of the directive which results in the delay and/or refusal of planting of GMOs. France recently banned the planting of MON 810 corn. The general food law is Reg. 178/2002 and evaluates potential risks for food/feed. Under this law, EFSA was created in 2004. The law also stipulates a general obligation for traceability. Transboundary movement of LMOs is Reg. 1946/2003 which is the application of the Biosafety Protocol. This regulation governs transboundary movement, documentation, liability and redress. The approval and labeling regulation is 1829/2003 which has the requirement to furnish a method detection and certified reference material. It also covers the labeling of processed GM-derived products even when continued presence of the GM material cannot be demonstrated. It covers the labeling of food and feed. The labeling threshold is 0.9% for adventitious presence of authorized GM products. There is 0% tolerance for unauthorized GM products. The traceability and labeling regulation is 1830/2003 which guarantees the traceability/labeling of GM products throughout the food chain. Traceability must extend back to the farm. The EC has published general co-existence guidelines for GM and non-GM products. National co-existence regulations are being developed with EC guidance. The European Commission recently created the new JRC Institute for Prospective Technological Studies (IPTS) Bureau for GM co-existence. Discussions are now occurring on fortuitous GM (authorized) presence in seed for planting. The EC proposals are 0.3-0.7%, depending on crop, while some Member States are requesting 0.1%. Thus, there is no general agreement.

Food safety assessment is the responsibility of EFSA. EFSA's conclusions are subject to enormous political interference. GMO traceability/labeling and co-existence are not part of EFSA and are not food safety issues. "Labeling provides information for consumers

and users of products and allows them to make an informed choice". This is counter-intuitive and badly understood. The EU submission process is:

Company submission → Member State → EFSA → EU Commission →Standing Committee on Food → EU Council → Vote → No QMV → EU Commission → Community Register of GM

There is a growing EU request for traceability/labeling to ensure free choice, ensure quality/authentication, necessity for compliance with EC directives and regulations on labeling of GM products and necessity for traceability of GM plants under new EC directive and regulations for approvals of GM crops/imports. Traceability is not about food safety.

There are several programs on food safety/quality/detection methods under the FP5 Research Programs. These include DNAtrack, QPCRGMOFOOD, GMOCHIPS, ENTRANSFOOD. These provided the first insights into detection methods and demonstrated how these could influence GM regulations. The PETER Project is promoting traceability excellence and research. There is an urgent need for rapid consolidation and dissemination of EU expertise to developing countries and SMEs so that they can have access to EU markets. The project comprises a network of key projects: TRACE, Co-Extra, SEAFOOD, PLUS, GTIS, CAP and GeoTrace.

Co-Extra deals with GM and non-GM supply chains for co-existence and traceability. There are 53 partners, including Brazil, Argentina and Russia, in 18 countries at a cost of 23 million euros. The objective is to fill the gap between the set EU legal framework and practical implementation. The project encompasses eight work packages with detection methods being dealt with in work packages 4, 5 and 6. Certified reference materials are costly, do not commute to all matrices, have limited stability and limited availability. For DNA : mass ratio, different varieties have different ratios. Environmental growth conditions have an effect and ploidy content differ. There is no easy, cheap solution for stacked trait analysis. Single kernel analysis is expensive. Unknown GM detection is difficult since they lack a detection method and the EC has no legal right to request. Instance of GM admixtures have been detected in collaboration with companies. New methods rely on the supposition that the unknown GM will contain commonly used DNA sequences. In conclusion, there are numerous difficulties in interpretation/decisions to take. The EU DSS (decision support systems) must be generalized to take harmonized appropriate decisions. The labeling threshold is by ingredient. For example, if a cargo containing 99.99% non-GM but has 0.01% authorized GM, the cargo must be labeled "GM". Asynchronous approvals are increasing. The 0% tolerance threshold may lead to price rise in animal feed and will become worse by present corn prices.

Seedcalc 8.0—A Bayesian Approach for AP Testing (K. Remund, Monsanto):

Seedcalc 8.0 is available on the ISTA website (http://www.seedtest.org/en/content---1--1143.html). The old functionality is still present, however, a Bayesian sheet has been added. A Bayesian approach uses historical information about a process. This sheet has

only been implemented for semi-quantitative testing plans. In the older versions of Seedcalc, the current information was used to determine information about a lot. With the Bayesian sheet, historical information can now be incorporated to make decision about a process.

For example, a conventional seed lot is tested by using 1500 seeds resulting in 5 seeds out of 1500 being GM. Historical data (test results on each lot for many years) and can be used to assess the prior probabilities. Conditional probabilities given the observed data are posterior probabilities. If prior probabilities are multiplied with likelihoods = posterior probabilities. The posterior probabilities are added. The gains from using the Bayesian sheet include being able to use historical information, improving the efficiency of inferences and allowing the easy, direct interpretation of results.