AEIC Spring Meeting 2009 Hosted by: Monsanto Company St. Louis, MO April 1-2, 2009

Secretary's Minutes (P.L. Hunst)

Wednesday, April 1

The meeting was brought to order by Gina Clapper (AEIC Immediate Past President) who was filling in for Mike Thompson (AEIC President).

<u>David Grothaus</u> (Monsanto) welcomed the group to St. Louis on behalf of Monsanto Company. Dave remarked that AEIC was first conceptualized at an EPA Meeting in Las Vegas, NV in 1992. The first meetings were held in 1993 to formulate the by-laws of the group. During the initial years, AEIC was focused on the acceptance of immunoassays for agricultural/environmental chemicals. As agricultural biotechnology has become more prominent, the group evolved to topics, issues and technologies related to it as well as mycotoxins and allergens. The group includes agricultural biotechnology technology providers, immunoassay kit developers, PCR kit developers, analytical laboratories and seed quality facilities.

AEIC BUSINESS MEETING

Secretary's Minutes of Fall Meeting 2008: A motion was made, seconded and voted positively by the membership to accept the Secretary's minutes.

Treasurer's Report (D. Layton):

2008 Report

	Projected	Actual
Starting Balance	\$12399	\$12399
2008 Membership Dues	8000	9400
TOTAL Revenue	8000	9400
Expenditures		
Scientific Paper	4000	
Wire Transfer Fees		
DE Franchise Tax	25	25
ANSI/ISO TAG	2750	2925
Board Meeting	100	
2008 Spring Meeting	1000	1162
Website	500	265
Bank Service Charge		10
2008 Fall Meeting	1000	445
Graphic Design (Brochures)		50
Brochure Reprints	300	283
Subscriptions (conferences)	100	500
Miscellaneous	100	64
TOTAL Expenditures	9875	5708
BALANCE	10524	16091

Certificate of Deposit	10000	10000
CD Interest	500	1179
TOTAL BALANCE	21024	27270

2009 Budget		
Balance	16091	16091
2009 Membership Dues	8000	2250
TOTAL Revenue	8000	2250 (YTD)
Expenditures		
Scientific Paper	4000	
Wire Transfer Fee		
DE Franchise Tax	25	25
ANSI/ISO TAG	2925	
Board Meeting	100	
2009 Spring Meeting	2000*	
Website	500	
Bank Service Charge		
2009 Fall Meeting	2000*	
Graphic Design		
Reprints (brochures)	300	
Subscriptions (conferences)	100	
Miscellaneous	100	
ISLI Workshop Travel**	3000**	
TOTAL Expenditures	15050	25
Projected Balance	9041	18316 (4/1/09)
Certificate of Deposit	11179	11179
CD Interest	235***	
TOTAL Balance	25455	29495

* Amount increased by vote of membership to accommodate invited speaker travel.

** Expenditure added by vote of membership to assist in covering travel of invited speakers to ILSI Training Workshops.

***CD was renewed at interest rate of 2.1%.

A motion was made, seconded and voted positively to accept the Treasurer's report.

Membership Update (D. Layton):

Membership Category	Number	Membership Dues
Large Company	16	
Small Company	9	
Associate	2	
Individual	2	
TOTAL	29	\$10550

*Outstanding dues: Agdia, VIP Consulting.

Dean will contact Chet or Brent at Agdia.

AEIC Website (G. Clapper): Gina reviewed the statistics provided by the webmaster on number of hits, new hits, what pages viewed and how often, etc. The webmaster is providing periodic updates on the website traffic. From the launch of the new webpage in October 17, 2008 to October 31, 2008, there were

138 unique visitors. From November 1 - 7, 2008, there were 83 unique visitors. The "mostly viewed" pages on the site included the home page, the jobs page and the white papers. A graphic representation of the information from 2008 is given below along with updated statistics for 2009 from the webmaster which were received after the AEIC Meeting:

	:2083/awstats.pl?month=10&year=2008&output=main&config=aeicbiotech.org⟨=en&framename=ir 🚩 🔁
File Edit View Favorites Tools	Help
Statistics of: aeicbiotech.org	Unique visitors Number of visits Pages Hits Bandwidth
Summary	Traffic viewed * 138 187 478 2057 57.67 MB (1.35 visits/visitor) (2.55 Pages/Visit) (11 Hits/Visit) (315.81 KB/Visit)
Vhen: Aonthly history	Traffic not viewed * 888 1773 152.92 MB
ays of month ays of week lours Yho:	* Not viewed traffic includes traffic generated by robots, worms, or replies with special HTTP status codes.
Countries Full list	Monthly history
Iosts Full list Last visit Unresolved IP Address Authenticated users Full list Last visit Robots/Spiders visitors Full list Last visit Navigation:	
iles type	Jan Feb Mar One Max Jun Jul Oug Sen Oct Nov Dec
Visits duration iles type ™iewed ■ Full list ■ Entry ■ Exit >perating Systems	Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec 2008 2008 2008 2008 2008 2008 2008 2008



AEIC Brochures (D. Layton): The AEIC brochure is available to members as a handout at meetings they attend. Brochures may be obtained by sending Dean an e-mail (<u>dean.layton@envirologix.com</u>) and Dean will send out the requested number of brochures.

AEIC By-law Revisions (G. Clapper): The Board proposed changes to the by-laws concerning Article V, Section 5.1, Article V, Section 5.17 and Article V, Section 5.18. The revisions are as follows:

Article V, section 5.1 (current)

The officers of the AEIC shall be chosen by the full members either at the annual meeting or by electronic or paper ballot held within 30 days of the end of the annual meeting. Except as hereinafter provided in the case of vacancies, directors and officers shall be elected by the members. The President and Vice-President shall be elected to serve until the next annual meeting of the members, or the time at which the new incumbents are elected. The Secretary shall serve for a period of 2 years, and the Treasurer for 3 years, their terms ending with the election of the new incumbents. The Treasurer and Secretary may serve multiple consecutive terms.

Article V, section 5.1 (Proposed)

The officers of the AEIC shall be chosen by the full members either at the annual meeting or by electronic or paper ballot held within 30 days of the end of the annual meeting. Except as hereinafter provided in the case of vacancies, the Vice President, Secretary and Treasurer directors and officers shall be elected by the members. In order to maintain Board continuity, the Vice President will move into the office of President as the the President moves into the office of Immediate Past President. The President and Vice-President

shall be elected to serve until the next annual meeting of the members, or the time at which the new incumbents are elected. The Secretary shall serve for a period of 2 years, and the Treasurer for 3 years, their terms ending with the election of the new incumbents. The Treasurer and Secretary may serve multiple consecutive terms.

Article V, section 5.17 (current)

The Vice-President shall, in the absence of disability of the President, perform the duties and exercise the powers of the President, and shall perform such other duties as the board of directors or executive committee may prescribe or the President may delegate to them.

Article V, section 5.17 (proposed)

The Vice-President shall, in the absence of disability of the President, perform the duties and exercise the powers of the President, and shall perform such other duties as the board of directors or executive committee may prescribe or the President may delegate to them. The Vice President shall lead the planning of the content for the Fall Meeting.

Article V, section 5.18 (current)

The Immediate Past President shall have such duties as specifically conferred by the board of directors. The Immediate Past President shall serve as chair of the Nominating Committee.

Article V, section 5.18 (proposed)

The Immediate Past President shall have such duties as specifically conferred by the board of directors. The Immediate Past President shall serve as chair of the Nominating Committee. The Immediate Past President shall lead the planning of the content for the Spring Meeting.

After a discussion by the membership of the changes, a motion was made, seconded and voted to accept the changes, as proposed, to the by-laws.

Fall Meeting 2009 (F. Spiegelhalter): Frank has asked BASF whether they will host the meeting in RTP, North Carolina and they will check. Frank also asked the membership to e-mail him (<u>FrankSpiegelhalter@eurofinsus.com</u>) with dates of any other association or industry meetings that are occurring in September/October, 2009 so that the AEIC meeting dates will not conflict. Possible topics/areas of interest for the next meeting that were suggested included:

- Canola or soybean or corn?
- Marker analysis
- Enhanced ELISA methods
- LC MS/MS methods
- Detecting multiple traits at once
- Ionian Technology rapid DNA testing
- Others?

UPDATES

Codex Committee on Methods of Analysis and Sampling (CCMAS; R. Shillito): A biotech document was started a few years ago to be a guidance document for acceptance of detection methods forGMO products. Identification of GMOs as 'special' has certain possible impacts at WTO. A coalition of stakeholders (grain handlers, ethanol producers, technology providers, etc.) agreed last year that it made sense to broaden the document to cover both DNA-based and protein-based methods in food. The US, Argentina, Colombia and certain scientific organizations supported the broadened document at the Codex meeting in March, 2009. However, Canada and Australia disagreed which resulted in an agitated discussion at the Codex. The result was that the document went back to the electronic working group which means it might be several more years before a final document reappears. R. Jenkins (USDA GIPSA) brought up that there is concern in the US government that China now feels the sampling plan for GMOs is not appropriate and needs

modification (this is based on the fact that China is the chair of SC4). It was agreed to table this discussion to the ISO TAG meeting following the AEIC meeting on April 2. More information on CCMAS may be obtained at:

http://www.fsis.usda.gov/Codex_alimentarius/Codex_Committee_Analysis_Sampling/index.asp

ISO/TC 34/SC 16 (G. Clapper): Subcommittee 16 (SC 16) is devoted marker analysis, methods for finished products, varietal identification, pathogen detection, etc. The first plenary session was held in November, 2008 and was attended by 10 member countries (Canada, France, EU JRC, Germany, US, Japan, India, United Kingdom, Thailand, etc.). Mike Sussman (USDA AMS) is the chair of the sub-committee and Gina (AOCS) administers the TAG work. More information on SC 16 can be found in the AEIC Fall 2008 meeting minutes on the website.

USDA AMS (D. Srivastava): The National Science Lab (NSL) of AMS conducts chemical, microbiological and bio-molecular testing, as well as supporting the Agency's commodity program. Methods are developed and validated such as for the use of microsatellites. NSL has developed tomato genotype markers and avocado genotype markers. The biotech section of the NSL is a suite of containment labs, each with positive pressure and HEPA filters to reduce any contamination. Testing includes DNA-based and protein-based methods such as PCR, electrophoresis, ELISA, etc. as well as microsatellite screening.

INVITED TALKS

Maintaining Genetic and Trait Integrity: Purity Testing in the Seed Industry (D. Hondred, Pioneer Hi-Bred/DuPont): Pioneer is committed to increasing customer productivity and profitability. Company success is directly linked to customer success and confidence in the product provided. Genetic purity refers to whether the product is what we think it is, i.e., the correct genetics, whether off-types, selfs are present, whether product is genetically "fixed". Trait purity refers to whether the trait is present, whether it is in a homozygous state and what level of purity. Low level presence (LLP) refers to the adventitious presence of GM product in a non-GM product or of unintended GM products in other GM products.

Testing is required at key transfer points in product development such as passing seed from research/inbred-hybrid development to parent seed; parent seed to supply; and supply to the customer. Purity testing involves looking at the genetics (correct inbred or hybrid). Trait purity is conducted to verify the transgene and event confirmation is done to the verify the correct event in the lines. A zygosity screen verifies if the transgene is fixed and LLP testing looks for unintended GM events in non-GM or GM products. Traditional testing involved field grow-outs which is one of the oldest practiced tests. This is based on phenotypic differences and has an extremely limited use since there is very limited resolution and does not support the current short product development timelines. Another traditional test is isozyme testing. Isozyme analysis is used for a basic genetic purity test and is inexpensive and allows the examination of a number of loci. It can identify selfs and out-crosses. Seven enzyme systems may be analyzed from one gel.

Current trait testing utilizes ELISA, which is antibody-based, sensitive/specific and protein-based. ELISA allows a rapid turnaround time of samples and a large number of individuals can be screened. It is employed in trait purity testing and LLP determination. It is also highly amenable to robotics. PCR is extremely sensitive and specific, allowing trait to event specificity. The choices for specificity to analyze for include genetic elements, junctions between genes and genomic flanking regions. A sample of 1 positive per 3000 seeds gives a 0.1 - 0.3 % level. General PCR tests are conducted to look at genetic elements common to many GM products such as the 35S promoter or the Nos terminator. More specific PCR tests look at the coding sequences and can be construct specific. The current state-of-the-art is analysis by molecular markers. Single nucleotide polymorphisms (SNP) look at a difference in the DNA sequence of a single base. This analysis is PCR-based and SNP markers are mapped throughout each chromosome. SNPs are generally proprietary to each company.

Testing at the stage of moving from research to inbred conversion or to parent seed includes SNP analysis, trait testing, event PCR and LLP testing. Research testing utilizes SNP analysis. Supply utilizes SNP, isozymes, trait testing, event PCR and LLP testing.

Introduction to Romer Labs (C. Brewe, Romer Labs): Romer Labs is a new member of AEIC. Romer Labs has been around for 26 years and originally was started in Washington/Union, MO. Their expertise is in mycotoxin analysis. In 1999, Romer was purchased by an Austrian company and since has expanded to having facilities in Singapore and Brazil as well as the US and Austria. Romer does direct and distributor sales and support in 50+ countries.

Romer does reference testing for mycotoxins, GM traits, allergens, pesticides and melamine. Their analytical services unit tests for mycotoxins via HPLC, LC MS/MS and ELISA; GM products by lateral flow immunoassays and PCR, melamine by HPLC, LC MS/MS and food allergens by ELISA. Romer markets rapid methods for mycotoxins and GM products which include AgraStrip (lateral flow immunoassays), Fluoroquant (flurometric tests) and AgraQuant (quantitative ELISAs).

Romer also performs consulting and technician certification as well as providing customers total QA, testing protocols, sampling protocols and training. They also provide customized workshops with hands-on training.

LC MS/MS analysis for mycotoxins is state-of-the-art and allows the analysis of multiple mycotoxins in one analysis with minimal clean-up. It provides confidence in the identification based upon retention time, ionization, transition and internal standards. LC MS/MS consists of first conducting HPLC followed by MS/MS (mass spectrometry) in 3 quadrapole regions. The first quadrapole region is used to identify the compounds in the sample; the second to fragment and the third to resolve the fragments. Matrix interferences result in different ionization fo the analyte in the sample compared to the pure standard calibrant and different signal intensities. Matrix interference limits methods using MS as a detector for liquid chromatography. Internal standards are a must. The current best internal standards are isotope labeled (full ¹³C) which allows accounting for the matrix interference, signal suppression and results in greater confidence in the results and better analytical recoveries.

Romer currently has GM tests (LFDs) for Roundup Ready, YieldGard, Cry34Ab1, Cry9C and Cry3A. A full ¹³C standard is available and more information can be found at <u>www.biopure.at</u>.

Pesticide Residue Analysis in Apiculture: A Technical Perspective (R. Simonds, USDA AMS): USDA AMS is currently engaged in a project looking at the origins of the colony collapse disorder (CCD) in honey bees. Scientific American just published an excellent article on CCD.

CCD is a malady affecting honey bee colonies which has caused loss of up to 90% of commercial bee hives in some areas over the last two years (30% nationwide). Research is being conducted by USDA ARS and Penn State University into the causes of CCD. The project involves three areas of research: parasites, pathogens and pesticides. At one time, cell phones were even implicated as a cause.

Honey bees are exposed to chemicals through in-hive miticide treatments and external pesticide applications to plants that bees forage on. They are also exposed to environmental contaminants (such as PCBs) and thus, they are good "sentinels" or environmental indicators. USDA AMS began testing in 2007 for pesticide residues in beeswax, pollen, honey, brood, royal jelly, nectar and flowers. The QuEChERS method (Quick, Easy, Cheap, Effective, Safe) extraction method, with modifications, was employed. The advantages of using QuEChERS were that it was easily adapted to variable sample sizes by proportionally adjusting reagents, can be used for wax samples. Solid phase extraction (SPE) clean-up was utilized for GC/MS screening due to the complexity of pollen and wax matrices. A buffered method was used for samples with high water content. Pigments are not real issue with samples but lipids/wax do pose issue for pollen and beeswax. The sorbents used were C18 and PSA. Pesticide analysis was conducted via the use of LC MS/MS, GC/MS in EI mode and GC/MS in NCI (negative chemical ion) mode. A total of 1147 samples have been analyzed in two years. 180 pesticides were screened and 135 were identified. For pollen, one sample was found to have 31 pesticide residues and one wax sample had 39 residues. The in-hive miticides for varroa mite were the most prevalent and most concentrated. Other external pesticides of interest were chlorpyrifos, chlorothalonil and pyrethroids. Neonicotinyls were found but not frequently.

Honey analysis was added to the Pesticide Data Program of USDA at the request of EPA. Honey was screened for 164 pesticides but few were found and those were well below the EPA tolerance limit.

The outcomes of the CCD research to date is summarized as follows:

- No commodity has had as many detections at such high amounts in so few samples over such a short time as bee pollen.
- The highest detections were in-hive varrocides, fluvalinate, coumaphos but 130 other pesticides/metabolites were also found.
- Pyrethroids are known to impact foraging behavior.
- No individual chemical presence is likely to explain CCD.
- The impacts of multiple pesticide residues in bee food most likely will be via synergistic interactions at sublethal levels on key behaviors.
- The role of pesticides and disease such as IAPV (Israeli acute paralysis virus) in CCD development remains to be reconstituted in the lab bioassays at relevant doses.

Emerging Technologies for Biofuels: Photosynthesis, Microalgal Biotechnology and Biocassava Plus (R. Sayre, Donald Danforth Plant Science Center (DDPSC)): R. Sayre is the Director of the Enterprise Rent-A-Car Institute for Renewable Fuels at DDPSC and originally came from the Ohio State Unviersity.

The DDPSC has extensive knowledge on lipids for biofuels. Oils have advantages over ethanol such as energy density of the fuel product. Algae have a rapid growth rate, high oil content, 100% of the biomass may be harvested, harvest interval is 24/7 (not seasonal like corn), 4-50% lipid biomass, 50-90% other biomass. An algal system can be up and running after crash within weeks and microalgae are 10-30 times more production than any terrestrial biofuel system. It is estimated that a pond the size of the state of Maryland could provide the transportation energy need for the US.

Production issues include a) optimizing oil yield, b) improving production and harvesting systems, c) enhancing biomass and d) reducing the light harvesting complex (LHC) to reduce photoinhibition in dense cultures. Algal biology is important in that one wants the fastest growing, highest biomass yielding strains, a wide phenotype range, transformable strains, stable transgene expression and oil accumulation with minimum biomass. Production and harvesting systems need to enhance photon flux capture (wavelengths utilized in photosynthesis), environmental control and optimization, control contamination from algae, bacterial, viruses, grazers (Daphnia, etc.). They must also contain the GM algae and be able to remove growth-inhibiting waste products. The growth media should be recycled to reduce the environmental impact and should be compatible with harvesting and oil extraction processes. Currently, the "raceway" pond system is employed for algal cultivation. To enhance biomass, the intent is to capture UV light and promote a frequency shift to 450nm and capture green light (predominant light that impacts Earth) and frequency shift it to 650nm for photosynthesis. The proposed strategies for frequency shifting include using RNAi constructs to turn off chlorophyll b and over-express genes to convert chlorophyll a to chlorophyll b. Biomass may also be enhanced via increasing CO₂ fixation and providing a heterotrophic boost by supplementing the media with glycerol. Algae are very good at converting sugars to oil. Absence of the LHC reduces photoinhibition in dense cultures, allowing greater light penetration. At high light intensities, it was found that photosynthesis is 4-5 times greater in cells lacking the LHC. However, it was also found that shallow ponds with algae having the LHC produce much more biomass which means they require much less water and thus, save money in the culture process.

The traditional harvesting system consists of a) grow the algae, b) nutrient deprive the culture which results in c) storage of nutrients as lipids, d) algal cells are then killed, e) oil is extracted and distilled. A new system referred to as "milking the culture" has recently been unveiled. This system utilizes biocompatible solvents, such as straight chain alkanes (C10-C16), in the culture to extract the neutral lipids (not the membrane lipids). The milking process may be conducted several times. The advantages of the process are that the biomass does not have to be regrown each time to obtain the lipids which saves costs and gives higher yields. This process has the capability to transform the algal oil production to be much more affordable.

Ethanol Policy and State of the Industry (J. Caupert, National Corn-to-Ethanol Research Center)— The mission of the National Corn-to-Ethanol Research Center (NCERC) is to facilitate commercialization of new technologies for producing fuel ethanol more effectively and serve a variety of clients as a place for demonstration research and industrial/commercial testing. NCERC has an analytical lab, fermentation lab and a pilot scale plant. NCERC is funded by donations from industry, academia, government trade association and other donors.

Ethanol is a renewable biofuel which reduces greenhouse gas emissions and reduces the nation's dependence on foreign oil while promoting rural development and job creation. Ethanol is not a new fuel. It is the same product that was produced and sold at gas stations in the 1930's. Farmers revitalized the current ethanol industry to create a value-added market for corn. In 2007, 18% of the total US corn production went toward ethanol production. In 2008, that number rose to 25-27% of the US corn production. An ethanol plant impacts a local economy by creating 50-75 full-time jobs but it also supports between 1000 to 1300 other peripheral jobs.

The US imports 65% of its petroleum needs and two-thirds of the known oil reserves reside in the volatile Middle East. The US spends \$1.70 to \$3.40 per gallon of gasoline to keep ocean freight lanes safe in hostile waters. This is not reflected at the gas pump but is part of the Department of Defense taxes. Production of 6.5 billion gallons of ethanol displaced 230 million barrels of imported oil. This is more than oil than the US imports from Iraq and half of the oil imported from Venezuela. The Western Hemisphere produces >70% of the world's ethanol. The largest producers are the US, Brazil, EU and China. The Energy Independence and Security Act (signed into law in 2007) mandates that 36 billion gallons of renewable fuels be produced by 2022 and of that, 15 billion gallons are required to be ethanol derived from corn.

Fuel ethanol use impacts the environment by reducing greenhouse gas emissions. In 2007, greenhouse gas emissions were reduced by 10 million tons which is equivalent to taking 1.5 million vehicles off American roads. Water use for ethanol production has been an issue raised in the media. Currently, 408 billion gallons of water are used for all purposes in the US. Industry uses 18.5 billion gallons. Ethanol production utilizes 85 million gallons of water per day which is 0.5% of daily industrial use. For the future, technology improvements are being made to reduce water usage to 1.5 gallons per gallon of ethanol. Strides have been made since in 1994, 6 gallons of water were used per gallon of ethanol. This number had been cut to 3.45 gallons in 2006 and 2.91 gallons in 2007. To put the use of 2.5 gallons of water use per gallon of ethanol produced in perspective, it requires 24 gallons of water to produce 1 lb of plastic, 150 gallons to produce the average sized Sunday newspaper and 107,000 gallons per home per year. The daily public water usage in the city of Chicago is 5 times greater than the water utilized by the ethanol industry.

The ethanol feedstock of the future is cellulose. Cellulose-based ethanol must work by utilizing corn kernel fiber, corn cobs, corn stover, etc. The cellulose-to-ethanol may be optimized by pre-treatment methods and fermentation ingredients. There are challenging opportunities such as how to harvest cellulose feedstocks, how to transport cellulose feedstocks and how to store the feedstocks.

Cassava: Virus Resistance and Nutritional Enhancements (N. Taylor, DDPSC)-

The Donald Danforth Plant Science Center (DDPSC) was established in 1998 and is a not-for-profit research institute. It is independent of other institutions and company affiliations and is supported by gifts, research grants and contracts. DDPSC owns the intellectual property that is developed by it. The mission is to move basic science to the farmer in the US Midwest and in developing countries.

The DDPSC International Lab for Tropical Agricultural Biotech is focused on sub-Saharan Africa, mainly cassava. The objectives are nutritional enhancement (biofortification), increased resistance to viral diseases and building human capacity and infrastructure. Projects in the lab include BioCassava Plus and Virca.

Cassava is the most important source of calories in the tropics after rice and maize. It is grown in 100 tropical countries on a total of 160 million hectares by mainly small, resource poor farmers. It is eaten by approximately 700 million people daily and is a major component in microeconomies of many developing countries.

The BioCassava Plus project is funded by the Gates Foundation and is a multi-national collaboration. The management of the project is based at DDPSC. Cassava roots are a rich source of calories but do not supply complete nutrition since they are low in iron, zinc and vitamins A and E. The objectives of the project are:

- Increase bioavailable levels of zinc and iron by 6 times
- Increase nutritionally valuable protein content by 4 times
- Increase vitamins A and E by 10 times
- Reduce cyanogenic glycosides in foodstuffs by 10 times

The solutions to the objectives are based on GM technologies since these are the only effective way to stack all these attributes together.

Lack of vitamin A results in childhood blindness which affects 0.25 to 0.5 million children each year. More than half of the affected children will die within a year of becoming blind since their immune systems are compromised (40% of affected children). To increase vitamin A content in cassava roots, DDPSC followed the strategies that have been successful in maize and rice (i.e., golden rice). Transformation and expression of phytoene synthase in cassava has been successful but the plants were orange resulting in little photosynthesis. The promoter was changed to the patatin promoter to target expression in the roots which has worked. However, up-regulating the vitamin A pathway suppresses the vitamin E pathway. If both DXS and phytoene synthase are expressed, the vitamin E will not be suppressed. For the enhancement of nutritionally valuable protein, the expression zeolin (a fusion protein of phaseolin and zein) was achieved in the root tissues. There was no apparent impact on the plant phenotype and the protein increased to 12%. However, there are allergenicity issues with phaseolin in a segment of the population so sporamin has now been substituted with promising results.

The Virca project is dealing with obtaining virus-resistant cassava and is funded by the Gates Foundation and Monsanto Company. The cassava mosaic disease (CMD) causes 30-40% yield reduction with losses of 30-50 million tons of food (equivalent to \$1 billion). CMD is caused by a bipartite geminivirus which is transmitted by whiteflies. One method of virus resistance is via siRNA to achieve post-translational gene silencing. The plant-made anti-sense attacks the virus and disrupts its ability to infect the plant. Proteinmediated strategy, using ssDNA binding protein, is also being tested with encouraging results (50-70% of the transgenic plants have resisted virus infection). The intent is to combine both strategies in the plants which should be additive.

The next step is to conduct field trials in Africa to test the plants in the intended environment. The provitamin A field tests have been approved for planting in June, 2009 in Nigeria. Field tests of the virusresistant cassava plants have been approved in Uganda for 2009. Field trial applications have been made for pro-vitamin A and virus resistant plants in Kenya.

Update on the CropLife International Detection Methods Team (D. Grothuas, Monsanto)-

The CropLife International (CLI) Detection Methods Team focuses on positioning and policy. It is composed of the major 6 biotech technology providing companies.

Testing occurs by seed companies for their products and by grain handlers/food companies for their products and by governments. CLI member companies develop detection methods and make them available to the public. Reference materials for the methods are produced according to international standards and guidelines and are made available to the public via AOCS and IRMM. Reference materials are available as ground seed or as genomic DNA on a single event basis.

The goal of the CLI Detection Methods Team (CLI DMT) is to promote global methods harmonization. The CLI DMT works with governments' standardization bodies. There is not yet a global agreement on how to validate and use methods. Numerous government agencies, global standards organization and industry organizations are attempting to develop standardization guidelines for testing.

Since methods and reference materials contain intellectual property, CLI DMT has principles for transfer of these materials. These include:

- For non-commercial use, companies will license the methods/reference materials
- For commercial use, parties must license the methods/reference materials from the providers
- Methods and materials will be validated
- Methods and materials will be used for analysis and characterization
- For any publications, CLI members request review of papers utilizing their technologies
- For discontinued products, terms for discontinuance need to be considered

CLI DMT provides messaging for various regulatory requests such as the following recent activities by government authorities:

- India's request for 0.01% LOD for PCR
- Korea's request for 100% purity for reference materials
- China's request for the transformation plasmid

The CLI DMT is also involved in conveying LLP and other messages.

Thursday, April 2nd

The group took a tour of the NCERC facility in Illinois during the morning.