AEIC 2022 Spring Meeting Minutes

P.L. Hunst, AEIC Secretary

Virtual Meeting

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AEIC Spring 2022 Meeting Minutes

April 6-7, 2022

Virtual Meeting

P.L. Hunst (BASF), Secretary

The AEIC Spring 2022 Meeting was held virtually on April 6-7. Matt Cheever, AEIC Past President, welcomed everyone to the virtual meeting and presided over the round table introductions following the antitrust reminder.

AEIC BUSINESS MEETING

Approval of 2021 Fall Meeting Minutes: A motion was made and seconded to approve the minutes posted on the website. Motion was approved by member vote.

Treasurer Report (L. Muschinske): The Treasurer presented the 2022 budget as follows:

ITEM	PROJECTED	ACTUAL
Beginning Balance	39966	40029
2022 dues	7050	3350
Mtg registration - Spring	--	--
TOTAL REVENUE	**7050**	**3350**
Expenses		
Scientific paper	2000	--
DE Franchise Tax Report	25	25
ANSI/ISO Initiative	2900	2900
Board Meeting Expenses	300	--
Spring Meeting 2022 Expenses	1000	--
Website Expenses	500	
Credit card proc	150	63
Fall Meeting 2022	6000	--
Graphic design		--
Marketing (brochure)		--
Subscriptions		--
Miscellaneous		
TOTAL Expenses	**12875**	**2988**
BALANCE	**34131**	**40391**

The cost for the 2022 Fall Meeting could be more if AEIC is able to have an in-person meeting. A motion was made/seconded and voted positive to accept the Treasurer update.

Membership Update (L. Muschinske): The following table depicts the current membership composition of AEIC:

Category	*Number*	*Projected Dues (Paid)*	*# Paid*	*Paid amount ($)*
Large Companies	7	3500	4	2000
Medium Companies	11	2750	5	1250
Small Companies	8	1000	4	500
Associate Members	3	75	1	25
Individual Members	2	100	1	50
TOTAL	**31**	**$7425**	**2**	**$3825**

The Gates Foundation Agricultural Program is in the process of becoming a new member of AEIC. The decrease in dues fees is a temporary order by the AEIC Board due to the Covid pandemic.

AEIC Vice President Introduction: Donna Houchins, Romer Labs, was introduced by Kristen Kouba, AEIC President, to the group as the AEIC Vice President.

Protein Working Group Updates (C. Ament/Eurofins): The Protein Working Group (PWG) is co-chaired by Chis Ament (Eurofins) and Tao Geng (Bayer) The PWG currently has 5 active work streams (Multiplex Validation, MS for Protein quantification, Allergen Analysis, Extraction Efficiency, Intractable Proteins/Characterization). The **allergen analysis** work stream has 12 members who meet monthly and is working on ISO standard for the pepsin digestion assay. The plan is for a publication and designation as an ISO method. The work stream is evaluating EFSA's position on pepsin digestion which was published in 2022. The **multiplex validation** work stream has 7 members who are working to publish guidance for validation. The first draft is being worked on with a projected completion date of end of 2022. The **MS for protein quantitation** has 10 members and is drafting a paper reviewing/summarizing ELISA and MS (2nd draft round and version 7). The **extraction efficiency** group has 8 members and is discussing methodologies and plan to publish a paper on these. They expect to draft the paper by the end of 2022. The **intractable protein** group has 14 members and is working on reviewing protein characterization, production and quantification methods to address technical challenges with intractable proteins. The goal is to standardize methods and harmonize endpoints of characterization. Currently drafting a manuscript. The PWG is

also discussing "ambiguous results for protein methods" and whether this should be a standalone workstream or incorporated into another workstream.

Composition Working Group (M. Bedair, Bayer): The CWG is currently co-chaired by Mohamed Bedair (Bayer) and Phil Brune (Syngenta). Phil is stepping down so a new co-chair will be designated by the CWG. The group is working on ways to support acceptance of combustion vs the Kjeldahl method in the biotech industry for estimation of crude protein levels. The literature review is done. The group will map out the way forward to provide the necessary support for the combustion method (Dumas). The Dumas method uses non-corrosive chemicals and is capable of high throughput. The group is considering a lab round among the member companies using crop forage samples (64 samples) to measure total nitrogen. Forage samples from conventional varieties will be used and will be analyzed at Eurofins and EPL. The CWG is also looking at folate analysis by LC-MS/MS to replace the microbiological assay. This work is being led by EPL.

Nucleic Acid Working Group (F. Ghavami, Eurofins BioDiagnostics): The group was established in 2021 and has 14 members. The NAWG is discussing updating the AEIC website with latest technology information such as information on NGS methods, digital PCR, RT PCR, endpoint PCR, isothermal methods. They are currently working on the FAQ section. The group is also thinking on harmonization of nucleic acid analytical tests standards (ISO).

Ambiguous Results Working Group (R. Shillito, BASF): The group has 14 members and has met once in 2022. Ambiguous results are not the result of bad science. They need to be classified as a business decision based on the best available science so knowing how to classify them is important. A process for specific implementation at each lab may depend on their internal processes or the requirements of the method provider. A process which is pre-determined and harmonized is preferable. The group suggests that ambiguous results be dealt with in the NAWG or PWG.

Website Updates (D. Houchins, Romer Labs): The group is working on the editing of the "About" section. They have also gone through the links and websites under "References" and are now working on 'FAQs'. For the slide deck, the webmaster created a template which now needs to be in 16:9 format. It was also suggested to switch out a lot of the green on the slides which is a hinderance to color-blind persons.

Fall Meeting 2022 (D. Houchins): The Fall Meeting may be a face-to-face meeting depending on the spread of Covid variants and company travel policies. Matt will reach out to Merieux to see if they may be interested in hosting the Fall 2022 meeting (depending on travel policies). Another suggestion is whether Syngenta and BASF would consider jointly hosting and holding it at the NC Biotechnology Center. Eurofins Madison Lab is also interested in hosting a meeting (probably a fall meeting). Another suggestion was holding the AEIC Meeting before or after a meeting of another seed industry group. A question was raised as to whether the next meeting will be a hybrid

format (in-person and virtual). The logistics may be complicated and the cost could be quite high if a hotel was involved.

Suggested topics to consider for the Fall 2022 meeting were:

- Issues in seed testing
- SNP assays for seed purity testing
- Genome edited animals
- Genotyping in animals
- Presentations from grain guys (Cargill, Bunge, etc)
- Seed IP and patenting
- Effect of genome editing on patent decision
- GMO testing in highly refined foods/ingredients
- Presentation skills for scientists

ISO Update (R. Shillito, BASF): ISO TC34/SC16 is the Biomarker Group which has 45 countries interested in its work. There are 8 WGs in TC34/SC16 which include: meat speciation, sub-sampling of seeds/grains, rapid nucleic acid amplification methods, biobanking for agriculture and food production, molecular biomarkers of agricultural fiber-cotton, microarray detection, genetically engineered content detection and quantification, single laboratory validation of qualitative real-time PCR. TC34 has five active documents, one of which is the PCR methods general document. A new ISO standard will be developed for PCR and will not be limited to GMO detection. The intent is to incorporate the latest technological advances. For more information, contact Sherry Whitt (sherry.whitt@basf.com). The IEC/Standards Exploration Group 12 BioDigital Convergence is looking for needs for standards for the purpose to propose a propose a roadmap for standardization in the area of bio-digital convergence. This is a complex combination of new conceptual and practical connections between engineering, biology, physics, nanotechnology and information science. There are 7 WGs, one of which is agricultural bioengineering (WG5). Membership is open to anyone and requires no nomination by a National Standards Body. Experts may join at: https://www.iec.ch/dyn/www/f?p=103:186:402677069320547::::FSP_ORG_ID,FSP_LANG_ID:27561,25

Contacts for more information on ISO TC34/SC16 are:
Ray Shillito (Raymond.shillito@basf.com) and Denise Williams (denise.williams@aocs.org)

AFSI Crop Composition Database (N. Gillikin, BASF): There are 9 WG members and 2 government liaisons from US FDA. The Crop Composition Database is publicly available and was first released in 2003 (www.cropcomposition.org). It contains nutritional composition data of conventionally-bred crops (no GMO data). Currently, there are data for 13 crops (apple, canola, field corn, sweet corn, cotton, mustard, potato, rice sorghum, soybean, strawberry, sugarbeet, sugarcane). The data is subjected to data acceptance criteria which gives non-biased, high quality datasets. The database was formerly the ILSI Crop Composition Database. Version 9.0 was released on 31 Jan 2022 and includes more than 1.37 million data points for 223 analytes. A new data feature is the sample ID-specific report which enables the user to view the data for multiple

analytes for a sample. Release of new data will occur every 2 years (next release in 2024). Compositional data for red pepper has been received and is being processed. The group is also seeking data for cassava and cowpea. The curator contact is Dr. Bhavneet Bajaj.

National Alliance of Independent Crop Consultants (NIACC) (C. Ament, Eurofins): The NIACC met in January in Orlando, FL. The group is focused on field trial activities. The meeting included training, trade shows, etc. The key issues for 2022 are:

- Endangered species act and biological evaluations of pesticides for registration review
- FIFRA revision and Protect America's Children from Toxic Pesticides Act
- Worker protection standards
- IR-4 minor crops
- Waters of the US (WOTUS)
- Carbon markets/sequestration questions/concerns

The next meeting will in Nashville, TN in Jan 2023.

The AEIC Business Meeting was adjourned. Meetings of the PWG, CWG, NAWG were held for rest of Day 1.

INVITED TALKS

Detection of Genome Editing in Crops: Opportunities and Challenges (C. Fan, Syngenta): Genome editing (GE) using CRISPR has been used since 2012. The enzymes Cas9 and Cas12 have been widely used. GE greatly reduces the breeding time in plants. There are 3 types of changes for which CRISPR CAS is used for: SDN-1, SDN-2 and SDN-3. SDN-1 (site-directed nuclease) produces a double-strand break in the plant genome without the addition of foreign DNA. SDN-2 produces a double-strand break also but a small nucleotide template is supplied which is complementary to the area of the break which is used by the cell to repair the break. SDN-3 also induces a double-strand break in the cell DNA but it is accompanied by a template containing a gene or other sequence of genetic material. Molecular characterization of GMO vs GE is similar. For GM, a construct is made, events are sorted and the product is developed. Transgene characterization, absence of transgene in later generations, trait or target gene expression and heritability are all the same for GMO and GE products. GE detection is PCR amplification-based (cleaved amplified polymorphic sequence, allele specific primer, mismatch cleavage assay, Taqman, digital, NGS amplicon sequencing). Taqman real-time PCR is the gold standard since it is even specific and component assays of trait genes can be done. There is a need to develop detection methods with comparable sensitivity and specificity as for GMOs. Methods should routinely and reliably detect GE derived indels in bulk grain samples. There is also a need for a high quality database which would include all genotypes of GE plants as reference. In summary, GE can greatly accelerate trait development and crop breeding. GE products require different analytical methods during trait development to characterize editing alleles. PCR-based and NGS-based technologies complement each other.

Where's the BEef? Commercial and Technical Challenges of Complying with the National Bioengineered Food Disclosure Standard (J. Haudenshield, Merieux NutriSciences): Customers want to comply with laws and standards which helps facilitate new GM products and their movement. The National Bioengineered Food Disclosure Standard (BE Food) covers food for human consumption. Any ingredient or food on list is to be labeled BE unless it is proven not to be. Also, ingredients on the off-list for BE may be classified BE if it is known to the producer that it is BE. The list of BE food includes alfalfa, apple, canola, corn, cotton, eggplant, papaya, pineapple, potato, salmon, soybean, squash and sugarbeet. There are compliance challenges such as what needs to be tested for (marketing); finding reference materials and test methods (technical). Reference materials are needed for test onboarding in a facility as well as a calibrant. There are some available for corn, soybean, canola and sugarbeet but very limited availability for cotton, potato and none for papaya, eggplant, alfalfa, applies, salmon and pineapple. Same is true for test methods. Canada does supply reference material for one flaxseed event. For rice, there are 3 test methods and one reference material (LL62 rice). A few more test methods are becoming available but reference materials are still lacking. Test methods are often hidden behind pay walls and access controls. Without compliance to law, it will become a trade barrier.

Regulation of Plant Biotechnology: An Overview (B. Juarez, USDA APHIS): The Biotechnology Regulatory Services (BRS) is under APHIS in the USDA. BRS has the "Am I regulated?" program so clients can determine if their plant product regulated or not. 135 products have been designated as not regulated and BRS has issued 40,000 permits for others. BRS recently rolled out an update to biotechnology regulations. The modernization is based on advances in science, technology and experience. The agency focuses on areas of plausible risk using as clear, consistent science-based and risk-based framework. The update has been implemented for 2 years now. GM does not introduce an inherent plant pest risk as a technology. Conventional crop breeding has a history of safe use related to plant pest risk. Plants are exempted that have certain modifications which are achievable via conventional breeding. Philosophy is to treat similar products in a similar way. A plant pest risk assessment is done first and if the plant is found to unlikely pose increased risk, it is not subject to the regulations. Also, plants with same exempted plant-trait mechanism qualify for the same exemption. Developers may voluntarily request a letter confirming exempt status. Developers may also request a regulatory status review. The submission contains information on the biological properties, trait, mode of action, etc. An initial review (180d) is performed. If there is a likelihood of risk, a plant pest risk assessment is done, followed by a public comment period. Whole process takes about 260d. Permits are granted for import, movement and/or release. Supplemental conditions may be part of permit to protect plant health. Application requirements and permitting conditions may be found in regulations. USDA's mission is to protect plant health and enable innovation. Early submissions in process signal innovation beyond standard row crops. Confirmation requests have included applies, wild tobacco and camelina. BRS suggests that

developers should have a pre-submission meeting to help move process. More information can be found at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about

High Resolution Phenotyping (R. Hadar, Vibe Imaging Analytics): Visual inspection is used across the food supply chain for taste, texture, food safety, etc. Digital imaging devices have not been able to replace manual visual confirmation. Phenotype is the observable characteristics of an organism. Human visual inspection error is 20-30%. Humans see 10M of 16M combinations of red, blue and green. It is not an intuitive color scale. Other scales use hue, saturation and value (brightness). What we see is not what we measure. High resolution phenotyping allows accurate measurements, relevant parameters, large amount of data and digital records. Pixel level measurements are done and classified. Movement to digital eliminates human and statistical error rate, insufficient data, labor and expertise availability. It is time to move to digital for better results.

Simplot Innate® Potatoes: Development to Commercialization (G. Rudgers, Simplot): Simplot is a family-owned international food company with 13,000 employees in six countries. Simplot distributes products to over 100 countries. The Simplot Plant Sciences Group was established in 2000 and has 85 employees with all startup functions under one roof. Innate potatoes were commercialized in 2015 and 2017 and have DNA from wild potatoes put into commercial potato varieties (Russet Burbank, Ranger Russet, Atlantic, Snowden). GEN-1 potatoes have non-browning, reduced blackspot/lower reducing sugar accumulation/reduced free asparagine. GEN-1 potatoes do not brown after cutting so less waste. Reducing free asparagine cuts down on interactions with reducing sugars which results in acrylamide formation when potatoes are fried. GEN-2 has the same traits as GEN-1 with 2 additional traits—late blight resistance and further lowering of reducing sugars. The VNT-1 protein is expressed which induces a hypersensitive response to the late blight pathogen. RNAi was used to down regulate vacuolar invertase to further reduce sugars. Potatoes are autopolyploids, highly heterozygous and subject to inbreeding depression. Processors need a uniform crop. Potatoes are generally grown in tissue culture and vegetatively/clonally propagated. But they are always started in tissue culture. Potatoes cannot be conventionally crossed to produce a stacked trait, rather, each must be transformed to introduce quality traits. Most countries regulate by event and each event must be approved. A full data package had to be produced for each Innate potato event and have had no luck in convincing agencies otherwise. Potatoes have multiple varieties with T-DNA using potato DNA sequences. There is a need for primer sets that do not amplify native potato DNA while still being construct specific. This allows quick determination of the presence of Innate events. Potatoes are unfamiliar to most regulatory agencies, i.e., they are vegetatively propagated. Agencies still want data to show traits are stable across generations and they still request measuring analytes that are not important in potato such as dietary fiber. Also, RNAi is not well understood by agencies. Simplot has

develop a detailed rationale of siRNA safety for both humans and animals based on published data. Also, VNT-1 protein is intractable so Simplot published a weight of evidence paper for R-protein safety. GEN-3 potatoes will have same traits as GEN-1 and GEN-2 with the addition of PVY resistance and the addition of 2 more genes for late blight resistance. Innate potatoes are the most sustainable since fewer inputs are needed by growers, consistent sugars for storage, reduced bruising resulting in less waste. Simplot is working to change attitude of major grocers (Kroger, WalMart, etc.) not to market Innate potatoes.

Earning Public Trust in Gene Editing (A. te Plate-Church, Center for Food Integrity): The Center for Food Safety has been around for 15 years and is dedicated to earning consumer trust. Public trust is a valuable intangible asset. Without a plan to earn trust, a R&D strategy is not complete. How does the public feel about genome edited (GE) food? 41% of consumer have heard about GE food and 25% care a fair amount about it. 33% rate their understanding as good or excellent. There is limited consumer knowledge about plant breeding but 66% say they want to learn more and have a favorable impression of farmers. How do we turn this into earning trust? We must demonstrate the benefits that align with public desires such as stewardship, disease resistance, animal health, nutritional benefits, etc. Consumers are least interested in feeding the world. Thus, messages should focus on benefits to consumers—environment, plant and animal health and stay away from profit, yield and increased efficiency (www.geneediting.foodintegrity.org). A conversation starter: "GE makes precise, intentional, beneficial changes in genetic material of plants and animals which improves health and well-being" (www.innovature.com). Lead with human health connection since advancements of GE in human health are looked on favorably. Talk about evolution of food production and not revolution. Consumers trust science leaders and farmers about food. Least trust is with companies/retailers who sell food. Regulators are also viewed favorably. Share analogies and visuals. The key takeaways: a) concern about risks often outweigh benefits; b) consumers have more questions about use of science in animals; c) Gen Zs want to know more than older generations; d) describe GE in easy, understandable terms.

International Trade Policy: Potential Impacts for Plant Biotechnology (L. Goodwin, CropLife International): CropLife International works with policy makers and influencers. Global conversations have included the desire to hear about environmental benefits of biotech. The UN Conference on Food Systems was held in 2021 where a lot of coalitions were built. The EU has joined coalition on productivity. **Ukraine/Russia:** The war in Ukraine has spotlighted food safety concerns. 13 million people were put in jeopardy for food in the last 6 weeks. The FAO advocates protecting production and market activities to meet domestic/global demands, find more new and diverse food suppliers, and reduce non-tariff barriers. **EU:** The EU green deal has a mirror clause which one product is banned, it also bans crop and they have reduction targets. Things may be changing some as 4 new GMO approvals came out last week. **China:** China is shifting to cultivation of GM crops and maybe to becoming a potential exporter. Field trial

guidelines were released at the end of January for GE products. **Mexico:** Current political regime banned use of glyphosate and GM corn for human consumption by 2024. Resulted in the regulatory pathway shutting down for products. US and Canada are putting on pressure to restart Mexico systems to comply with USMCA. Challenges are politically motivated and could impact trade outside of country. **Africa:** GM cotton is popular in many countries on continent. Kenya, Nigeria and South Africa recently released guidance on genome editing. Key messages for international trade: a) need open and fair trade; b) there is more than one type of farming; c) ag innovation can help address global needs; d) benefits in one area may unintentionally impact benefits in other areas.

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