



AEIC 2019 Fall Meeting Minutes



P.L. Hunst, AEIC Secretary

Des Moines, Iowa



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AEIC Fall 2019 Meeting Minutes

October 9-10, 2019

Des Moines, Iowa

P.L. Hunst (BASF), Secretary

The AEIC Fall 2019 Meeting was held in Des Moines, IA on October 9-10. Corteva Agriscience hosted the group at the Hilton Garden Inn.

Welcome (T. Davis, Corteva Agriscience): Corteva Agriscience is a new agriculture company for a new world. Corteva draws on the strength of three agriculture leaders: DuPont, Dow and Pioneer Hi-Bred. The mission is to enrich lives of those who produce and those who consume, ensuring progress for generations. The brand values are a) enrich lives, b) stand tall, c) build together, d) be curious, e) be upstanding and f) live safely. The challenges for agriculture include increasing farm pressures, feeding a growing population, food security and the impact of climate change on production. Supply and demand need to be connected by aligning food chain from end to end. To do this means leveraging technology and bringing innovation by harnessing data, applying precision science and modernizing farmers' operations. Securing the food supply and sustainable agriculture depends on global food security, knowledge sharing and improved products. What makes Corteva different is understanding producers and consumers by expanding service options, providing end to end solutions and looking to the future. Corteva sells into 130 countries and has 140 R&D facilities across the globe. The seed product line includes alfalfa, canola, corn cotton, rice, wheat. Crop Protection produces products for cereals, citrus, cotton, potatoes, rice, peanuts and soybean. Corteva has digital ag in the Granular and AcreValue platforms.

AEIC BUSINESS MEETING

Approval of 2019 Spring Meeting Minutes: A motion was made, seconded and voted positive to approve the minutes as posted on the AEIC website.

Treasurer Report (L. Muschinske): The Treasurer presented a graph of the meeting expenses vs revenue over time. The 2019 budget was presented as follows:

Item	Projected (\$)	Actual (\$)
Beginning Balance	21020	21020
2018 Dues	1000	1000
2019 Dues	15000	14600
Spring Meeting Registration	2250	2350
Fall Meeting Registration	2250	2950
Total Revenue	20500	20900



Expenses		
Paper	2000	
DE Franchise	225	225
ANSI/ISO	2900	2900
Board Mtg	800	655
Spring Meeting	5000	4012
Website	2000	434
Credit Card Fees	600	567
Fall Meeting	5000	3272
Graphic design		
Marketing	1500	
Subscriptions	100	
Miscellaneous	100	100
TOTAL Expenses	20225	12165
TOTAL	21295	29756

A motion was made, seconded and voted positive to approve the Treasurer report.

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

Category	Number	Projected Dues (\$)	Unpaid	Unpaid amount (\$)
Large Companies	8	8000	1	1000
Medium Companies	13	6500	0	
Small Companies	10	2500	1	250
Associate Members	2	100	0	
Individual Members	3	150	0	
TOTAL	36	\$17350	2	\$1250

AEIC Brochure (B Johnson): Brenda showed the group a mock-up of the trifold brochure with recent edits finished. The plan is to complete all changes by the end of October and then send to a print shop for 500 copies. Members wanting copies of the brochure to hand out at other meetings should contact the Treasurer (L. Muschinske).



Vice President Nominations (All): Nominations were opened for Vice President of AEIC. The VP will serve as VP the first year, President the second year and Past-President the third year. Nominations were entered for Matt Cheever (BASF) and Kristen Kouba (Corteva Agriscience). The election will be via email and the ballot will be distributed by the Secretary via email to member companies (1 vote/company). The election will begin November 1.

Spring Meeting 2020 (B. Johnson): The Spring Meeting will be hosted by Merieux Nutriscience in the Chicago area in early April. James Haudenshield would entertain any feedback or suggestions for the venue (by O'Hare Airport or downtown Chicago). The group made the following topic suggestions for the meeting:

- ✓ Food safety
- ✓ Aqua Bounty update
- ✓ Speciation testing
- ✓ Fire ant quarantine work with USDA
- ✓ Technical challenges in meeting new regulatory guidance for GM products in the EU and China
- ✓ Detection of GMOs in enzymes
- ✓ Food adulteration
- ✓ Use of social media for educational purposes

Fall Meeting 2020 Planning: BASF indicated it may be able to host in Research Triangle Park in North Carolina or Bayer Crop Science may be able to host in St. Louis, MO.

Composition Working Group (P. Brune, Syngenta): The CWG has been discussing the use of the Dumas method for crude protein instead of the Kjeldahl method. The group is planning a white paper that reviews the literature in order to gain support for the Dumas method from regulators. For crude fat in canola, there are three methods recorded in the ILSI composition database. Thus, it would be good for all to align on one method. EPL Labs also has written a multiplex method for fat soluble vitamins but the status of this work is being determined.

Protein Working Group (M. Cheever, BASF): The Protein WG has ongoing workstreams. Allergen analysis workstream discussed assembling a database for endogenous allergens (similar to the ILSI composition database). The group felt it was a bit too early to do this as more information is needed. The workstream also discussed mass spectroscopy for peptides (EU guidance) and peptidomics. The workstream for mass spectroscopy for protein quantitation concluded MS is a viable protein technique and have outlined a paper. Writing of the paper is now beginning. The Multiplex Validation workstream also plans to publish guidelines for standard validation parameters for single and multiplex protein methods and is currently working on harmonizing validation terms and parameters. The protein slides currently on the website have been converted from graphics to text to more easily do revisions. The WG is also discussing whether to put together a harmonized method for extraction efficiency of newly expressed proteins and to consider the EFSA dietary exposure statement.



ISO/TAG Meetings: A request was made to ask R. Shillito to provide an update at the next meeting.

The Business Meeting was adjourned.

INVITED TALKS

Ruminations on the Tools and Direction of Molecular Diagnostic Use in Seed Purity (K. Kenward, 20/20 Seed Labs Inc.): Seed purity is a multi-layer concept of diagnostics, germination, etc. Seed purity is regulated internationally. Physical side of purity is defined by ISTA and this will need molecular technology in the future to determine.

20/20 Seed Labs was established in 1989 and is independently owned and operated in Canada. It provides services to farmers, seed growers, etc. It operates domestically but is accredited internationally (CFIA, ISTA, Canada Seed Institute, ISO9001). Seed quality is tested via germination, purity and vigor. Seed health is determined via molecular analysis, looking for plant pathogens, varietal identification, GMO, refuge content.

Canadian purity standards for wheat include requirements for disease resilience and qualitative parameters. Varieties are divided into classes by functional characteristics and the region where they are grown, i.e., dough strength, milling quality, protein content, Eastern vs Western. KVD (kernel visibility determination) was a process discontinued in 2008, however, in 2015 U.S. wheat varieties were registered in Canada that were non-KVD compliant. In 2018, mixed classes of KVD were registered. The certified seed system tracks variety, handlers, generation. The field inspection schedule requires three passes through the field, observing 3000-5000 plants/pass. In post-harvest purity thresholds/certification, only certified seed is identified by variety. Elevator declarations and checks are made, and the variety must be declared.

Molecular tools for physical purity include isozyme testing which is easily deployed, requires basic equipment, however, its variability is insufficient for mainstream crops. The Barcode of Life is based on genetic sequencing where a minimum number of markers are picked which have enough variability to identify to the species level. Next Gen Sequencing is a great discovery tool but provides too much information for diagnostic work and it is not quantitative. Genetic fingerprinting using microsatellites requires individual seed analysis. High throughput adds a layer of complexity to any method. Bulk testing seems to be the solution using PCR target-specific amplifications based on defined unique DNA sequences/constructs. qPCR cannot actually reliably estimate. SNPs are cheap to run and can be used on bulks. Digital PCR allow quantitation and a bulk extract can be used. The challenges with methods are quantitating, i.e., count vs weight vs copy number.

Confirming Both Internal and External Reliability (A. Patin, SGS): A valid method needs to be reliable, repeatable, applicable, have appropriate reference materials, account for different matrices and biological/analytical factors. Labs want methods that are rapid and inexpensive but are also accurate, precise, sensitive, specific, have a LOD/LOQ, range of quantitation, linearity and robustness. The quality of the sample really determines how accurate the analysis will be. Sampling requires clean



equipment, use of appropriate size of probe, vertical sampling (using a partitioned probe). AOSA standard for germination requires repeatability and uniformity. It is important to look at the tolerance tables and compare the calculated error to what is acceptable. An internal quality control is needed to detect variation in a test. For vigor check, a standard seed lot for which values being tested are known is needed. Lab to lab comparison is also done. The control identifies when the test result may be altered within a tolerance range. The control is selected annually and is screened for vigor and germination. The control needs to be free of mechanical injury and disease with the germination being high but the vigor moderate. There should be enough quantity of control for the entire season.

In the herbicide bioassay, the control is required for the trait. There should be a positive and a negative control. The use of check samples assures the test is running adequately. For protein testing, there should be controls and standards on each plate. Controls should be negative plant, positive plant, negative standard, positive standard and a substrate blank. The same is true for DNA testing. Certified reference materials are used in proficiency testing, purity checking and as positive or negative controls. Certified reference material has known result and is acceptable. The certified reference material certificate should indicate how good it is, when it expires and limits of detection/quantitation. Proficiency testing should be done with sufficient sample size. Samples should be homogenized. Benchmarking should include analysis of target analytes over multiple days. Proficiency testing allows for new methods to be compared across labs. In-house controls are created by spiking of a standard solution. Certified reference materials may be acquired from IRMM (in EU) and AOCS.

PHYTO 101: Seed International Shipment (R. Pruisner, Iowa Dept. Ag & Land

Stewardship): Foreign countries establish plant quarantine regulations for entry into their country. U.S. does not require the export certificate for shipment of commodities. The export manual (XPM) contains all the standards for export. The IPPC (International Plant Pest Convention) makes all the international standards. NAPPO (North American Plant Pest Organization) makes standards for U.S., Canada, Mexico. USDA is the U.S. representative organization to NAPPO. The PExD is the phytosanitary export database which may guide exporters to obtain import permits. The PCIT is the phytosanitary issuance and tracking database. It is the online system for applying for and issuance of state and federal phytosanitary certificates. Information is stored for 3 years. Persons who are authorized by USDA to sign phytosanitary certificates are referred to as "ACOs" (authorized certification official). Form 577 is used for export of U.S.-origin commodities. Form 579 is for the export of foreign-origin commodities. A phytosanitary certificate means the shipment is apparently pest-free, i.e., cannot have more than 2% level. Phytos must be backed by a visual inspection which may require sampling, inspection, testing and treatment. In Iowa, the fee for a phyto is \$85. Iowa will only issue phytos via PCIT and will not accept cash or checks. ACO will not inspect commercial or large shipments as these must go through federal grain inspection. Exporter will pay full price for a replacement phyto certificate. The origin of the seed cannot change. A shipment cannot be certified if it is known to contain a harmful organism which is known to be quarantined by a specific country. Required treatments (by importing country) must be recorded on the phyto and the ACO must witness the treatment. Treatments



appearing on a foreign phyto certificate should not be listed on U.S. certificate. Treatments listed on foreign seed labels cannot be attested to by U.S. ACO. No commercial information is allowed on phyto such as letters of credit, trade names, tariff numbers, GMO status, tax identification number, etc. Field inspections are done by states, counties and entities accredited by National Seed Health System (NSHS). The export certificate is good for a 30-day period.

Seed movement: Stewardship (A. Khandelwal, Bayer Crop Science): Product stewardship is responsible for the development, management and use of technology and products. Stewardship span across the entire product life cycle—from discovery to launch. Stewardship protects customers, products and the environment as well as adding business value and aligns with industry standards and provide license to operate. Excellence Through Stewardship (ETS) is a global industry organization which includes academics, researchers, food/feed manufacturers, producers/growers, industry, regulators/government authorities, seed companies. All the seed multinational corporations are members. The ETS implementing practices include supporting regulatory compliance; maintaining product integrity; assisting in prevention of trade disruptions; maximizing technology benefits; sharing best practices and promoting stakeholder engagement. The ETS audit program certifies member organizations. External auditing is used to verify implementation of ETS guidance. Within Bayer, the key activities are partnered with the business. Stewardship reviews are done to assure documentation and verification and then an audit is conducted for verification. The ETS Module 5 – Commercial Plant and Seed Distribution – is available to the public and chronicles analysis product integrity concerns, determination of critical control points, how to establish and implement. Seed movement is vast and complex since seed law requirements are specific to each country. Sanitary and phytosanitary measures (SPS) sets out basic rules and allows countries to set their own standards. Standards must be based on science, however. SPS encourages the use of international standards, guidelines and recommendations. The ISPM is the International Standard for Phytosanitary Measures and addresses international movement.

U.S. – China trade: Impact on the Seed Industry (A. Struxness, ASTA): ASTA (American Seed Trade Association) collaborates with and has representations in other associations. ASTA provides industry feedback to the U.S. government for seed issues. It also coordinates and hosts workshops/training to promote harmonization of policies and works to improve market access and address seed movement operational issues. Seed movement has a complicated supply chain. Seed can cross up to seven country borders from time of breeding to farmer/growers. China is the third largest market for planting seed. The seed industry has been strengthening ties. ASTA has a memorandum of understanding to promote a beneficial relationship between U.S. and China.

The vegetable and flower seed industry has been impacted by the tariffs when 20 different vegetable and flower seeds were assessed tariffs. A tariff is an additional tax imposed on the importer. U.S. companies are paying for their seed to come back from China. There has been 15 months of negotiations, but they have slowed down over the summer months. U.S. – China coming back to negotiation table in mid-October but



only a small movement is expected in agriculture. The next round of tariffs in December will hit consumers directly as these impact clothing, toys, appliances, etc. China has been distracted with the impact of the swine flu on their pork supply and the demonstrations occurring in Hong Kong. ASTA filed a request to remove 20 seed products from the tariff list as it was felt growers were unfairly caught up in the tariff.

ASTA is engaged in other activities outside of politics. These include scientific exchange, ASTA corn seed pilot, plant breeding innovations, seed law revisions and other regional trade agreements (i.e., Japan).

Key Trends, Challenges and Issues for Food and Agriculture (J. Byrne, V-Fluence): There is a globally coordinated anti-conventional agriculture campaign which was started in 2008-09 and launched in 2012. It will now be extended to 2020 to disparage non-organic, big agriculture and technology-linked product systems. This impacts GMOs, antibiotics and pesticides as they are now being integrated with the broader anti-agriculture campaign. In 2019, 30% of global GMO content was conflated with pesticides. The themes for crop protection include health hazards, pollinators and biodiversity, environment and water, corporate control of agriculture, trade issues and MRLs and herbicide resistance. For biotechnology, the themes are registration and labeling, GMOs conflated with pesticides, trade, new breeding technologies and synthetic biology, corporate control of technology, and health hazards. The themes for markets and production systems include organic agroecology and biodiversity apocalypse. The EU is pushing out the message that it has better standards because it bans GMOs.

Conversely, the characteristics of biotechnology to emphasize are: addresses specific problems, new product development for growers and consumers. For crop protection, the characteristics to promote are reduced use, safe as organic, not harmful if used as labeled. Unfortunately, Russia is also interfering in agriculture as well as elections. The common tactic is the use of stories of villains, victims, heroes and urgency. This leads to policy making without the facts such as for honeybees and neonics.

NGOs are principally U.S./EU funded and driven. Food/agriculture NGOs global annual advocacy exceeds \$10 billion. Global formal organic sales are \$110 billion annually. Lifestyles of health and sustainability (green marketplace) is \$1 trillion annually. Organic is the gateway drug for broader LOHAS (Lifestyles of Health and Sustainability) market capture. Organic customer acquisition growth driven by absence claims and comparative fear-based marketing. LOHAS and organic sector make major investments in advocacy as part of their marketing. There is a multi-billion dollar mass tort industry targeting crop protection (i.e., glyphosate), biotechnology and food labeling. Russia is a major source of disinformation in agriculture. There is also a proliferation of GMO and pesticide testing labs in Russia. EU is manipulating world food growing via MRLs.

Agroecology is a politicized approach to food production. The main idea is to grow food without any inputs, hybrids, etc. and to solely rely on organic practices. It is being advocated as the solution to the climate crisis. FAO was supporting agroecology but there is now new leadership so it may move away from this stance. Advocates of agroecology are trying to de-stabilize agriculture industry.



There are many challenges including IARC opinions, expansion of U.S. toxic tort litigation model moving into EU and growing allegations of greenwashing claims around the risks of green chemistry solutions involving biological alternatives coming from corporate-driven gene editing.

Strategic Partnership and Collaboration (A. Sims, Iowa AgriTech Accelerator): The Iowa AgriTech Accelerator brings start-up companies to Des Moines to train them how to accelerate their businesses. The pillars of the accelerator are outreach to engage startup ecosystem, increase collaboration, identify ag technology trends; mentorship to work and collaborate with mentors and investors; and recruitment to identify strong start-ups that have innovations for agriculture. The accelerator is backed by companies such as Corteva, John Deere, banks, insurance companies, etc. Des Moines is great for start-ups since it has a low cost of living, resources with bigger companies, home of the World Food Prize and the Normal Borlaug Foundation. The accelerator is also connected with global accelerators for start-ups. The accelerator utilizes social media and other news outlets. The executive director is Nadilia Gomez and the program manager is Allison Sims. Start-ups chosen for the accelerator training receive \$40,000 seed funding, access to mentors, continuing education, and provided housing/food while in Des Moines for training. Start-ups may have 4-5 mentors for their 90 day training session and beyond. Currently, there are 120+ mentors who participate in the program. Some of the start-ups which have benefited from the accelerator program include Dronesar (drone technology to see below plant canopy), Raks (identify water non-efficiency in crops), Farmatronix (private greenhouse workforce education), Otrafy (inefficiencies identified in collecting information in the supply chain).

Overview of Commercially Available Seed Applied Technologies (K. O'Bryan, Corteva): Seed applied technologies (seed treatments) include dyes, biologicals, fungicides, polymers/binders, inoculants, insecticides. The goal in using seed applied technologies is to deliver a valued product with technologies. Seed treatments may be applied professionally at seed treatment facility or on farm. For either method, there must be accuracy, convenience, safe, and easy to use. For seed products, seed treatment is just one of the factors that go into an integrated seed product. As with any technology, seed treatments are evaluated as to whether they can be used without a great regulatory burden to the company. Seed treatments have evolved;

Broad spectrum fungicides → specific fungicides → insecticides → nematocides → microbials

More and more microbial treatments are coming to the market. SDHI compounds are both fungicidal and nematocidal. One of these is ILeVo which was developed by Bayer and Pioneer Hi-Bred. Oxathiapiprolin is a fungicide with a novel MOA and has no cross resistance to other fungicides. It is effective in controlling Phytophthora and downy mildew. Ethaboxam control Pythium in corn and soybean as it stays in the seed zone. Anthanilic diamides are insecticides active against lepidopteran. The diamides



transports from seed to V5 corn to help with insect control. Chlorantraniliprole, a diamide, works with Bt in soybean.

Bioassay Herbicide Trait Purity Testing (B. Johnson, Eurofins BioDiagnostics): A bioassay is done to assess the biological activity of a substance by testing its effect on an organism and comparing the result to an agreed upon standard. Trait providers require trait purity testing to meet standards as indicated in licensing agreements. One bioassay is the towel method. Paper toweling is soaked in a working solution containing the herbicide. The seeds are placed on the towels using a planting apparatus. The towel is then rolled up and placed in an environment chamber to allow growth of seedlings. A control is also done using the working solution without herbicide. Following the growth period, the control seedlings are assessed first to determine if the experiment worked. Then the sample seedlings are assessed by looking at each individual seedling. Each seedling is classified as normal, abnormal or dead. Only the normal seedlings are assessed for herbicide tolerance. AOSA rules are followed. Non-tolerant seedlings appear abnormal due to the herbicide presence, i.e., an adverse condition. Trait purity is determined as follows:

$$\% \text{ trait purity} = \frac{\text{number of normal tolerant seedlings}}{(\text{number of normal tolerant seedlings} + \text{number of normal non-tolerant seedlings})}$$

Ideally, the GM event is present in the seedling and the gene produces protein in a sufficient amount within seedling to convey tolerance. Non-tolerant seedlings may not have the event present or the seedling has the event but the gene is not expressing or the seedling has the gene but protein expression is too low or there is too much seedling damage. The bioassay is only testing the reaction of the seedling to herbicide application. Results may be confirmed with lateral flow immunoassay, ELISA or a DNA method. To conduct the bioassay, analysts must have a good understanding of events, genes, protein, stacked traits in order to perform correct confirmation.

Digital Farming (J. Janni, Corteva): R&D data analytics drives ability, productivity, innovation in discovery and product development. High crop quality genomes enable product design. Molecular characterization selects the best product and high resolution phenotyping prioritizes varieties with desired characteristics. Drones are now being used to measure plant height and other characteristics in the field. This yields 50 million data points which are fed into a scenario analysis via a crop growth model. Germplasm information is used to predict characteristics in growth model, i.e, predictive breeding, to identify the product with the highest potential on the farmer's fields. Digital phenotyping generates high quality product characterization. Predictive tools provide actionable advice to farmers: crop modeling → canopy growth → ear development. Disease risk is also added in. Data is gathered by the farmer using apps on a cell phone to scout fields. This allows the finding and fixing of anomalies earlier in the fields which saves time and resources. The farmer can efficiently prioritize during the season using the growth model. Ear photometry is used to make yield estimates.



Nitrogen monitoring, true color imagery, crop health, drone measured stand count, etc. are also fed into the model.

Intractable Protein Discussion (J. Zhang, Corteva): Intractable proteins are proteins with properties that make it extremely difficult or impossible with current methods to a) express in heterologous systems for production; b) isolate or purify from plants; c) quantitate due to low plant levels; d) demonstrate biological activity; and e) prove equivalency with plant proteins. Examples of intractable proteins are transmembrane proteins, transcription factors or signaling proteins. Membrane proteins lose their function if not in the membrane but for regulatory authorities a safety assessment is still needed. If there is no technical solution to produce enough active protein for a safety assessment, can a compromise be reached with authorities. Potential hazard identification for proteins is determined by history of safe use, bioinformatics, mode of action, expression level and exposure, digestibility and heat stability. Potential hazard characterization is usually done via rodent feeding studies to determine by limit dose the margin of exposure. For intractable proteins, *in vitro* models may be needed such as using human intestinal epithelial cell line monolayers. Since EPA has decided to phase out animal studies by 2025, *in vitro* test systems will be needed. Some intractable proteins have been expressed in liposomes which would allow them to be purified in the native state. Tagging of proteins for purification might also be an option but it can affect solubility of the protein.

BREAKOUT SESSIONS

Session 1: Proficiency Test and Reference Materials (B. Johnson): Some seeds are hard to access, especially for varietal certified reference materials (CRMs). Canada does provide some breeding samples. It is also hard to obtain material for pathogen testing since it is often too old. AOCS is a provider of GM CRMs. Particle size is important in CRMs. If it is not acceptable, the cryogenic method should be used. DNA or powders as CRMs do not allow checking the real world samples. Old traits have to come from devitalized seed. AOCS would like to be able to sell devitalized seed. Also need availability of confirmed negative seed. GM salmon have no testing method or CRM. The suggestion was made to form a working group for reference seed/materials. Mariana Campanholi Daher (BASF) volunteered to chair this working group.

Session 2: Political Challenges for Crop Protection and Ag Biotech (J. Byrne): Need to be able to discern information from disinformation. Check stories for hero, villain and victim scenarios. The profit motive needs to be taken away from the NGO groups. FDA laws should be enforced and industry needs to push for this. Industry associations should be supported more as well as looking at other associations such as the U.S. Chamber of Commerce which is broader than agriculture. Industry needs to engage more in “fuzzy” control of associations, i.e., give the support but not supervise closely. Industry should also support other existing networks of advocates.

AEIC Fall Meeting Attendees:





Composition and Protein Working Groups Minutes (Oct 8):

AEIC Composition and Protein Working Group Meeting Minutes

1:00 pm – 6:00 pm, October 8, 2019

Des Moines, Iowa

Participants

Agdia: Chris Culkin

AOCS: Scott Bloomer, Denise Williams

BASF: Matt Cheever, Nancy Gillikin, Penny Hunst, *David Roberts

Bayer: Mohamad Bedair, *Andy Deffenbaugh, Tao Geng, Zi Lucy Liu, Rong Wang, *Yanfei Wang, *Yongcheng Wang

Corteva: Sarah Brustkern, Kristi Harkins, Norma Houston, Kristen Kouba, Carl Maxwell

EnviroLogix: Art Trombley

EPL: Brian Claque, Matt Patricio, Dilini Ralalage, Crystal Watkins

Eurofins BDI: Brenda Johnson

Eurofins FI: Chris Ament, David Levin, Ann Scaife, Jeff Shippar

Eurofins ML: Luke Muschinske

Eurofins NAC: Kai Liu, Keith Persons

Romer: Donna Houchins

Syngenta: *Mark Bednarcik, Phil Brune, *Simone Cummings, *Valerie Messmer

*Called in

Welcome and introductions

Review of anti-trust statement

Composition Working Group (CWG)

Discussion led by Phil Brune (Syngenta)

Total Protein Method: Kjeldahl vs Dumas

- Background on principles of Kjeldahl method
 - Organic nitrogen converted by acids/chemicals, low throughput multi-step method with more chance for error, more toxic method, more established method
- Background on principles of Dumas method
 - All nitrogen converted by combustion so safer and quicker, higher throughput, usually higher results because all nitrogen is recovered, less prone to human error
 - It is difficult to compare the results because the literature is not consistent; sometimes it shows good correlation and others not
- There was discussion about what the CWG could do
 - One option discussed was developing a conversion factor that could include lab studies across AEIC participating labs and correlate the results

- Scott Bloomer (AOCS) indicated that AOCS could help coordinate any lab trials
- Could do white paper based on current literature and make recommendations to try and gain regulatory acceptance
 - White paper from FOSS published in 2017 discussed using different methods
 - Instead of trying to harmonize on one method, a whitepaper could be written in a way that allows either
- Do we always need to convert or could we provide both values for regulators?
- If study of interest is comparative in nature (e.g. typical composition study for GM approvals), then either method should be fine in the context of the study
- Codex Alimentarius meetings often include this kind of discussion
 - Could possibly get acceptance at Codex
 - "Smaller" countries use Codex for guidance
- Action: A decision was made to explore drafting a whitepaper
 - Volunteers: Carl Maxwell (Corteva), Nancy Gillikin (BASF), Keith Persons (Eurofins)
 - Most available data is Kjeldahl but some Dumas
 - AOCS may be able to provide some data on pulses
 - Should focus on a few main crops and matrices where there is already data in the ILSI database
 - Keith Persons has already compiled canola data with both methods from ILSI database
- Kjeldahl can't go away because it is required for the grain trade
- Feed control official group wants an amino acid method, which gives actual protein nitrogen levels but is difficult to reproduce

Harmonized Crude Fat Method for Canola

- Three methods for canola in ILSI database - two AOAC methods and one AOCS
 - Two methods capture free fats (extraction without hydrolysis), one captures total fats (extraction after acid hydrolysis)
 - Comparison and discussion -
 - Acid hydrolysis will facilitate the extraction of fatty acids from glycerides, glycolipids, phospholipid and sterol esters. It is mainly applicable for forage samples, backed product and pet foods
 - Action: Search literature studying crude fat results using both methods

Vitamin multiplexing method (A, E, D, K)

- There is a draft method
 - Action: Matt Patricio (EPL) will provide a contact person and circulate the draft
 - Keith Persons (Eurofins) may also have a copy of the most recent version.

Protein Working Group (PWG)



Discussion led by Kristen Kouba (Corteva)

Review of PWG mission statement

Updating the Protein-Related AEIC Slides

- Valerie Messmer (Syngenta) and Beth Matthews (formerly Syngenta) have converted the slides from solid graphic to text and graphics
- Action: Valerie agreed to continue leading an effort to update the slide content and graphics
- Volunteers: David Levine (Eurofins), Chris Ament (Eurofins)
- Action: All to discuss with colleagues and see if any others interested in helping

Extraction Efficiency Assessment Method

- Matt Cheever (BASF) introduced the topic and asked if a new workstream should be started
- From a technical perspective what is the best way to assess extraction efficiency?
 - A harmonized technical method may be easier to complete than harmonization in the regulatory/registration space
 - AEIC's responsibility is to give a method option that is harmonized across companies. This could be comparative or give guidelines.
 - A western method may not be an option, what to do then?
- Update from the CLI working group – there has been no agreement on a correction factor, they are talking to EFSA. AEIC (technical side) could recommend a harmonized method and CLI (policy side) or EuropaBio could take it to EFSA. Or individual trait providers could take the method to EFSA.
- A new workstream will be started to publish a method paper for assessing extraction efficiency for trait protein quantitation methods
- Volunteers: Valerie Messmer (Syngenta), Simone Cummings (Syngenta), TBD (Matt Cheever - BASF), TBD (Kristen Kouba - Corteva), TBD (Andy Deffenbaugh - Bayer)
- Action: All to discuss with colleagues to get and additional volunteers to participate

Intractable Proteins

- Kristen introduced the topic and led discussion based on the Bushey, et al. (2014) paper
- This general topic had been suggested for the PWG but no clear actionable topics were raised
- A decision was made to wait until after John Zhang's (Corteva) talk in the main AEIC session to see if specific topics or activities for a workstream were raised
 - John Zhang's talk – there was interest in following up on the Bushey, et al paper, specifically where to we go next?
- Volunteers: John Zhang (Corteva), Rong Wang (Bayer)
- Action: All to consider what tangible goals or activities this worksteam will cover and to get additional volunteers to participate

EFSA 2019 Statement on Human Dietary Exposure

- Matt introduced the topic and asked if there were topics that AEIC should pursue
 - Assessing newly expressed proteins (NEP) in foods has many considerations such as the type of foods (oils, isolates, food substances i.e. pollen) and how they are processed
 - The number of replicates for expression is indicated as three replicates at five sites, however, this is not stipulated in any previous EFSA requirement or guideline documents
- Action: All discuss at companies and Kristen/Matt add to next PWG meeting agenda with an update on developments

Allergen Analysis Workstream Update

- Norma Houston (Corteva) and Tao Geng (Bayer) led the discussion
- The workstream discussed starting a database for endogenous allergen data but determined that it is too early to do this
 - Incorporation into ILSI database was discussed but there are too many variables, including different methods
 - If it would be done in the future it would be a second database with ILSI
 - One consideration is to evaluate and publish all current data together
- The workstream is working on a publication to evaluate technical challenges and aspects of the requirement to evaluate peptides from *in vitro* digestion studies with LC/MS
 - Paper to consider this is technically feasible, what it could tell us and what not
 - Current draft title – “Value and Limitations of Peptidomics to Evaluate *In Vitro* Digestion as part of the Allergenicity Risk Assessment of Genetically Modified Crops”
 - Technology focus 1) current state of peptidomics, 2) Applicability of peptidomics
 - There was a suggestion to consider including processed products in the scope of the article and not only raw agricultural commodities
 - HESI-PATB are working on testing matrix effects on digestibility, possibly using chocolate and/or mousse

Protein Quantitation by Mass Spectrometry Workstream Update

- Mark Bednarcik (Syngenta) led the discussion
- The workstream is drafting a paper to review and summarize evidence supporting ELISA and LC/MS/MS valid analysis techniques for analyzing trait proteins in biotech crops
 - Completed a critical review of literature related to ELISA and MS
 - Soy allergens, transgenic proteins in plants and other biomarkers, etc.
 - Parameters considered include method sensitivity, matrix, validation criteria, cost, equipment
 - Identified journals to potentially target for publication
 - Goal to have a draft by early November with a preliminary goal to submit for publication by July 2020
- Yanfei Wang (Bayer) agreed to be a co-chair for the workstream with Mark

Multiplex Method Validation Workstream Update

- Kristen Kouba (Corteva) led the discussion
- Goal of the team is to produce scientific literature that outlines standardized validation parameters for single and multi-plex protein analysis methods, including Luminex, MSD and Mass Spectrometry
- The team has:
 - Reviewed and summarized published guidance
 - Held in depth discussions on the validation parameters
 - Evaluated what different companies are doing
 - Established standard guidance on Accuracy and Precision so far
 - Compared criteria for single versus multiplex methods
- Will survey stakeholders for input on parameter criteria in Spring 2020
- A question was raised about whether the team has considered doing a ring trial like for the Lectin method, however, this is not likely in scope for this activity because it is not aimed at developing a specific method

Breakout Session: Allergen analysis Workstream

- Norma Houston (Corteva) and Tao Geng (Bayer) led the breakout session
- Soy allergen method/database: agreed to work on method harmonization and may consider a database later
- Action items and responsible persons
 - A survey of LC-MS/MS method details – Jeff Shippar (Eurofins)
 - FTO to address two patents of LC-MS/MS for allergens – Norma
- The digestion paper: a good shape; agreed to narrow down the outline, so it could be published as a short communication or letter to the editor
- Action items and responsible persons
 - A new outline by the week of Oct. 21th – Matt/Norma/Rong/Scott McClain (Syngenta)
 - A Journal list – Tao
 - Reshape quantification section – Norma/Yanfei
 - A couple of sentences of computation in data interpretation section – Kristi Harkins (Corteva)
 - Reshape the introduction section after the new outline – all
 - Next check-out in the week of Nov. 4th – Tao