Protein Working Group (PWG) Update

Since Spring PWG meeting

- Finalized PWG mission statement
- Solidified three topic workstream teams
 - Validation of multiplexed protein analytical methods
 - Mass spec as a protein expression analysis method
 - Endogenous allergen analysis (combined with composition working group)
- October 8 PWG meeting
 - Updates from workstream teams
 - New topic Discussion of EFSA explanatory note on protein expression level analysis and method validation

PWG Workstreams and Teams

Multiplexing method validation

- Kristen Kouba (Corteva)
- Simone Cummings (Syngenta)
- Ann Onisk (Romer)
- Jeff Shippar (Eurofins)
- Andy Deffenbaugh (Bayer)
- Yongcheng Wang (Bayer)
- Yanfei Wang (Bayer)
- Lucy Liu (Bayer)
- Matt Cheever (BASF)

Protein quantification by mass spec

- Mark Bednarcik (Syngenta)
- David Levin (Eurofins)
- Kristen Kouba (Corteva)
- Simone Cummings (Syngenta)
- Valerie Stratico (Syngenta)
- Jeff Shippar (Eurofins)
- Yanfei Wang (Bayer)
- Lucy Liu (Bayer)
- Matt Cheever (BASF)

Endogenous allergen analysis

- · Tao Geng (Bayer)
- Norma Houston (Corteva)
- Jeff Shippar (Eurofins)
- Lucy Liu (Bayer)
- Matt Cheever (BASF)

Team leaders are underlined



Multiplexing Method Validation Update

- Established goals around working towards publishing a set of guidelines
- Discussed multiplex techniques to consider
- Gathering participants (simple survey)
- Will develop survey for collecting current multiplex validation parameters and practices, along with literature review
- Refine and publish guidelines > implement standard



Protein Quantification by Mass Spec Update

- Reviewed topic
- Discussion on international acceptance of mass spec EFSA included in Aug 2018 explanatory note, Asia-Pacific still reticent
- Caution that AEIC should not advocate for a single technique
- Could develop a review or position paper supporting validity of mass spec in context of all suitable protein quantification techniques, educational workshops



Edogenous Allergen Update

- Review of EFSA 2017 guidance on allergenicity and EFSA sponsored study to evaluate additional digestibility endpoints (due Sep 2019)
- Push to support a "position" publication before Sep 2019
- Discussion about a database of endogenous allergen result, but need a standard method – will evaluate this topic further
- EU proposal of mass spec vs Asia-Pacific guidelines for Ig banding can workstream follow lectin model?
- Potential change in the workstream name to reflect the broader set of topics encompassed by the guidance (protein characterization and allergenicity assessment endpoints)

August 2018 EFSA Explanatory Note

- Overview of EFSA 2018 explanatory note driving for harmonization of submitted data
- Sometimes strongly suggests specific techniques where others may also be valid or overly proscriptive of information to be provided
- First principles Risk assessment and then how to get there
- What technical questions could AEIC could address, relative to the explanatory note, to support equally valid alternative techniques or to provide justification for not submitting "extraneous" information?
- How to work with EuropaBio to respond to the note? Does EFSA have evidence that what they are asking has an effect on risk assessment?

PWG Mission Statement

The mission of the Protein Working Group is to leverage the collaborative expertise across the agricultural biotechnology and analytical industries to:

- Support the development and adoption of high quality and scientifically sound protein analytical methods, particularly for new techniques, applications or modernization of existing methods.
- Seek standardization of protein analytical methods, where beneficial, for increased efficiency and international acceptance.
- Produce and publish scientific literature and standard documentation to support protein analytical methodologies.

