ILSI

International Food Biotechnology Committee

Workshop on Safety of GM Crops: Compositional Analysis

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ABSTRACT: Opening Presentation and Discussion

The Genetics and Consequences of Crop Domestication

Sherry Flint-Garcia, USDA ARS, USA

Genetic analysis and improvement of crops relies on variation in genes controlling traits of interest. Genetic variation has arisen naturally over millions of years and continues to arise in all plant species, and a proportion of this genetic variation contributes to phenotypic variation within the species. Phenotypic variation has been manipulated by humans during the domestication of crop plants, which occurred primarily between 3,000 and 10,000 years ago in the various centers of origin around the world. The process of domestication has had profound consequences on crops, where the domesticate has moderately reduced genetic diversity across most genes in the genome relative to the wild ancestor, and severely reduced levels of diversity for key genes targeted by domestication. The question that remains is whether reduction in genetic diversity across the genome or for specific key genes has impacted crop production today.

A case study in maize (Zea mays) demonstrates the application of understanding the relationships between genetic diversity and phenotypic diversity in the wild ancestor and the domesticate. As an outcrossing species, maize has tremendous genetic variation compared to most other crop species. The complementary combination of genome-wide association mapping (GWAS) approaches, large HapMap datasets, and germplasm resources such as association mapping panels, the Nested Association Mapping (NAM) population, and teosinte-maize introgression lines are leading to important discoveries of the relationship between genetic diversity and phenotypic variation. The evaluation of NAM and maize-teosinte introgression lines allow us to understand the impact of domestication on trait variation and reintroduce valuable genetic variation into modern maize.

SESSION 1 ABSTRACTS: Conventional Development of New Crop Varieties

Session Chair: Wayne Parrott, University of Georgia, USA

Presentation 1.1: Traditional and Modern Plant Breeding Methods with Discussion of Cases on Rice

Flavio Breseghello, Embrapa, Brazil

Plant breeding can be broadly defined as all the alterations caused in plants as a result of their use by humans, ranging from unintentional changes resulting from the advent of agriculture to the application of molecular tools for precision breeding. The vast diversity of breeding methods can be simplified into three categories: i) Plant breeding based on observed variation: selection of plants based on natural variants appearing in nature or within traditional varieties; ii) Plant breeding based on controlled mating: selection of plants presenting recombination of desirable genes from different parents; iii) Plant breeding based on monitored recombination: selection of specific genes or marker profiles, using molecular tools for tracking within-genome variation. The continuous application of traditional breeding methods in a given species could lead to the narrowing of the gene pool from which cultivars are drawn. This could, on the one hand, make the produce of those plants safer for food use, but on the other hand, render crops vulnerable to biotic and abiotic stresses and hampering future progress. Modern molecular methods could help introducing exotic variation into elite gene pools without the undesirable consequences normally observed through traditional methods. Cases of application of different breeding methods in rice are discussed for illustrating the potential and limitations of each approach.

Presentation 1.2: Genomic Variation in Plants Recovered Through Plant Cell and Tissue Culture

John Finer, The Ohio State University, USA

Cell and tissue culture techniques are routinely utilized in crop propagation, germplasm preservation, crop breeding and genetic engineering applications. Although tissue culture is often used to clonally reproduce plants of a given genotype, phenotypic and genetic variation can occur among regenerated plants in a process termed somaclonal variation. Genomic changes observed in cultured cells and regenerated plants include point mutations, chromosome additions/losses, translocations, segmental insertions/deletions, polyploidization and/or epigenetic changes. These changes can lead to phenotypic variation of both qualitative and quantitative traits among cells and plant regenerants. The type of genetic and phenotypic variation that is recovered from plant cell and tissue culture is quite similar to that observed in nature and that derived through traditional, mutation breeding techniques. Variation in composition of tissue culture-derived, regenerated plants is essentially equivalent to that encountered through standard breeding manipulations. Plant breeders have utilized this additional source of genomic variation to select for beneficial traits and to develop improved crop varieties both within the U.S. and worldwide.

Presentation 1.3: Mineral Biofortification Strategies for Major Staples: The Example of Common Bean

Matthew Blair, Universidad Nacional de Colombia, Colombia and Cornell University, USA

This presentation will look at the goal of seed mineral enhancement in staple crops. The activity of seed mineral improvement falls under a more general program for crop biofortification, which is the breeding of higher nutritional quality into plant parts that are consumed as major parts of the diet in areas with nutrient deficiencies. For both cereals and legumes, the goal of enhanced seed mineral accumulation is an important way to address iron (Fe) and zinc (Zn) deficiencies in human populations. The improvement of Fe-Zn concentration in staples can be based on both transgenic and plant breeding approaches. Transgenesis requires a detailed understanding of genes involved in mineral uptake and partitioning while plant breeding

relies on natural variability for Fe-Zn concentration traits in crops. Domestication and modern breeding have each favored seed size and palatability traits while invisible traits such as mineral content have generally not been selected for until now. Selection against anti-nutrients is probably widespread but is limited by the role that phytates and tannins play in seed viability. In general the inheritance of both seed mineral and anti-nutrient traits has been oligogenic although underlain by important genes for mineral acquisition and transport in the case of Fe-Zn or key genes from biochemical pathways in the case of phytates and tannins. Genotypes with high seed mineral traits exist in both the cultivated genepools and wild relatives of crop plants. Multiple sources require strategies of recurrent selection and multiple backcrossing to accomplish pyramiding of genes for bioavailability and high mineral content. Wild relatives meanwhile can be used in breeding programs especially using the advanced backcrossing strategy. The molecular tagging of mineral and anti-nutrient traits is important for future breeding programs as is an understanding of how environmental variability affects mineral accumulation. The promise of association genetic approaches and marker assisted breeding for high seed mineral accumulation will also be discussed.

Presentation 1.4: Natural Variability in Wheat Grain Composition

Peter Shewry, Rothamsted Research, UK

Cultivated hexaploid wheat is immensely diverse, with over 25,000 varieties which are adapted to different environments. This wide diversity results from a high level of genome plasticity, making wheat an excellent system to explore the range of natural genetic variation within a major crop species. The mature wheat grain comprises three groups of major components, starch, proteins and cell wall polysaccharides, which together account for about 90% of the dry weight, and minor components which include lipids, terpenoids, phenolics, minerals and vitamins. However, these components differ in their distribution within the grain. In particular, the starchy endosperm, which is recovered as white flour on milling, contains about 80% starch and 10% protein with low contents of cell wall components, minerals and phytochemicals while the bran, which comprises the aleurone layer, the outer layers of the grain and the embryo, lacks starch and is enriched in minor components with nutritional and health benefits.

Starch generally accounts for about 80% of the dry weight of the starchy endosperm and comprises a mixture of two polymers, amylose and amylopectin, in a ratio of about 1:3. Although natural mutations have been detected in genes which lead to higher proportions of amylopectin (waxy starches) or amylose (resistant starches), these mutations have little impact on starch composition unless they are present on all three genomes. The protein content of wheat varies more widely than the starch content, with selection during plant breeding resulting in differences in protein content of about 2% dry wt when modern breadmaking and feed wheats are grown under the same conditions. However, a much wider range of variation in protein content results from the effects of nutrition, and particularly the level of applied nitrogen fertiliser.

The most detailed information on variation in wheat grain composition has come from the EU FP6 HEALTHGRAIN programme, which determined the contents of bioactive components (phytochemicals, B vitamins and dietary fibre components) in up to 150 wheat lines and determined their heritabilities in multisite trials. This showed ranges in content from about 1.4-fold (sterols in whole grain) to 3.6-fold (total phenolic acids in whole grain), and heritabilities ranging from over 70% (arabinoxylan in flour, tocols in whole grain) to less than 30% (total phenolic acids and folates in whole grain). Wide diversity in the profiles of metabolites (including choline, betaine, sugars and amino acids) has also been demonstrated by NMR and ESI-MS analyses of extracts made in methanol:water.

These studies provide a basis for the comparison of transgenic and conventionally bred lines and this will be illustrated by reference to field trials of transgenic wheat carried out from 1998–2001.

SESSION 2 ABSTRACTS: Development of Crops Using Modern Biotechnology

Session Chair: William P. Ridley, Consultant (Monsanto Company, retired), USA

Presentation 2.1: A Look at Product Development with Genetically Modified Crops: Examples from Maize

Rita Mumm, University of Illinois, USA

Crop genetic improvement involves the cycle of creating genetic diversity and then exploiting that diversity to derive an improved cultivar with outstanding performance for specific traits of interest. Genetic modification through transformation essentially expands the genepool to facilitate access to genes otherwise not available through crossing. Transgenic events are defined by the DNA sequence that has been incorporated into the target genome and the precise point(s) of insertion. In the development of a new transgenic trait, typically many events are generated and evaluated with the aim of identifying one exhibiting consistent trait expression at or above specified thresholds, stable inheritance, and the absence of any negative effects. Once commercial candidates have been identified, these events are introgressed into elite lines, often through the use of molecular markers which can accelerate the breeding process. Converted elite lines are yield-tested to ensure performance equivalency with their unconverted counterparts. Finally, before commercial sale of seed, quality control monitoring is conducted to ensure event identity and purity and the absence of any unintended events. This monitoring complements other quality control measures to ensure seed viability and line/hybrid purity and uniformity in seed treatments, all in an effort to safeguard customer satisfaction.

Presentation 2.2: Bringing a Transgenic Crop to Market – Where Compositional Analysis Fits

Laura Privalle, BASF Plant Science, USA

In the process of developing a biotech product, thousands of genes and transformation events are evaluated to select the event that will be commercialized. The majority of events are not promoted. The ideal event is identified based upon multiple characteristics including but not limited to: performance (meeting product specifications), the molecular characteristics of the insert, and agronomic performance. Specifically considered: does the event perform and stably demonstrate the efficacy desired? Is extraneous DNA present; are new proteins unintentionally produced? Has the insertion of the new genetic material disrupted plant performance? Once selected, the commercial event is subjected to a rigorous safety evaluation that takes a multipronged approach. The assessment considers the safety of the gene, the safety of the protein produced by the gene, plant performance, impact of the biotech crop on the environment, agronomic performance, and equivalence of the crop/food to conventional crops/food. This last point is addressed by compositional analysis which is comprised of a comparison of the nutrient and anti-nutrient composition of the consumed portions of the crop between the event, its parental line (variety) and various conventional lines (varieties). Different regulatory agencies in the various geographies have different requirements for the compositional analysis studies. Among the parameters that vary are the number of years (seasons) that should be evaluated, the number of locations, the appropriate comparator(s), the reliance on the ILSI Crop Composition Database or other published values, the analytes to be evaluated, and the statistical analysis. Specific examples of compositional analysis results will be presented. Biotech products are the most highly characterized food substances consumed.

Presentation 2.3: Availability and Utility of Crop Composition Data

Kazumi Kitta, National Agriculture and Food Research Organization, Japan

The cultivation of genetically modified (GM) crops has expanded in many parts of the world, and large amounts of GM crops and their products have been consumed worldwide. In Japan, as of July, 2012, 189 GM crops have already been authorized and considered marketable. The safety assessment of GM crops has been mandatory in many countries. While the most important factor taken into account in the safety

assessment is the primary effect derived from newly introduced traits, possible unintended effects attributed to the insertion of defined DNA sequences have to be carefully examined in parallel. However, food is complex mixtures of compounds characterized by wide variation in composition and nutritional values. The food constituents are significantly affected by cultivars and environmental factors and thus it is very difficult to detect any potential adverse effects. A comparative approach focusing on the determination of differences between the GM food and its conventional counterpart will elicit potential safety issues and is considered the most appropriate strategy for the safety assessment of GM foods. This concept has been generated through enthusiastic discussion among the Organization for Economic Cooperation and Development (OECD), World Health Organization (WHO), Food and Agriculture Organization of the United Nations (FAO) and Codex Alimentarius Commission (Codex). This is represented in Codex's guidelines, i.e., "Principles for the risk analysis of foods derived from modern biotechnology" and "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants", and their derivative guidelines or standards which have been actually used for the safety assessment in each country.

For the efficient safety assessment of GM crops, an easily accessible wide compilation of crop composition data are required for use by researchers and regulatory agencies. To achieve this, we developed an internet-accessible food composition database comprising macro-, micro-, and anti-nutrients, endogenous toxicants, and physiologically active substances of staple crops, such as rice and soybeans. The International Life Sciences Institute (ILSI) has also been addressing the same matter and has provided a crop composition database. In this talk, the role of composition data in safety assessment processes will also be discussed.

SESSION 3 ABSTRACTS: Compositional Analysis Methods

Session Chair: Joanne Holden, USDA ARS (retired), USA

Presentation 3.1: OECD Composition Consensus Documents

Kathleen Jones, US FDA, USA

The Organisation for Economic Co-operation and Development Task Force for the Safety of Novel Foods and Feeds (Task Force) seeks to promote international harmonization in the safety assessment of novel foods and feeds, especially the products of modern biotechnology, in part through the publication of science-based consensus documents for use in safety assessment. The main and perhaps most well-known products of the Task Force are consensus documents on compositional considerations for new varieties of food and feed crops. Each composition consensus document is developed to serve as a compendium of composition and other food and feed safety data and information for the particular crop. These documents are intended to be used by academic scientists, breeders, developers of novel plant varieties including those produced using modern biotechnology, as well as regulators and risk assessors. The Task Force's process for developing a composition consensus document will be discussed, using a recently-published consensus document as an example. The Task Force's composition consensus documents are available at http://www.oecd.org/document/2/0,3746,en_2649_34385_46814658_1_1_1_1,00.html.

Presentation 3.2: How Composition Methods are Developed and Validated

Hilary Rogers, Eurofins Scientific, USA

Method validation is a critical prerequisite to performing analytical methods in the laboratory. A given analytical method is validated for a specific matrix, or matrices. If the matrix to be tested is not included in the original scope of method validation, a validation must be performed to determine if the method is applicable to that particular matrix. A number of organizations, such as AOAC and ISO, publish peer-reviewed methods for cross-industry matrices, while others, such as AOCS and AACC, are focused on specific industry segments (fats/oils and cereal grains). Where no validated method is available for the analyte of interest, method development and validation must first be performed to ensure that correct identification and quantification of the analyte is being observed and measured. Development of a new method requires an understanding of the chemistry and properties of the analyte to be tested, as well as the various types of instrumentation currently available. Method development and improvement is a continuous process, as technology advances and new instrumentation and techniques become available. This paper addresses the various approaches to method development and validation as it applies to compositional testing of foods and commodities, the factors that determine method selection and how extensive the validation need be.

Presentation 3.3: Evaluation of Endogenous Allergens for the Safety Evaluation of Genetically Engineered Food Crops: A Review of Methods and Relevance

Richard Goodman, University of Nebraska-Lincoln, USA

In 1996, an ILSI-IFBiC scientific panel recommended assessing potential changes of endogenous allergen expression as part of safety assessment of foods derived from genetically engineered (GE) crop plants. This suggestion was restricted to commonly allergenic crops and only if there were reasons to suspect the GE construct might alter expression of allergens. Specific serum IgE tests by immunoblot or ELISA were recommended. However, current guidelines call for testing without qualification, without data demonstrating increased risk associated with altered expression, and without guidance regarding the magnitude of change that would be unacceptable. Until recently, evaluation of endogenous allergens has only been performed for commonly allergenic soybean and wheat. Serum IgE binding tests were performed using one-dimensional immunoblots or ELISA inhibition, either with individual serum samples or pools. Recently, regulators in Europe and Asia have asked for tests using individual donors only, by one and two-dimensional blots and direct ELISA. Some scientists have used proteomic tests rather than immunoassays. A few regulators have

asked for test data for relatively non-allergenic GE maize (corn) and rice. By 2012, the allergens of many foods are well characterized, but reactions are not ascribable to individual proteins and the natural variation in foods is relatively unknown, but evidence suggests highly variable. Both immunoassays and proteomics have significant limitations in measuring allergenicity. Furthermore, those with specific allergies should avoid consuming their allergens without regard to dose. Examples from maize, soybeans and wheat are reviewed along with consideration of possible relevance.

SESSION 4 ABSTRACTS: Interpretation of Composition Data

Session Chair: Bill Price, US FDA (retired), USA

Presentation 4.1: Food Safety, Importance of Composition

Wilna Jansen van Rijssen, personal capacity (retired from the South African Department of Health), South Africa

Food safety is not inherent but is based on a history of safe human and animal use. Because it is difficult to compare safety of whole food, compositional analysis is important. This is a starting point for safety assessment. The "search light" in the assessment focuses on those food nutrients, anti-nutrients and toxicants that are biologically important for a specific crop plant product. Differences are further evaluated, including intended and unintended differences, as well as food safety issues such as the source of the organism and gene(s) and the newly introduced proteins. Retention of nutritional value and human dietary exposure are also important issues. A comparison assessment of the composition of edible parts of the plants is a sensitive method that complements molecular characterization and agronomic/phenotypic analysis. Samples are generated in controlled field trials, analyzed using validated methods and assessed using a variety of uni- and multi-variant statistical approaches. A summary of the past fifteen years of biotech crop composition analysis has shown that variability in composition is primarily due to growing region rather than the presence of the biotech trait. The results contributed to a much better understanding of the importance of environmental effects on crop plants in general. With our current knowledge of plasticity of the genome, environmental effects and the usefulness of plant breeding practices, we have an improved handle on judging unintended effects. Intended changes have brought application of toxicological principles, consideration of biological significance and processing of the plant products to the forefront. The future global needs for expanded food and feed, therapies for treatment of worldwide health problems such as Vitamin A deficiency, and the emergence of new technologies such as RNAi form the basis for a need to reevaluate the compositional analyses currently required for biotech crop safety assessment, to make sure they are both necessary and sufficient.

Presentation 4.2: Biological Importance and Statistical Significance

David Lovell, University of London, UK

The objective of this presentation is to illuminate some of the statistical ideas used in the analysis of experiments related to the composition of crops and the genetic factors which underlie their composition. It will concentrate on concepts rather than detailed statistical formulations and equations, aiming at the participant who wants to know why something is done rather than how it is done. These methods are also directly applicable to other areas of research. The intention will be to illustrate how statistical analysis and biological considerations are complementary rather than contradictory.

It will be stressed that the statistical analysis of a dataset is dependent upon the experimental design and that no amount of statistical sophistication can rescue a badly designed study. Often, whether a finding is considered statistically significant or not predominates the discussion about and the interpretation of the results. It will be argued here that the traditional Null Hypothesis Significance Testing (NHST) approach has severe limitations and that less emphasis should be given to the concept of statistical significance and P-values. Identifying statistical significance should not be the primary objective of a statistical analysis. Instead, more emphasis should be given to the estimation of effects and the precision of these estimates. This should be linked to the identification of size of effects that are considered biologically important or relevant which can then be used in the design of experiments in terms of sample size and statistical power. Identifying what these effects are is very much the responsibility of the domain scientist.

Issues to be discussed include the use of multiple comparison methods, equivalence testing and assumptions underlying analyses. In all cases the paramount importance of good experimental design will be emphasized.

Presentation 4.3: Regulatory Perspectives on How Composition Data are Interpreted – Food
Lynne Underhill, Health Canada, Canada

This presentation will describe how the safety assessment of novel foods fits into the mandate of Health Canada with respect to food. The regulatory framework for pre-market safety assessment of novel foods in Canada (including Codex principles and other guidance) will be presented. The multidisciplinary safety review process for foods and feeds in Canada will be briefly described. Elements of the safety assessment will be covered, with emphasis on the importance and purpose of compositional analysis. Importance of study design, selection of comparators, use of literature and commercial (GM and non-GM) variety reference values will be discussed. Some of the regulators' challenges will be presented. For example, how much data is needed? What is "nice to know" vs. "need to know?" How to interpret statistical differences? Finally, assessment of plants intentionally modified for nutritional or health benefit will be discussed.

Presentation 4.4: Regulatory Perspectives on How Composition Data are Interpreted – Feed
Bill Price, US FDA (retired), USA

This presentation focuses on the compositional comparison of feed derived from plant varieties altered by modern biotechnology to that of feed derived from its conventional counterpart (the parental variety or other commonly consumed varieties). Our government mandate requires that such feed is as safe as feed derived from conventionally bred commonly consumed varieties a history of safe consumption by man and animals has been established. The US's unified approach to regulating feed derived from bioengineered plants will be discussed. Why animal feeds are extremely important in the evaluation process will be explained. The history of regulation of bioengineered food, including feed will be reviewed including how OECD and CODEX fits in. Emphasis is on the 'key' components as described in the Codex Alimentarius publication "Foods Derived from Biotechnology" (2004). Key components include key nutrients, anti-nutrients and natural plant toxicants. Suggested key components for common food and feed plants are delineated in the OECD (Paris, France) Consensus Documents on Compositional Considerations in the series on the "Safety of Novel Foods and Feeds". What nutrients, toxicants and anti-nutrients are of key importance from an animal feed standpoint will be explored. Why experimental design, including good sampling and analytical techniques, is of upmost importance will be a topic. How much data is needed will be discussed. The question of when would data requirements be more than compositional analytical data will be addressed, including the role of the evaluation of molecular data and agronomic phenotypic observations. Finally, the presentation will emphasize the bottom line: not materially different, i.e., substantially equivalent.

BIOGRAPHIES

Gerard Barry, PhD

International Rice Research Institute, The Philippines

Dr. Barry joined the International Rice Research Institute (www.irri.org) in November 2003 as the Coordinator of the Golden Rice Network (www.irri.org/goldenrice), and is also the HarvestPlus Rice Crop Team Leader (www.harvestplus.org). In addition, Dr. Barry serves as the Global Product Coordinator for the Global Rice Science Partnership (GRiSP) "Healthier Rice Varieties" products (www.grisp.net/main/summary). Prior to joining IRRI, Dr. Barry spent more than 20 years with Monsanto Company in St. Louis, USA, where he had various responsibilities, including co-head of the Rice Business Team, head of the Rice Genome and Rice Genomics projects, and Director of Research for developing country research cooperation. He received B.Sc. and M.Sc. degrees from University College, Cork, Ireland, and his Ph.D. from Columbia University in New York, and he was formerly Charge de Recherche at the Institut Pasteur in Paris. Dr. Barry is co-inventor on 20 patents and co-author of more than 50 research articles.

Andrew Bartholomaeus, PhD

University of Canberra; University of Queensland, Australia

Dr. Bartholomaeus, B.Pharm, Ph.D., Cert Ag (III), obtained a bachelors degree in pharmacy from the University of Sydney and following professional practice in pharmaceutical manufacturing, hospital and military pharmacy completed a Ph.D. in toxicology at RMIT University in Melbourne. Over the past 17 years Dr Bartholomaeus has worked as a toxicologist across a broad range of chemical regulatory areas including agricultural, veterinary and industrial chemicals, complementary medicines, and gene technology products. Prior to June 2008 he held the position of Chief Toxicologist with the Prescription Medicines area of the Therapeutic Goods Administration in Australia with responsibilities in the area of preclinical assessment and in leading the TGAs response to the Australian National Nanotechnology Strategy. Dr. Bartholomaeus subsequently took up the position of General Manager of the Risk Assessment Branch at Food Standards Australia New Zealand. Dr Bartholomaeus holds extramural appointments with the University of Queensland Medical School as an Adjunct Professor, the University of Canberra as an Adjunct Professor of Toxicology and Pharmacy, and the WHO, as an expert advisor on the JMPR toxicology panel. In June 2009 Dr. Bartholomaeus chaired the FAO/WHO Expert consultation on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications. Dr. Bartholomaeus is a member of the Society of Toxicology and ACTRA.

Matthew W. Blair, Ph.D.

Universidad Nacional de Colombia, Colombia and Cornell University, USA

Dr. Blair is an adjunct professor at the National University of Colombia and at Cornell University in the plant breeding department. He has been a Germplasm Specialist and Senior Scientist with the International Center for Tropical Agriculture (Centro Internacional de Agricultura Tropical or CIAT) in Cali, Colombia. He received a B.S. in Plant Breeding from Cornell University, as well as an M.S. in Agronomy from the University of Puerto Rico. After conducting graduate study at the University of Florida Institute of Food and Agricultural Sciences, Dr. Blair returned to Cornell University, where he received a Ph.D. in Plant Breeding. He has been responsible for plant improvement in large-seeded Andean beans, and a leader of laboratory-based projects using molecular markers for basic research and for applied plant breeding goals in beans. His work includes collaboration with national agricultural research programs and regional networks in Latin America, Africa, Europe, and North America. In addition to his research activities, Dr. Blair has served as an advisor or co-advisor to more than 115 graduate students, international trainees, and undergraduate students. He has also published extensively in US and international publications, and his works include over 140

refereed articles, 75 non-refereed articles, and 12 book chapters, as well as GenBank entries for over 120,000 Sanger sequences and 4 Crop registrations.

Flavio Breseghello, Ph.D.
Embrapa, Brazil

Dr. Breseghello was born in Jales, state of São Paulo, Brazil, on July 30th, 1968, and was raised in Goiânia, state of Goiás. Graduated in Agronomy in 1991, by the Federal University of Goiás, and received a Master degree on plant breeding, by the same University, in 1995, when was hired by the Brazilian Agricultural Research Corporation - Embrapa (www.embrapa.br), as a Research Assistant. From 1995 to 1999 was positioned in Rondonópolis, state of Mato Grosso, running the state-level upland rice breeding program. Became Junior Researcher in 2001, when started a Ph.D. program at Cornell University, with Prof. Mark Sorrells. Conducted studies on association mapping in bread wheat, publishing one of the earliest papers on the application of this method in crop plants (*Genetics*, 172: 1165–1177, 2006). Graduated in 2005, having received the Gerald O. Mott Award and Scholarship from the Crop Science Society of America. Returning to Brazil, became Senior Researcher at Embrapa, working on rice breeding and genetics. Represented Embrapa in several international scientific missions. Has been appointed as Head of Research and Development at "Embrapa Rice and Beans" (www.cnpaf.embrapa.br) for the period of 2008–2013, supervising a team of fifty scientists, working on several aspects of genetic improvement and crop management for the rice and common bean (*Phaseolus vulgaris*) crops in Brazil. Since 2012 is a member of the Program Management Committee for the Embrapa Corporation.

Phil Brune, Ph.D.
Syngenta Crop Protection, USA

Dr. Brune currently holds the position of Technical Expert for Compositional Analysis, Product Safety for Syngenta Crop Protection, LLC in Research Triangle Park, NC, USA. He has been in this position since 2009. Dr. Brune received a B.A. degree in Biology from Wittenberg University (Springfield, OH), and a M.S. degree in Plant Pathology from The Ohio State University. He then went on to obtain a Ph.D. degree in Plant Pathology from North Carolina State University. In 1995 to 1997, Dr. Brune held an assistant professorship in the Math and Science Department at St. Mary's College (Raleigh, NC). In 1997, he accepted a position with Syngenta Crop Protection (at the time Novartis Crop Protection, Inc.), where he has held positions as a research scientist (conducting field research on disease control of most major field, fruit, and vegetable crops), data management (data capture, analysis, and mining; experimental design), and team lead for Compositional Analysis of genetically modified crops.

John J. Finer, Ph.D.
The Ohio State University, USA

Dr. Finer is a professor in the Department of Horticulture and Crop Science at The Ohio State University, where he has been the director of the Plant Transformation Laboratory for over 25 years. Dr. Finer received a B.S. in Botany from Miami University and both an M.S. and Ph.D. in Plant Physiology from Texas A&M Univeristy. After a post-doc in Plant Molecular Biology with Ciba-Geigy (now Syngenta), he joined the faculty at The Ohio State University. Research efforts in his laboratory have focused on somatic embryogenesis, genetic transformation and gene expression in crop plants. Publications from his laboratory include work on tissue culture and regeneration in soybean, cotton, corn, white pine, Chinese yam, garlic, bentgrass, wheat, sunflower and Ohio buckeye. His laboratory was the first university laboratory to report consistent recovery of transgenic plants of cotton, soybean and corn. Current efforts in his laboratory include promoter isolation and characterization using robotic tracking and image analysis of tissue growth and gene expression. In addition to his research activities, Dr. Finer serves on numerous editorial boards and is the Editor-in-Chief of *In Vitro Cellular and Developmental Biology – Plant.*

Sherry Flint-Garcia, Ph.D.
USDA ARS, USA

Dr. Flint-Garcia is a Research Geneticist with the USDA-ARS, in Columbia, MO. She grew up on a dairy farm in central Minnesota, which was very important to her agricultural view of science. She received her B.A. in Biology in 1996 from Saint Mary's University of Minnesota, and she received her Ph.D. in Genetics in 2001 from the University of Missouri. She was a postdoctoral research fellow at North Carolina State University and USDA-ARS in Raleigh in 2002–2004 (project: Association Analysis in Diverse Maize) and USDA-ARS in Columbia, MO (project: Artificial Selection in Maize Amino Acid Pathways). She then became a research geneticist with the USDA-ARS in Columbia, MO (2006-present). In addition to her current role, Dr. Flint-Garcia is also an Adjunct Assistant Professor in the Division of Plant Sciences, University of Missouri since 2008. Her research accomplishments from last 10 years are as follows: 1) leading role in the development and characterization of diverse maize resources in including the 302 diverse inbred line association mapping panel, nested-association mapping population, and teosinte introgression populations; and 2) leading role in the analysis of kernel traits in the NAM population including kernel composition and kernel weight. Dr. Flint-Garcia's other ongoing research projects include the following: 1) co-PI on the Maize Diversity Project, led by Ed Buckler; 2) analysis of kernel weight and composition in the teosinte introgression population; 3) development of a maize landrace-based allele mining platform called the Allelic Diversity Project in conjunction with the USDA Germplasm Enhancement of Maize (GEM) Project; and 4) germplasm evaluation and genetic analysis of native resistance to western corn rootworm.

Richard Goodman, Ph.D.
University of Nebraska-Lincoln, USA

Dr. Goodman joined the Dept. of Food Science and Technology and the Food Allergy Research and Resource Program at the University of Nebraska Lincoln in 2004 as a Research Professor. He has co-authored 37 peer reviewed papers including *Nat Biotechnol*, 2008, 26(1):73–81; *Food Chem Toxicol*, 2008, 46 Suppl 10:S24–34; and *Reg Tox Pharma*, 2008, 52(2):94–103. His Ph.D. in Dairy Science at The Ohio State University (1990) focused on molecular biology. Postdoctoral studies included 3 years in immunology at Cornell University and 4 years as a Research Scientist in immunology (pulmonary fibrosis, responses to specific pathogens and transplanted rejection) at the University of Michigan. He was employed by Monsanto Co. (1997–2004) as Project Manager for the allergenicity assessment of genetically modified (GM) crops. He manages the AllergenOnline.org database at UNL (funded by six international agricultural biotechnology companies). His six Ph.D. students work on food allergens identification, IgE binding methods, basophil activation, animal models of sensitization and databases for celiac and allergen screening. He has mentored USDA Borlaug fellows and Grand Challenge 9 visiting scientists from Africa, China, India and the Philippines, on GM crop safety methods. He represented the ILSI-HESI PATC at the Codex Task Force working group that developed the 2003 Codex allergenicity assessment guidelines. He has directed studies evaluating potential changes in endogenous allergens for six GM products and consults on evaluating insect protected cowpeas (Africa), Golden Rice (Philippines), GM mustard (India) and human lactoferrin in transgenic cows (China).

Angela Hendrickson Culler, Ph.D.
Monsanto Company, USA

Dr. Angela Hendrickson Culler is a Plant Biochemist and Lead of Monsanto's Composition Platform. Dr. Hendrickson Culler is Co-Chair of the International Life Sciences Institute's (ILSI) Crop Composition Taskforce (TF12), and one of the organizers of the Crop Composition Workshop. Dr. Hendrickson Culler has published in the areas of auxin analysis, auxin biosynthesis, and compositional and metabolite variability in safety assessments. Dr. Hendrickson Culler obtained her B.A. in Biology from Hamline University in Saint Paul, Minnesota, and her Ph.D. in Plant Biological Sciences from the University of Minnesota. Dr.

Hendrickson Culler completed a postdoctoral research fellowship at the University of Minnesota, and then joined Monsanto in 2008. She has worked in the area of compositional analysis since joining, and led the Metabolism and Pathways function within the Composition Platform prior to assuming her current role.

Owen Hoekenga, Ph.D.
USDA ARS, USA

Dr. Hoekenga is a Research Molecular Biologist with the Agricultural Research Service of the US Department of Agriculture. His assigned area of research is the detection and mitigation of unintended effects to food quality and composition in transgenic crops. Research has been conducted in both tomato (using novel transgenic events) and maize (using commercially sourced varieties). The Hoekenga Laboratory has applied liquid chromatography/tandem mass spectrometry to examine the metabolome of field grown tomato fruits and maize grain using diverse conventional germplasm, to explore the boundaries of stakeholder acceptable chemical (metabolomic) diversity. These data were then used to benchmark variation observed in transgenic varieties. The Hoekenga Laboratory has also adapted multivariate statistical approaches developed for analyzing and visualizing gene expression (transcriptomic) datasets and applied them to metabolomic datasets. The goal of this public sector research is to provide information to stakeholders, regulatory scientists and other members of the scientific community regarding the range of metabolomic diversity in conventionally improved and transgenically enhanced crops.

Joanne M. Holden, M.S.
USDA ARS (retired), USA

Ms. Holden received her B. S. in Foods and Nutrition from the University of Delaware, Newark, Delaware, and an M.S. in Human Nutrition Research from the University of Maryland. She joined the Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA, as a Support Scientist in the Carbohydrate Metabolism Laboratory where she assisted in the conduct of research on the effects of carbohydrate intake and metabolism. Then, Ms. Holden worked as a Research Nutritionist in the Food Composition Laboratory (now FCMDL), BHNRC for 20 years. She sampled and analyzed various types of foods for nutrient content, using state-of-the-art methods and analytical reference materials. Later she was responsible for developing food sampling plans to be used for various FCL research projects. With Drs. Wayne Wolf and Gary Beecher, she developed expert systems for evaluating the quality of analytical data for foods.

Until her retirement in 2012 Joanne Holden was the Research Leader of the Nutrient Data Laboratory at the Beltsville Human Nutrition Research Center of the Agricultural Research Service, USDA. In this role she was responsible for coordinating the acquisition, evaluation, compilation, and dissemination of food composition data for the US. The primary product of USDA's food composition research is the National Nutrient Database for Standard Reference ("SR"), which serves as the foundation for most food composition data applications. These data are disseminated on the internet (www.ars.usda.gov/nutrientdata) and are available to everyone free of charge and without license requirements. Ms. Holden's personal research interests include food sampling and the evaluation of the quality of data for foods.

Wilna Jansen van Rijssen, M.S.
Personal capacity (retired from the South African Department of Health), South Africa

Wilna Jansen van Rijssen has master degrees in plant biochemistry (University of Pretoria, South Africa), toxicology (University of Surry, UK) and public administration (University of Pretoria, South Africa), and qualified as a pharmacist with an honors degree in pharmacology. She joined public service (Department of Health) as a pharmacist in pharmaceutical services, subsequently joined the Medicines Control Council and then moved on to the Directorate: Food Control (Department of Health) where she was responsible for chemical safety related aspects of food. This included safety of food from genetically modified organisms. She

represented South Africa on Codex Alimentarius meetings on pesticides and the first set of ad hoc meetings on modern biotechnology when the Codex guidelines were developed. After she retired in 2005 as Deputy Director, Food Control, she was appointed to the GMO Advisory Committee, as well as to the Veterinary Clinical Committee of the Medicines Control Council with responsibility of toxicological assessment of pesticides. She has represented South Africa since 2004 on the OECD Task Force for the Safety of Novel Food and Feed and the last two years also on the Working Group on Harmonization of Regulatory Oversight in Biotechnology. She is a member of the Board of the South African Agricultural Research Council, the Advisory Committee for Biotechnology and Biosafety of the Southern African Development Community (SADC) and has been a guest trainer at many training sessions in Southern and Eastern Africa. Wilna is currently working on a doctoral study on risk governance of GMOs and phyto-pesticides.

Kathleen Jones, Ph.D.
US FDA, USA

Kathleen M. Jones, Ph.D. leads the food safety evaluation component of the Animal Biotechnology Group in the Center for Veterinary Medicine at the Food and Drug Administration (FDA). Dr. Jones oversees the team conducting risk-based approaches to the full life-cycle oversight of genetically engineered animals, and serves as coordinator for international activities related to animal biotechnology. She has spent the last twelve years at the FDA working on scientific and policy matters related to food biotechnology. She is an internationally recognized expert in the safety assessment of foods derived from modern biotechnology, serving as a scientific expert for the Codex Alimentarius Commission Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology, a scientific expert and U.S. delegate for the OECD Task Force for the Safety of Novel Foods and Feeds, and as an invited expert for the Food and Agriculture Organization of the United Nations. Kathleen currently serves as Chair of the Organisation for Economic Co-operation and Development (OECD) Task Force for the Safety of Novel Foods and Feeds.

Kazumi Kitta, Ph.D.
National Agriculture and Food Research Organization, Japan

Dr. Kazumi Kitta currently serves as the head of GMO Analytical Evaluation Laboratory in the National Food Research Institute (NFRI), National Agriculture and Food Research Organization (NARO) in Japan. In that role, she is responsible for the development and validation of methods for the detection and quantification of Genetically Modified Organisms (GMO). She also has been involved in work related to food allergens. She joined NFRI in 1992. She received her academic training at Tohoku University, Japan and University of California, Davis, USA in food science and biochemistry. Her Ph.D. study was on signal transduction in animal cells. She also worked as a visiting scientist from 1998–2000, at Jean Mayer USDA Human Nutrition Research Center, Tufts University, on aging. She is professionally active in the development of detection methods for GMO and she is also a member of the Expert Committee of Genetically Modified Foods in Food Safety Commission, Cabinet Office, Japan, and a national expert for ISO/TC34/SC16.

David Lovell, Ph.D.
University of London, UK

David Lovell is Reader in Medical Statistics at St George's Medical School, University of London. Previously he was Reader in Medical Statistics at the Postgraduate Medical School, University of Surrey, and an Associate Director and Head of Biostatistics support to Clinical Pharmacogenomics at Pfizer Global Research and Development (PGRD) in Sandwich, Kent, providing data management and statistical support to pharmacogenetics and genomics. His Ph.D. was from the Department of Human Genetics and Biometry at University College London in 1980. Before joining Pfizer, David was the Head of the Science Division at BIBRA International, Carshalton, which included Molecular Biology, Genetic Toxicology, Biostatistics and Computer Services. At BIBRA David managed the statistical and computing group providing specialised

statistical support to BIBRA's Clinical Unit and contract research work. He conducted and managed research programmes on genetics, statistics and quantitative risk assessment for the EU and UK Government Departments. His research interests at BIBRA were in the use of mathematical and statistical methods together with genetic models in the understanding of toxicological mechanisms and risk assessment problems. David had previously been a Senior Research Officer with the MRC Experimental Embryology and Teratology Unit, a visiting Postdoctoral Fellow at the NIEHS in North Carolina, USA, a Geneticist at the MRC Laboratories, Carshalton and a Research Assistant in Cytogenetics at Birmingham University. He has acted as a consultant to a number of organisations, has considerable experience of working with Regulatory Authorities, has many publications related to his work and has wide experience of making presentations to a wide range of audiences. He was Vice Chair of the Scientific Committee of EFSA (the European Food Safety Authority) from 2009–12 and is a member of the UK Government's Advisory Committees on Mutagenicity and Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COM and COC) and the Independent Scientific Advisory Committee (ISAC) for MHRA database research.

Rita Mumm, Ph.D.
University of Illinois, USA

Rita Mumm serves the Director of the Illinois Plant Breeding Center at the University of Illinois and Associate Professor of Quantitative Genetics and Plant Breeding, working mainly with maize. She continues as a consultant and principal for the firm, GeneMax Services, in Urbana, IL, specializing in applications of biotechnology to crop improvement.

Dr. Mumm earned an A.S. degree with an emphasis in Agriculture at Joliet Junior College in Joliet, IL, in 1987, a B.S. degree in Agricultural Science at the University of Illinois at Urbana-Champaign in 1989, and a Ph.D. in Genetics and Plant Breeding at UIUC under the supervision of Professor John Dudley in 1993. Entering the seed industry as transgenic product development was in its infancy, she managed the value-added product development program for DEKALB Genetics Corp., facilitating commercial launch of four value-added traits, one each year from 1995 through 1998. She went on to lead a team in establishing a high-throughput molecular marker system for DEKALB, aimed at providing this technology as a powerful tool for the breeder in the development of corn hybrids with key performance characteristics and positioning DEKALB as an industry leader in implementing genomic information in seed product development. She led efforts to establish transgenic product development programs for Syngenta in cotton, wheat, barley, rice, and plant-made pharmaceuticals in safflower. She has extensive experience in developing Quality Systems to safeguard transgenic event identity and purity through Research, Development, and Commercialization phases of seed product development. She is a named inventor on four U.S. patents, one of which includes the GA21 transgenic source of glyphosate tolerance in corn.

Wayne Parrott, Ph.D.
University of Georgia, USA

Wayne Parrott has a degree in agronomy from the University of Kentucky, and M.S. and Ph.D. degrees in Plant Breeding and Plant Genetics from the University of Wisconsin. He is currently a professor of Crop Science at the University of Georgia, where he has been for the past 23 years. He conducts research on the development and deployment of transgenic crop plants. One major research thrust is the development of soybeans resistant to insects, nematodes and fungi, as well as modifying soybean for novel feed uses. Dr. Parrott has published over 85 journal articles in refereed publications, along with 14 book chapters and three patents. He has served on the Editorial Boards of *Plant Cell Reports*, *Plant Cell Tissue and Organ Culture*, and *Crop Science*. He has been elected chair of the biotechnology section of the Crop Science Society of America and of the plant section of the Society for In Vitro Biology, and is a fellow of the Crop Science Society of America and of the Society for In Vitro Biology. He is actively engaged in training graduate students and postdoctoral fellows, and teaches graduate-level courses in genetics and undergraduate courses in agroecology and

sustainable agriculture. The latter course is taught on-site in Costa Rica. He has traveled extensively throughout Latin America and other countries, and worked with legislators and regulators in the various countries with their legal and regulatory issues relating to biosafety and biotechnology.

Bill Price, Ph.D.
US FDA (retired), USA

Thirty years regulating GM crops for food and feed. Was a member of US Team that wrote the policy for the evaluation of food derived from New Plant Varieties and was the lead person responsible for animal feed evaluation. Until his retirement in 2010, was FDA's Center For Veterinary Medicine point person responsible for policy and evaluation of all New Plant Varieties for animal feed use. US representative for feed issues to the OECD Task Force on the Safety of Novel Foods and Feeds. Substantial contributor to many OECD Consensus Documents on Composition Considerations for New Plant Varieties, including maize, soybeans, cotton, barley, grain sorghum, sweet potatoes, tomatoes, rice, and cassava. Board Certified Animal Nutritionist by the American Registry of Professional Animal Scientists and a Fellow of the American Society of Animal Science. Was FDA Contract Officer for grants supporting the National Research Council's publications on Nutrient Requirement of Animals. Career Service and Directors Award winners of the US FDA CVM. Outstanding Achieve Award winner for Washington, DC, Chapter of ARPAS. B.S. from Michigan State University, and M.S. and Ph.D. in animal nutrition from Purdue University.

Laura Privalle, Ph.D.
BASF Plant Science, USA

Laura Privalle received her B.S. in biochemistry and M.S. in botany from Virginia Tech. She received her Ph.D. in biochemistry from the University of Wisconsin. Following a post-doctorate at Duke University, she joined Ciba-Geigy in their Agricultural Biotechnology Research Unit, currently known as Syngenta Biotechnology, Inc., in Research Triangle Park, North Carolina. Dr. Privalle headed the Regulatory Science Laboratory which had the responsibility for generating much of the data used in the safety assessment of transgenic products for global regulatory dossiers. She was part of the effort in registering the first transgenic maize product, Bt Event 176. In 2003, Dr. Privalle joined BASF Plant Science LP, where she is currently the Head of Regulatory Science. Dr. Privalle has served as the vice-chair and chair of the International Life Sciences Institute Health & Environmental Sciences Institute (ILSI/HESI) Protein Allergenicity Technical Committee and is currently on the International Food Biotechnology Committee. She also serves on two expert panels on behalf of Crop Life International. She serves on the Education Enhancement Grants panel for the North Carolina Biotechnology Center and has participated in many other NCBC sponsored activities. She is currently serving as past-President of AEIC, an organization that focuses on analytical detection method technologies.

William P. Ridley, Ph.D.
Consultant (Monsanto Company, retired), USA

William (Will) Ridley is currently a Consultant and Adjunct Instructor in the Department of Nutrition and Dietetics at St. Louis University in St. Louis, Missouri, USA. He received a Ph.D. in Biochemistry from the University of Minnesota in St. Paul, Minnesota and is a Certified Diplomate of the American Board of Toxicology. Will retired from Monsanto Company, December 2010, following a career of over 30 years that included 10 years as Team Lead of the composition analysis program for agricultural biotechnology products. He served as Chair for the ILSI IFBiC Task Force that developed the initial versions of the Crop Composition Database (www.cropcomposition.org) and has published numerous book chapters and articles in peer-reviewed journals on the topics of crop composition, comparative studies of conventional and biotechnology crops and agricultural chemical metabolism.

Hilary Rogers, M.S.
Eurofins Scientific, USA

Hilary Rogers is the Project Manager for Eurofins Scientific Nutrition Analysis Center (NAC) in Des Moines, IA, recognized as a Center of Excellence for Nutrition and the flagship laboratory for the Eurofins US food testing division. Analyses performed at the NAC include lipids, proximates, vitamins, amino acids and minerals in commodities, feed, ingredients, food, pet food and dietary supplements. Ms. Rogers manages the Method Development Department, which consists of a group of scientists whose primary focus is the development and validation of methods for the laboratory. Ms. Rogers has more than 25 years in the contract laboratory business with analytical experience in the areas of animal health, medicated feeds and premixes, vitamins, nutrition, microbiology and method validation. Ms. Rogers has worked in various laboratory departments, in Sales and Marketing and as Manager of Client Services, and as Laboratory Manager for the Vitamin and Nutrition Departments. Ms. Rogers has an in-depth knowledge of nutrition labeling and testing, created a nutrition labeling program and given presentations and training addressing nutrition labeling and testing, as well as contributed to articles addressing these topics. Ms. Rogers is a member of IFT, AOAC and SQA, holds a B.A. in Foreign Languages and an M.S. in Information Systems Management, and has extensive coursework in the areas of mathematics, biology, computer science and psychology.

Peter Shewry, Ph.D.
Rothamsted Research, UK

Professor Shewry is currently Distinguished Research Fellow at Rothamsted Research and Professor of Plants and Health at the University of Reading. He leads a research programme on the development, structure and composition of wheat grain focusing on improving the quality of wheat for human health, notably the content and composition of dietary fibre and phenolic acids, and for milling and breadmaking including grain architecture and the deposition, composition and properties of grain proteins and lipids. He is the author of over many refereed papers in international journals, has edited or co-edited 17 books (including co-editing the 4th edition of *Wheat: Chemistry and Technology*) and has written over 100 major reviews and book chapters. In 2000 he was awarded the Thomas Burr Osborne medal by AACC and in 2002 was the joint recipient (with Donald Kasarda) of the Rank Prize for Nutrition. Over a 40-year career he has collaborated with many international scientists, most recently on the EU FP7 HEALTHGRAIN project (Exploiting the bioactivity of European cereal grains for improved nutrition and health benefits). He is currently Reviews Editor for *Journal of Cereal Science* and a Trustee and Chair of the Nutrition Committee of the Rank Prize Funds.

Jannavi Srinivasan, Ph.D.
US FDA, USA

Dr. Srinivasan is an analytical chemist by training. She obtained her B.Sc. and M.Sc. from University of Bangalore, India and her Ph.D. from Wayne State University, Detroit, MI, in 1995, focusing her work on the development of laser-based mass spectrometric methods for rapid DNA and protein analyses. After her post-doctoral work at University of Michigan, she worked in the biotech industry at various positions of responsibility in analytical and process development in pharmaceutical, biologics and medical diagnostic applications. She joined US FDA in 2007 as a Review Chemist in the Office of Food Additive Safety, Division of Biotechnology and GRAS Notice Review. At FDA, Dr. Srinivasan reviews premarket notifications for safety of new GRAS ingredients added to food and foods from novel bioengineered plants. She also leads the Office Enzyme Safety Review Team. Dr. Srinivasan is the US FDA technical expert at OECD's Task Force for the Safety of Novel Foods and Feeds, the FDA liaison to Food Chemicals Codex's, Food Ingredients Expert Committee, and a member of US FDA's Codex Food Additive Standards Team that supports the US delegate to Codex Committee on Food Additives.

Lynne Underhill, M.Sc.
Health Canada, Canada

Lynne Underhill is Chief, Nutrition Premarket Assessment Division, in the Food Directorate at Health Canada. She has worked in regulation of novel feeds and foods since 1996, first at the Canadian Food Inspection Agency, around the time when the Regulatory framework for foods and feeds from plants derived from modern biotechnology were established. She worked on Guidance documents for petitioners preparing a regulatory submission, for both feeds and foods. She joined Health Canada in 2006, in the Bureau of Nutritional Sciences, and is the lead for assessment of the compositional component of the novel food safety assessment. She has been a Canadian delegate and Bureau member to the OECD Task Force for the Safety of Novel Foods and Feeds for several years, and has authored and contributed to many of the Task Force's Consensus documents. B.Sc. in Agriculture from Guelph, and M.Sc. from McGill.

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