GM FOOD / FEED SAFETY ASSESSMENT: TRAINING WORKSHOP FOR REGULATORS
7-8 August 2014
KCB Leadership Center
Karen, Nairobi, Kenya

PROGRAM

Faculty:
- Dr. Philip Brune (Syngenta Crop Protection, LLC, USA)
- Dr. Gregory Ladics (DuPont Pioneer, USA)
- Dr. Scott McClain (Syngenta Crop Protection, LLC, USA)
- Dr. Laura Privalle (Bayer CropScience, USA)
- Prof. Ronald van Ree (Academic Medical Center / University of Amsterdam, The Netherlands)

THURSDAY, 7 AUGUST 2014
9:00 – 16:00
[Breaks and lunch to be scheduled by hosts.]

1. Introduction and Background
   Dr. Gregory Ladics (DuPont Pioneer, USA)

   A. ILSI Health and Environmental Sciences Institute (HESI)
   B. HESI Protein Allergenicity Technical Committee

2. Selecting a Commercially Viable GMO Crop Variety
   Dr. Laura Privalle (Bayer CropScience, USA)

   A. Development of a GMO crop variety (including timeline and farmers’ needs)
   B. Elite event selection
   C. Safety assessment
3. Compositional Data Analysis in Safety Assessment of GM Crops  
   Dr. Philip Brune (Syngenta Crop Protection LLC, USA)
   
   A. Introduction to the comparative assessment: compositional analysis  
   B. ILSI Crop Composition Database  
   C. Discussion:  
      1. Design of field studies to control variability  
      2. Choosing components to be assessed as they pertain to safety  
      3. Interpreting compositional analysis (Breakout Groups)

4. Kenya Experience  
   [invitation extended to NBA]
   
   A. Perspectives on handling registrations  
   B. Needs for mammalian safety for food and feed in Kenya  
   C. Requirements for in-country field trials  
   D. Global protocols versus in-country  
   E. Codex applicable?

FRIDAY, 8 AUGUST 2014

9:00 – 16:00  
[Breaks and lunch to be scheduled by hosts.]

5. History of characterizing allergens  
   Prof. Ronald Van Ree (Academic Medical Center / University of Amsterdam, Netherlands)
   
   A. Formation of allergen databases  
   B. Prevalence  
   C. Taxonomic restriction of known allergen groups

6. Molecular and Protein Characterization of GMO Products  
   Dr. Scott McClain (Syngenta Crop Protection, LLC, USA)
7. Evaluation of Potential Allergenicity of GM Crops

*Dr. Scott McClain (Syngenta Crop Protection, LLC, USA)*

A. Data for each of the component characterizations  
B. Breakout Groups

8. Evaluation of Potential Toxicity of GM Crops

*Dr. Gregory Ladics (DuPont Pioneer, USA)*

A. Food safety: “as safe as”  
B. Weight of evidence: evaluation of novel proteins  
C. Evaluation of potential unintended effects  
D. Nutritional equivalence


*Dr. Gregory Ladics (DuPont Pioneer, USA)*

A. Case study  
1. History of safe use  
2. Substantial equivalence  
3. Potential protein allergy considerations  
4. Potential protein toxicity considerations  
5. Evaluation of potential unintended effects  
6. Nutritional equivalence

10. Emerging Area: Registering GMOs – Assessing the Safety of Nutritionally Enhanced Crops

*Dr. Laura Privalle (Bayer CropScience, USA)*

A. Addressing new technologies

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