NUTS & BOLTS OF U.S. REGULATORY DOSSIERS FOR GENETICALLY ENGINEERED PRODUCTS

September 19-21, 2023 – Virtual Workshop Agenda

Tuesday, September 19 | 11:00 a.m. – 5:15 p.m. EDT

11:00 a.m. Welcome and introductions – Kellye Eversole, Eversole Associates
Scope of Workshop & Agenda Overview

Session 1: Navigating the U.S. Regulatory System
Moderator: Kellye Eversole
11:10 a.m. Overview of the Coordinated Framework, Dusti Gallagher, Eversole Associates
11:25 a.m. Role of U.S. regulatory agencies within the Framework
  ▪ USDA-APHIS – Suma Chakravarthy
  ▪ FDA – Jason Dietz
  ▪ EPA – Alan Reynolds
11:40 p.m. Q&A Discussion

Session 2: Review & Discussion of Case Study #1: Purple Tomato
Moderator: Kellye Eversole
12:00 p.m. Case Study Overview: Purple Tomato, Nathan Pumplin, Norfolk Healthy Produce
12:30 p.m. EPA response – Alan Reynolds
12:50 p.m. APHIS response – Abigail Walter
1:10 p.m. FDA response – Jamie Zhu
1:30 p.m. Q&A discussion
2:15 p.m. Lunch Break

Session 3: International Regulations at a Glance
Moderators: Jessica Mahalingappa and Chris Dardick, USDA
2:45 p.m. National and regional regulatory frameworks for biosafety outside the U.S.
  Piet van der Meer, Ghent University and the Free University of Brussels, Belgium
3:15 p.m. Global overview of international regulations
  Chris Peterson, Trade Policy & Geographic Affairs, FAS-USDA
3:45 p.m. Practical trade considerations of Okanagan apple
  Neal Carter, Okanagan Specialty Fruits, British Columbia, Canada.
4:15 p.m. Feed the Future Insect Resistant Eggplant Partnership
  Maricelis Acevedo, Cornell University
4:30 p.m. Q&A Discussion
5:15 p.m. Wrap up & Adjourn – Dusti Gallagher

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Wednesday, September 20 | 11:00 a.m. – 4:45 p.m. EDT

11:00 a.m. Welcome and introductions – Dusti Gallagher, Eversole Associates

Session 4: Review and Discussion of Case Study #2: MON 87411-SmartStax Pro™

Moderator: Dusti Gallagher

11:00 a.m. Case Study 2 – MON 87411-SmartStax Pro™
Trait Overview and EPA response, Nina Ortiz

11:50 a.m. APHIS response, Katharine Swoboda Bhattarai

12:10 p.m. FDA response, Jason Dietz

12:30 p.m. Q&A Discussion

1:15 p.m. Lunch Break

Session 5: Dissecting the U.S. Regulatory System

Moderator: Jason Dietz, FDA

2:00 p.m. Ask the Regulator: Common mistakes, pitfalls, and misinformation about developing a regulatory plan for the U.S. regulatory system.

Panel participants: Carrie McMahon, FDA
Kenneth Haymes, APHIS
Mike Mendelsohn, EPA

Session 6: Understanding GE Microbes & U.S. Regulations

Moderator: Kellye Eversole

3:00 p.m. GE microbe technology, Nik Evitt, Switch Bioworks

3:30 p.m. Regulatory reactions from:
- USDA-APHIS – Kenneth Haymes
- FDA – Jason Dietz
- EPA – Mike Mendelsohn, Office of Pesticide Programs, Biopesticides and Pollution Prevention Division (BPPD), Emerging Technologies Branch
  Noland Deaver, Office of Pollution Prevention and Toxics (OPPT), New Chemicals Division, Risk Management Branch
  Gwen McClung, Office of Pollution Prevention and Toxics (OPPT), New Chemicals Division, Risk Assessment Branch

4:00 p.m. Q&A Discussion

4:45 p.m. Wrap-up & Adjourn – Kellye Eversole
Thursday, September 21 | 11:00 a.m. – 1:15 p.m. EDT

11:00 a.m. Welcome and introductions – Kellye Eversole, Eversole Associates

Session 7: Technology Advancements and the U.S. Regulatory System
Moderator: Kellye Eversole

11:00 a.m. Bioengineered products labeling requirements
Alexandria Fischer, MRP/AMS

11:30 a.m. A glimpse into EPA’s exemption process for PIPs
Wiebke Striegel, EPA

12:00 p.m. A glimpse into the SECURE Act Exemptions
Deshui Zhang, USDA-APHIS

12:30 p.m. Q&A Discussion

1:00 p.m. Workshop wrap-up, announcements
Kellye Eversole & Dusti Gallagher

1:15 p.m. Adjournment