

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



## September 19-21, 2023 – Virtual Workshop Agenda

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### 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 Mendelson**, 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*
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**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