

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

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## 2021 WORKSHOP AGENDA

**Tuesday, June 8 — 10:00 a.m. – 5:30 p.m. EDT**

10:00 a.m. – Welcome and introductions – Kellye Eversole, *IE-SCS*

### **Session 1: Navigating the *new* U.S. regulatory system**

Moderator: *Kellye Eversole, IE-SCS*

10:15 a.m. – Overview of the Coordinated Framework, *Sally McCammon*

10:45 a.m. – Overview of APHIS requirements, *Subray Hegde*

11:15 a.m. – Overview of EPA requirements, *Chris Wozniak*

11:45 a.m. – FDA consultations, *Jason Dietz*

12:15 p.m. – Discussion

1:00 p.m. – Lunch break

### **Session 2: Review & Discussion of Case Study #1: High Oleic Soybean**

Moderator: *Elizabeth Hood, IE-SCS*

1:45 p.m. – Case Study 1 Overview – High Oleic Soybean – *Chloe Pavely, Global Regulatory Director, Calyxt, Inc.*

2:15 p.m. – APHIS response, *Kenneth Haymes*

2:35 p.m. – EPA response, *Chris Wozniak*

2:55 p.m. – FDA response, *Patrick Cournoyer*

3:15 p.m. – Open discussion

### **Session 3: Myths and Truths about the U.S. regulatory system**

Moderator: *Elizabeth Hood, IE-SCS*

4:00 p.m. – *Suma Chakravarthy, USDA; Elizabeth Milewski, EPA; Carrie McMahon, FDA*

4:45 p.m. – Discussion and Wrap-up

5:30 p.m. – Adjourn for the Day

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## **Wednesday, June 9 — 1:00 – 5:00 p.m. EDT**

Welcome and introductions – *Alan McHughen, University of California, Riverside*

### **Session 4: Review and Discussion of Case Study #2: Blight Resistant Potato**

*Moderator: Alan McHughen, University of California, Riverside*

1:00 p.m. – Case Study 2 Overview – Blight Resistant Potato – *Matthew Pence, Regulatory Manager, J.R. Simplot Company*

1:30 p.m. – APHIS response, *Kate Rappaport*

1:50 p.m. – EPA response, *Natalya Baranova*

2:10 p.m. – FDA response, *Jason Dietz*

2:30 p.m. – Open discussion

### **Session 5: Various Case Studies: Review & Discussion of Unique Aspects of Case Studies as Identified by U.S. Regulatory Agencies**

*Moderator: Alan McHughen, University of California, Riverside*

3:15 p.m. – APHIS – *Deshui Zhang*

3:40 p.m. – FDA – Pink Pineapple – *Carrie McMahon*

4:05 p.m. – EPA – *Chris Wozniak*

4:15 p.m. – Open discussion and Wrap-up

5:00 p.m. – Workshop wrap-up and adjournment – *Kellye Eversole*