

Virtual Workshop

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

September 19-21, 2023

specialtycropassistance.org



Acknowledgement

**Funding for the workshop was provided through Award no.
2022-33522-37746 Biotechnology Risk Assessment
Research Grants Program (BRAG)**



National Institute of Food and Agriculture
U.S. DEPARTMENT OF AGRICULTURE

Snapshot of discussions

- **Workshop goal: assist developers in navigating the U.S. regulatory process**
 - ✓ **Coordinated framework designed to increase public confidence, efficiency, transparency & coordination of process**
 - ✓ **2 unique, diverse, and successful case studies**
 - ✓ **New elements: International perspective & open regulatory panel**
 - ✓ **GE microbe examples & regulatory perspectives**
 - ✓ **Labeling requirements and exemptions**
 - ✓ **Thorough Q&A and discussion**

Take Home Message: Contact regulatory agencies early & often

Reminders

- Available presentations will be posted to the SCRA website – www.specialtycropassistance.org
- Participant list of those willing to share contact details will be distributed
- Post-meeting survey – Scan the QR code
Link will be sent tomorrow
Please respond!



Future Plans - SURVEY

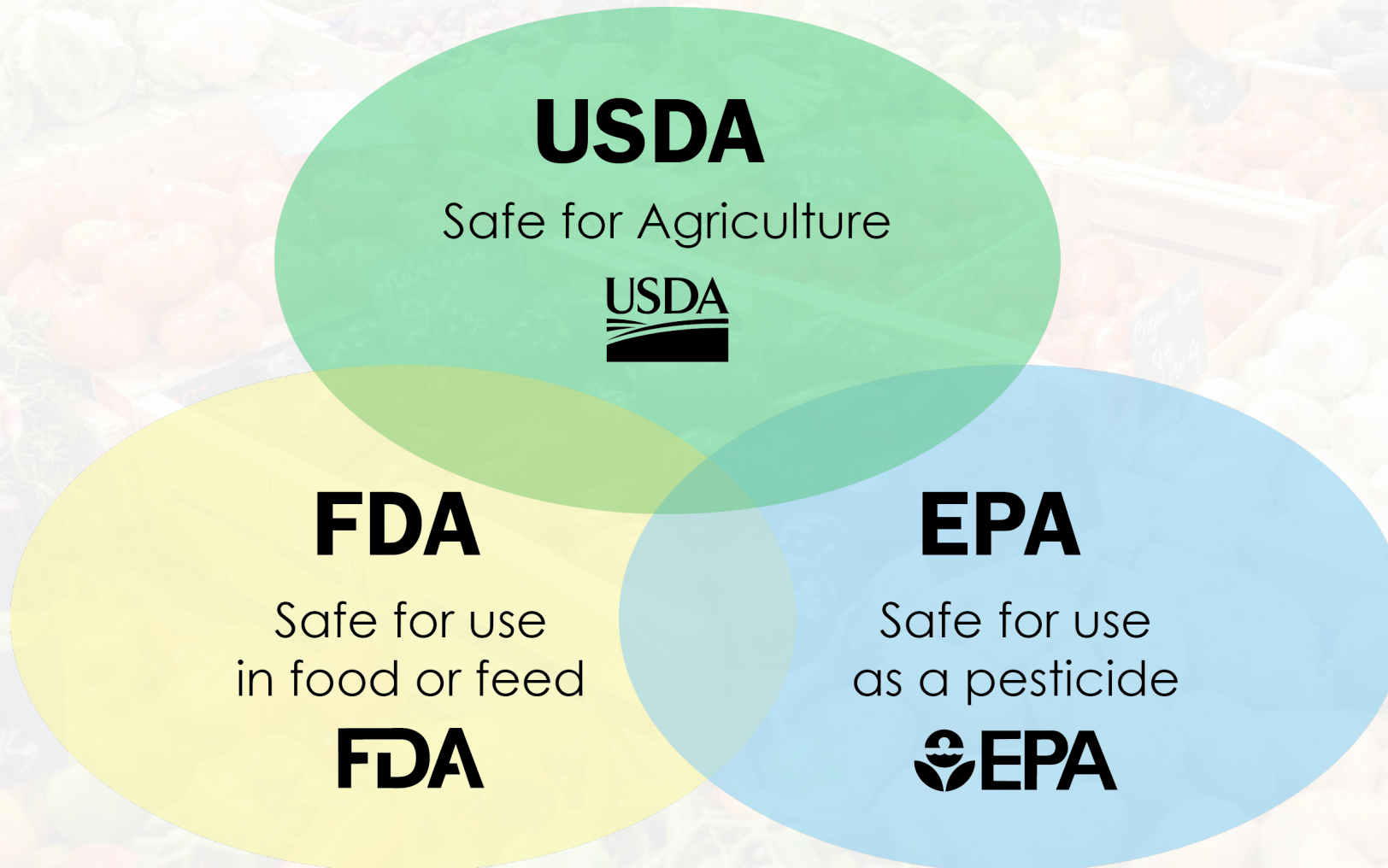
- **In person vs. virtual?**
- **Case study ideas?**
- **GE microbes?**
- **Speakers?**
- **Other ideas?**

All input will be evaluated by SCRA Steering Committee

The SCRA Steering Committee

- **Kellye Eversole, Executive Director, Eversole Associates**
- **Chris Dardick, ARS**
- **Jason Dietz, FDA**
- **Dusti Gallagher, Eversole Associates**
- **Subray Hegde, USDA APHIS**
- **Alan McHughen, University of California, Riverside**
- **Mike Mendelsohn, EPA**

Acknowledgements



Acknowledgements

- **Steve Fisher, Fisher Studios**
- **The Team at Eversole Associates**
 - **Isabelle Caugant**
 - **Dusti Gallagher**
 - **Lori Leach**
 - **Rolanda Young**



Thank you for your participation!

The Specialty Crop Regulatory Assistance initiative

www.specialtycropassistance.org

For more information:

Kellye Eversole, Eversole@eversoleassociates.com

Dusti Gallagher, Gallagher@eversoleassociates.com

