US Regulatory Policy Workshop: Genome-Edited Microbial Products for Agricultural Use

September 25 – Welcome Reception 6:00-8:00 pm at the historic Hotel Lombardy
2019 Pennsylvania Avenue NW, Washington, DC
September 26-27 - Workshop at the National Academy of Sciences Building
2101 Constitution Avenue, NW, Washington, DC

Day 1: *Start 8:00. Lunch 12:30-1:30. Finish for the day at 5:00.*

Topic	Speaker	Objective
Welcome	Danesha Seth Carley, CERSA, NC State	Welcome and logistics
Setting the Scene	Randy Deinhammer, Novozymes	Presentation of the workshop's main objectives
Security and Regulatory Considerations for the Bioeconomy	Steven Moss, National Academies of Sciences, Engineering, and Medicine	Security and Regulatory Considerations for the Bioeconomy
Political Perspective	Lesly Weber McNitt, Senior Professional Staff at the U.S. House Agriculture Committee Jeremy Witte, Professional Staff at U.S. Senate Committee on Agriculture, Nutrition, and Forestry	Representatives from House and Senate Agricultural Committees discuss support and challenges around genome edited microbials and agriculture policy
Government Support	Bernadette Juarez, Biotechnology Regulatory Services	Government support and commitment for working on the issues
Technical Background on Gene Editing		
What is CRISPR and what is its relevance to Agriculture?	Rodolphe Barrangou, NC State	Provide technical foundation on CRISPR gene editing
Scientific Perspective	Joe Bondy-Denomy, UCSF	Application and practical implications; real-world challenges

Academic Perspective on Risk	Katie Barnhill-Dilling, NC State	Reality Check and public perception of risk

10:45-11:00 *Break*

Panel 1 Facilitated by Rodolphe Barrangou		
Quick introductions and presentations		
APHIS Agency Perspective	Bernadette Juarez, Biotechnology Regulatory Services	*Presented earlier, but will also be a panel participant*
EPA Agency Perspective	Gwen McClung, EPA Office of Pollution Prevention and Toxics Mike Mendelsohn, Office of Pesticide Programs, Biopesticides and Pollution Prevention Division	EPA's perspective on Risk management oversight, risk assessment, and policy/rulemaking for gene edited products
FDA Agency Perspective	Jason Dietz, Food and Drug Administration	FDA's approach to genome edited products (Hint: Food safety is food safety)
Panel Discussion Facilitated by Rodolphe Barrangou		

12:30-1:30 *Lunch*

Panel 2 Facilitated by Randy Deinhammer		
Quick introductions and presentations		
Grower Perspective	Ariel Wiegard, American Soybean Association	Grower perspective on how genome-edited microbes may add value to agriculture
Industry Perspective	Tammy Zimmer, Joyn Bio Natasha Dixon, Bayer	Common definition of the current pathways and baseline on major hurdles towards commercialization. Statement of barriers and wishes from industry Industry perspective from a large international organization
Societal / NGO Perspective	Emma Kovak, The Breakthrough Institute	Perspectives from NGOs who aim to strike the right balance between leveraging gene editing technology and responsible use

	Charlie Arnot, Coalition for Responsible Gene Editing in Agriculture	

2:30-2:45 *Break*

Panel Discussion Facilitated by Randy Deinhammer	
Set Up Breakout Sessions for Day 2	Summarize key points and perspectives for the audience

Day 2: *Start 8:00. Finish for the day at 4:00.*

A discussion and workday leading to the collaborative understanding, development, and enhancement of risk-based regulatory framework for microbial genome editing		
Welcome back and introduction to the breakout sessions	Susanne Kjemtrup, Facilitator, Phyta BioTech Consulting, LLC	Collaborative understanding, development, and enhancement of risk-based regulatory framework for microbial genome editing
Breakout session 1	Leveraging what we know and what we learned: Elements and Key Considerations	Diverse, self-selected breakout groups participating in the workshop will consider case studies to contribute to the understanding, development, and enhancement of agency regulations

12:15 *Group Photo*
12:30 *Lunch*

Breakout session 2	Addressing limitations and advantages	Teams will share their work, inviting critical discussion of limitations and advantages
Summary, actions, and wrap-up for the day	Consensus building	Together we will develop a consensus statement to publicly share and drive next steps

<u>Organizing Committee</u>

Danesha Seth Carley, NC State, CERSA Director, ***Chair*** Mike Mendelsohn, EPA BPPD

Rodolphe Barrangou, Todd R. Klaenhammer Distinguished Professor, NC State, ***co-Chair***

Randy Deinhammer, Novozymes, Regulatory Affairs Lead for Americas, ***co-Chair***

Savannah Block, Novozymes

Tammy Zimmer, Joyn Bio

Natalie Hubbard, PivotBio

Jennifer Kuzma, NC State, Director for GES

James Burnette, NCDA&CS

Subray Hedge, Director, USDA BRS

Rebecca White, Pebble Labs