USDA Regulatory Permitting and Compliance Workshop
Louisiana State University Agricultural Center, 214 Efferson Hall
April 30, 2013

The USDA Regulatory Permitting and Compliance Education Workshop is focused towards academia and public researchers who conduct, or anticipate conducting, agricultural research with regulated genetically engineered (GE) organisms. Others who may benefit by attending the workshop include graduate students and post-doctoral researchers, field managers, and institutional biosafety officers.

The primary objectives of the Workshop are (1) to increase the participant's knowledge about the USDA BRS regulatory risk assessment application process , compliance inspection process, and compliance enforcement process; (2) learn how to navigate ePermits, the APHIS online electronic permitting tool; (3) understand the regulatory differences between permits and notifications; and (3) introduce the participant to available compliance assistance opportunities.

In addition, the Workshop provides an opportunity for participants to have their Level 2 eAuthentication accounts validated so that they can fully utilize ePermits as a USDA customer. Interested participants who have created a Level 2 eAuthentication account must bring their government-issued photo ID to the workshop for identify-proofing. For additional information regarding eAuthentication, please visit https://www.eauth.usda.gov/MainPages/index.aspx.

AGENDA

I.	**Opening Remarks**	9:00 to 9:30 AM
II.	**Session I: Overview of APHIS BRS Regulations under Title 7, Code of Federal Regulations, Part 340**	9:30 to 10:15 AM

This session will include a discussion of the key regulations of 7 CFR part 340 and the regulatory requirements for introduction (movement, import and environmental release) of regulated genetically engineered (GE) organisms. It will explain how different regulated articles and related activities are authorized under the Regulations.

At the end of this session, the participant will understand the definition of an introduction; the difference between an authorization under Notifications (340.3) and Permits (340.4); and who makes up the regulated community.

III.	**BREAK**	10:15 to 10:30 AM
IV.	**Session II: APHIS BRS Permits and Notifications**	10:30 to 12:00 PM

This session will walk the attendees through the BRS application process.

At the end of this session, the participant will understand the BRS risk assessment process and what information is expected from an applicant (e.g. design protocols, confinement details, NEPA/ESA). The participant will also learn to navigate

ePermits, the APHIS online electronic permitting tool.

V. LUNCH 12:00 to 1:00 PM

VI. Session III: APHIS BRS Compliance Inspection 1:00 to 2:00 PM

This session will provide an overview of the BRS compliance inspection program and explain how inspectors verify compliance during inspections.

At the end of this session, the participant will understand why and how APHIS conducts field inspections; the compliance inspection process; and how BRS determines compliance.

VII. BREAK 2:00 to 2:15 PM

VIII. Session IV: APHIS BRS Compliance Enforcement 2:15 to 3:15 PM

This session will provide an overview of the Compliance Evaluation and Enforcement Branch (CEEB) and how potential compliance incidents are resolved.

At the end of this session, the participant will understand the function and oversight of BRS CEEB; be able to define "potential compliance incident" and the source(s) of such incident; and understand BRS CEEB's response(s) to compliance incident(s).

IX. Session V: APHIS BRS Office of Compliance Assistance (OCA) 3:15 to 4:00 PM

This session will introduce a variety of tools offered by the Office of Compliance Assistance that are intended to facilitate compliance with 7 CFR part 340.

At the end of this session, the participant will understand the function of BRS OCA; know the services and tools offered by BRS OCA and how OCA assists organizations with regulatory compliance; and be equipped with BRS OCA contact information.

X. Evaluation & Conclusion 4:00 PM