Biotechnology

Through the Biotechnology Regulatory Services (BRS) program, the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) protects against risks to U.S. plant health by overseeing the safe import, interstate movement, and environmental release/field testing of certain organisms developed using genetic engineering. APHIS coordinates these responsibilities along with the other designated Federal agencies as part of the Federal Coordinated Framework for the Regulation of Biotechnology.

WHERE WE WORK

• Riverdale, MD (APHIS Headquarters)
• Fort Collins, CO
• Raleigh, NC

2020 Highlights

Published the final SECURE\(^1\) rule, the first-ever major revision of USDA’s biotechnology regulations, which streamlines and modernizes our system, providing over $8 million in annual cost savings.

With APHIS’ Plant Protection and Quarantine (PPQ) and States, performed more than 500 safety inspections of authorized field trials involving organisms developed using genetic engineering, with over 80% done virtually to maintain this essential function during the COVID-19 pandemic.

Completed 1 petition for deregulation bringing the total number of deregulated products to 133.

Responded to 86 “Am I Regulated” requests before retiring the process and launching the SECURE rule’s new exemptions and confirmation process.

Processed over 730 permits and notifications authorizing more than 17,000 locations and over 3,000 sites in 49 U.S. States and territories for the movement or field testing of organisms produced using genetic engineering.

Continued conducting a pilot version of eFile, APHIS’ new online permitting system—with 45 stakeholders participating this year and 40 permits and notifications issued in the new system.

Held 10 informational meetings, 2 technical webinars, and over 30 one-on-one sessions—all virtually—for more than 350 stakeholders to offer continued guidance on biotechnology regulatory processes throughout the COVID-19 pandemic.

Delivered presentations to 50 visitors representing 16 countries to offer technical information and build capacity abroad for regulating biotechnology.

Managed 8 FOIA (Freedom of Information Act) requests and released over 38,000 pages of records under FOIA, upholding our commitment to the public and transparency about biotechnology regulatory activities.

Provided over $260,000 in cooperative funding to universities and other partners for critical biotechnology work, including State inspections, risk assessments, and protecting natural plant heritage.

\(^{1}\)“SECURE” stands for “Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient”