USDA INVESTIGATES BIOTECH COMPANY FOR POSSIBLE PERMIT VIOLATIONS

WASHINGTON, Nov. 13, 2002—The U.S. Department of Agriculture's Animal and Plant Health Inspection Service, in close coordination with the Food and Drug Administration is investigating ProdiGene, Inc., of College Station, Texas, for violations of the Plant Protection Act.

During a compliance inspection in October 2002, APHIS found potential permit violations by ProdiGene at a site in Nebraska that had been used for small-scale field testing of genetically engineered corn in 2001. APHIS discovered tasseled volunteer corn plants growing in a soybean field that stands on the site of the 2001 field test. The presence of these plants is a violation of permit conditions. Following this discovery, APHIS instructed ProdiGene to remove the volunteer corn plants from the field, despite the fact that the corn plants did not have viable seed. However, the soybeans were harvested before all of the tasseled corn was removed. APHIS immediately placed a hold on the soybeans that were located at a single storage facility in Nebraska so that these materials would not enter the human or animal food chains.

APHIS also discovered possible permit violations at a ProdiGene 2001 test site in Iowa in September 2002. Volunteer tasseled corn plants were found growing in a soybean field and in a pile of volunteer corn plants removed from the field earlier in the season--both of which did not comply with permit conditions. At APHIS' request, and under APHIS supervision, ProdiGene has harvested and destroyed by incineration 155 acres of corn surrounding the field test site.

At the conclusion of the ongoing investigation into ProdiGene's regulatory permit compliance APHIS, in coordination with the FDA, will determine the appropriate enforcement action against ProdiGene.

Under the Federal Plant Protection Act, APHIS regulates the movement, importation and field release of genetically engineered plants. APHIS requires significant safeguards to prevent the unauthorized release of genetically engineered material. The Act provides criminal penalties for knowing violations as well as civil penalties. Any company or individual that violates the Act faces civil penalties of up to $250,000 per violation, or $500,000 per adjudication, and may have their permits revoked.

USDA has strengthened field-testing requirements for permits on genetically engineered traits that are not intended for commodity uses, such as pharmaceuticals, veterinary biologics and certain industrial products by adding new safeguards as a condition for all permits allowing the confined release of such products into the environment. These specific safeguards include comprehensive confinement procedures, performance standards, and required monitoring/auditing practices for ensuring that out-crossing or commingling with other seeds and commodities are prevented.