

Under the 1986 Coordinated Framework for the Regulation of Biotechnology, three Federal agencies share responsibility for the regulation of genetically engineered (GE) organisms. Under the authority of Plant Protection Act (2000), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture regulates the importation, interstate movement, and release of certain genetically engineered organisms that are, or are engineered using, plant pests in order ensure they are safe for agriculture and remain confined while under regulation. Once data and information are accrued to demonstrate that no plant pest risk is presented by the GE organism, a developer/researcher may petition APHIS for a determination of non-regulated status. A plant pest risk assessment is completed and is the basis for the decision on the petition. Via OECD and other mechanisms, APHIS meets regularly with counterparts in other countries for the purpose of working on joint projects and sharing scientific and regulatory knowledge, information and experience. The majority of organisms regulated by APHIS to date have been plants. However, APHIS has also regulated GE microbes and insects that are plant pests and has permitted the release of such organisms under defined conditions to prevent loss of confinement and mitigate risks to plant health. Field testing of two insects has been permitted; diamond back moth, a pest of crucifers, and pink bollworm, a major pest of cotton. Transgenic plant pests with gene drives can be regulated under existing laws; the challenge facing regulators is identifying hazards, assessing risks, and determining decision criteria and conditions for potential field releases.