

Case studies of modified plants not subject to the USDA modernized biotechnology regulations

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Abstract

The recent USDA modernization of biotechnology regulations enables the Animal and Plant Health Inspection Service (APHIS) to evaluate the regulatory status of organisms developed using genetic engineering (modified plants) with greater precision, while reducing regulatory burden for developers of sustainable bio-innovations. The modernized regulations accomplish this with two mechanisms: 1) exemptions to the regulations and 2) a regulatory status review (RSR). Exemptions apply to modified plants that could have otherwise been developed through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. In addition, plants with the same plant-trait-mechanism of action combination as in a plant APHIS previously determined to be not regulated are exempt. APHIS has issued confirmation of exemption letters for a variety of plants and plans to discuss some case studies. The RSR evaluates a modified plant using a risk-based model of its characteristics and not on the method used to produce it, with a minimal information requirement for the initial review. If APHIS is unable to identify a plausible pathway to increased plant pest risk in the initial review, APHIS then determines that the modified plant is not subject to the regulations. APHIS is expecting to have completed some initial reviews in this manner and to share some case studies. When a plausible pathway to plant pest risk is identified, developers will receive feedback about the type(s) of information that APHIS would need to complete a plant pest risk assessment, the result of which may or may not lead to regulation of the plant. Once APHIS determines that a modified plant is not subject to the regulations, subsequent transformation events using the same plant-trait-mechanism of action combination can then qualify for exemption from the regulations.

Key words: Exemptions, RSR, modernized biotechnology regulations, plant-trait-mechanism of action combination