

Gene Flow and Plant-Incorporated Protectants: an EPA Perspective. (C04-wozniak132106-Oral)

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Abstract:

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the U.S. EPA regulates pesticidal substances on plants intended for food or feed and establishes acceptable residues, respectively. Plant-Incorporated Protectants (PIPs) are pesticidal substances expressed and the genetic material necessary for their production in plants. Registered PIPs include endotoxins of *Bacillus thuringiensis* (B.t.) in maize, cotton and potato, as well as viral coat proteins in papaya and squash. Following review of product characterization, toxicity and environmental effects, the Agency may issue an Experimental Use Permit (EUP) for field evaluation or, if justified, registration for commercial use. The FFDCA authorizes EPA to establish a tolerance for a pesticide only if the residue in or on food is safe. Gene flow between crop varieties with a food tolerance in place does not represent a violation of FIFRA or FFDCA. If a food tolerance is not established, however, any commodity used as food or feed containing the PIP is adulterated. The Agency has restricted both EUP and commercial culture of cotton in areas where compatible wild relatives exist by imposing isolation distance requirements and use of border rows.

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