

WOZNIAK*, CHRIS A., and JOHN L. KOUGH, U.S. Environmental Protection Agency, Biopesticides and Pollution Prevention Division, 401 M Street, S.W., Washington, D.C. 20460. **Regulation and oversight of plant-pesticides by the U.S. EPA.**

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA), the Environmental Protection Agency registers all pesticides sold in the U.S. The advent of plant transformation technology has led to the production of transgenic plants with new pesticidal properties. These biopesticides are termed Plant-pesticides. This category includes plants produced by introduction of traits that would not normally be available by traditional plant breeding methods with sexually compatible relatives. An example would be the integration of bacterial gene sequences into sugarbeet for insect resistance. Prior to registration, each plant pesticide is examined to decide what data are needed to ensure that a reasonable certainty of no harm to man and the environment will result from its use. In general, details of the gene construct and expression levels of the introduced pesticidal substance, as well as information on the digestibility and allergenicity of proteins produced and toxicity profiles for humans and non-target species are requested from the registrant. To date seven plant pesticides (products) have been registered which represent six active ingredients (genotypes) expressed within three species: cotton, potato and corn. Resistance management is being developed for at least some of the crops expressing Bt-based insecticidal traits by incorporating non-treated refuges into planting design. Plants with herbicide tolerance traits are not regulated under the Plant-pesticide rule since the trait itself does not meet the definition of a pesticide under FIFRA. The herbicide, however, may need a new label and assessment for increased residues. All genetically modified plants are subject to oversight by the USDA's Animal and Plant Health Inspection Service under the terms of the Plant Pest Act and Plant Quarantine Act.