

BIOTECHNOLOGY: PLANT-PESTICIDE/PLANT-INCORPORATED PROTECTANTS (PIPs) FINAL RULE SUMMARY

THE FINAL RULE PACKAGE

- The final rule package includes two pesticide tolerance exemptions under the Federal Food, Drug and Cosmetic Act (FFDCA), a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) rule, and a supplemental notice. The FIFRA rule, also known as the biotechnology rule, was formerly called the plant-pesticides rule. These rules change the names of these pesticides from plant-pesticides to plant-incorporated protectants (PIPs).

WHAT THE FINAL RULES DO

- The final rules largely formalize the Environmental Protection Agency's (EPA) existing process for regulating plant-incorporated protectants and do not change significantly EPA's current system for scientifically evaluating a plant-incorporated protectant.
- The final rules clarify which plant-incorporated protectants are required to be evaluated under FIFRA and FFDCA and which plant-incorporated protectants are exempt.
- Under the final rules, most components of plant-incorporated protectants derived from genetic engineering will be subject to FIFRA and FFDCA requirements. (Certain components of the genetic material necessary for the production of plant-incorporated protectants will be exempt from the requirement for a tolerance under FFDCA)

EXEMPTIONS

- Where the Agency has determined that plant-incorporated protectants pose little or no health and environmental risk, EPA has issued the following exemptions from certain requirements:
 - Plant-incorporated protectants developed through conventional breeding will be exempt from all FIFRA and FFDCA requirements, with the exception of adverse effects reporting requirements for manufacturers.
 - The rules will exempt from tolerance requirements certain genetic material (DNA) involved in the production of the pesticidal substance in the plant.

OPPORTUNITY TO COMMENT

- The supplemental notice solicits public comment on the exemptions proposed in the 1994 proposal that are not finalized in this rule package. The supplemental notice also solicits public comment on the National Academy of Sciences (NAS) April 2000 report entitled

“Genetically Modified Pest-Protected Plants: Science and Regulation.” The exemptions not finalized address: (a) plant-incorporated protectants based on viral coat proteins, (b) plant-incorporated protectants derived through genetic engineering from sexually compatible plants, and (c) plant-incorporated protectants that act primarily by affecting the plant. The supplemental notice provides a 30-day public comment period on those science and policy issues that remain unresolved.