REGULATION OF BIOTECHNOLOGY FOR FIELD CROPS

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Abstract: Biotechnology innovations in field crops are jointly regulated by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, the U.S. Environmental Protection Agency, and the Food and Drug Administration, with the objectives of ensuring safety of the environment and human health. The coordination mechanism has been criticized, but seems likely to persist, barring some dramatic safety failure. Economic analysis has established costs of alternative refugia requirements for insect-resistance technologies, but has to date contributed little else to determining the nature and extent of regulatory oversight.

Key words: agricultural biotechnology, regulation, APHIS

1. INTRODUCTION

There are no U.S. laws specifically establishing the regulation of crop biotechnology. It is a stepchild, along with other agricultural biotechnologies, attended to by three parents.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture has primary custody under its authority under the Plant Protection Act to regulate agricultural pests. The U.S. Environmental Protection Agency (EPA) exercises oversight because it has authority to regulate pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and toxic substances under the Toxic Substances Control Act (TOSCA). Third, the Food and Drug Administration (FDA) bases its claim to parenthood on its responsibility for food safety under the Federal Food, Drug and Cosmetic Service Act (FD&C) and for pharmaceuticals under the Federal Health Act (FHA). Under the National Environmental Policy Act (NEPA), all three agencies must conduct environmental assessments for major actions.
This shared parenthood was a deliberate decision after discussions in the 1980s led to the rejection of a new law and new agency for agricultural biotechnology, in favor of the “Coordinated Framework for Regulation of Biotechnology Products.” This framework was established in 1986 by the Office of Science and Technology Policy (51 Fed. Reg. 23302). The coordinated approach is still being debated, however, as indicated by the concerns and proposals collated in a recent report by the Pew Initiative on Food and Biotechnology (2004).

Transgenic field crops are of two types for regulatory purposes. Those that produce grain for food and feed use are subject to a simpler regulatory process than the more exotic pharmaceutical-producing plants. Brief summaries of these current regulatory procedures follow.

2. THE REGULATORY PROCESS FOR TRANSGENIC FIELD CROPS WITH TRADITIONAL COMPOSITION

Details on the regulatory procedures of the three agencies can be obtained from their websites.¹ Recent studies that provide more detail and evaluation of these procedures include Nelson, Babinard, and Josling (2001), Belson (2002), National Research Council (2002), and the Pew Initiative on Food and Biotechnology (2004).

2.1. Animal and Plant Health Inspection Service

The Animal and Plant Health Inspection Service defines all transgenic crop organisms as having the potential to be “pests,” and they are therefore designated as “regulated articles.” A permit from APHIS is required to conduct a field test of any transgenic crop. Plants with insect or herbicide resistance, or enhanced grain qualities for food or feed use (often referred to as first- and second-generation transgenics), are becoming well understood and thus demand less stringent regulatory oversight than the more exotic third-generation transgenics with pharmaceutical or industrial traits.

A request for a field trial permit (“permit for introduction”) must contain extensive descriptions of the organism, and of the testing, monitoring, disposal, and reporting procedures to be followed, and it must disclose any evidence of unusual or harmful aspects of the plant. APHIS provides guidelines for testing and reporting (minimum isolation requirements, etc.), but applica-