

# SCIENCE

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# EDITORIAL

## Regulation of Transgenic Plants

Plants modified by recombinant DNA (rDNA) have been known since 1983 when three research teams independently reported the first stable integration of foreign DNA into plant cells and the regeneration of genetically modified plants. By 1987 rDNA-modified crop species were available that warranted field evaluation of traits conferred by the new genes. By the end of 1992 more than 40 species of rDNA-modified food and fiber crops will have been described and almost 600 field tests of rDNA-modified plants will be completed or in progress in more than 20 countries around the world. Many of these tests will involve plants of potential commercial value since they represent genetic improvements in disease or pest resistance, hybridization technologies, or value-added food traits such as nutritional or processing enhancements. The field tests evidence the substantial public and private commitments that have been made to agricultural biotechnology. They also provide tangible proof of very successful technology transfer from basic plant molecular biology laboratories to problem-solving research programs that should help ensure agricultural sufficiency into the next century.

A pipeline filled with commercial rDNA-modified plant products does not necessarily mean that consumers will rapidly and efficiently benefit from scientists' discoveries. While the information base underpinning plant biotechnology has grown exponentially over the last decade, the U.S. government regulations related to evaluation of rDNA-modified plants have evolved much less rapidly. They remain complicated by bureaucratic detail that stifles the research which provides the basis for new product development. One encouraging exception came from the U.S. Food and Drug Administration in May 1992—they ruled that rDNA-modified plants which do not pose characteristics that raise food safety questions will be subject to usual levels of government scrutiny, just like foods created by other means. This ruling focuses on the need for producers to consider the characteristics of the product that will be consumed, not the process by which it is created. In contrast, the current stance of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) is to regulate each rDNA-modified plant on the basis of the scientific protocol used to create it. Together, this bureaucracy means that plants are placed under essentially double jeopardy by having to meet two different types of regulatory standards.

The current regulations used by USDA-APHIS were formulated in 1987 when plant genetic engineering was in its very early stages. The Department's statutory authority rests on the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912 which expressed congressional intent to regulate the introduction of organisms that are or reasonably may be suspected to be capable of causing injury, damage, or disease in plants. This important goal was established long before the concept of plant genetic engineering was seriously contemplated as a tool for crop improvement and was intended to prevent the importation of pests that would jeopardize U.S. agriculture. USDA-APHIS, however, extended the regulations to include the products of genetic engineering and created a requirement to evaluate each rDNA-modified plant on the basis of whether it contained genetic material derived from a plant pest. The premise is that when plants are developed using genetic material from pathogenic sources or when a pathogenic organism is involved in causing the plant transformation, the resultant plant must be subjected to regulatory analysis to assure that it does not pose a risk to other plants. The scientific community acquiesced to these regulations, largely based on uncertainty of public acceptance of biotechnology products and the specter of interference from activists in field-testing research. The successes of the field tests conducted to date, arousing minimal concern even from strident anti-technology foes, removes the earlier uncertainty. In addition, the extensive information base derived from research on rDNA-modified plants has verified the scientific predictions of the 1980's—crops thoughtfully modified by rDNA do not become or create new plant pests! There is an urgent need to revise the USDA-APHIS regulations to focus on the behavior of rDNA-modified plants and not on experimental protocols. This would make the regulations compatible with recommendations of the National Academy of Sciences, the National Research Council, and the February 1992 White House policy on field research to increase U.S. competitiveness.

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