

Biotechnology Policy

The advent of a technology like genetic engineering poses important challenges to society. How should decisions be made about which applications of the technology should go forward and which should not? Current US institutions provide meager opportunities to openly evaluate new technologies in advance of their implementation. As a result, decisions about technologies are largely left to the private sector, which is given full latitude to produce whatever can be sold, subject only to regulation to avoid harm to health and the environment. While such regulation is important, it is no substitute for societal evaluation of the impacts of and alternatives to new technologies.

This timid approach to technology has led to an impression that it is somehow beyond social or political control. Yet choices between different technologies or between technological and nontechnological approaches to problems are being made all the time. Often the decisions are made in the context of funding decisions and the setting of research agendas, which occur far from public view. New institutions and arenas are needed to encourage open discussion of new technologies and to help the public participate in decisions about technologies.

US Regulation of Genetic Engineering Products

Three agencies currently regulate genetically engineered products under a handful of statutes. These statutes were originally designed to regulate other products and were put in place before genetically engineered products had even been imagined. Thus they have been adapted to a purpose for which they were not intended. The result is a patchwork of regulations and programs with different requirements and underlying philosophies.

In general, the products of genetic engineering are regulated for their health and environmental risks, and those risks are balanced against benefits. The major statutes applied to nonpharmaceutical and nontherapeutic uses of genetic engineering are implemented by three agencies: the Environmental Protection Agency, the Food and Drug Administration, and the United States Department of Agriculture.

The Environmental Protection Agency (EPA) oversees genetically engineered microbial pesticides and certain genetically engineered crops under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and nonpesticidal, nonfood microbial products under the Toxic Substances Control Act (TSCA). Organisms regulated under FIFRA are subject to stringent permit standards under which the EPA can require new studies on possible harm to health and the environment. By contrast, the legal provisions of TSCA require only 90-days notice to the EPA before the commencement of manufacture and provide less straightforward mechanisms for persuading companies to conduct studies of

risks. Currently, the EPA regulates Bt crops and microbial pesticides under FIFRA and microorganisms intended for pollution cleanup under TSCA.

The Food and Drug Administration (FDA) has the authority to regulate all genetically engineered foods under the Food, Drug and Cosmetic Act. Its only specific policy for genetically engineered foods applies to crops. Under the current FDA food policy, most genetically engineered crops are not subject to regulation. The agency does run a voluntary program under which companies producing engineered crops can consult with the agency to confirm the regulatory status of their products. Companies choosing to participate in the consultation process are not required to conduct any standard set of safety tests on their products. In fact, companies that have voluntarily conducted safety studies only need to submit summaries of those studies to the FDA. Because the FDA reviews only summaries, not data, from safety studies, it does not publish conclusions on the safety of individual genetically engineered foods. The FDA has conducted consultations on genetically engineered tomatoes, soybeans, and squash.

The US Department of Agriculture (USDA) regulates genetically engineered products under several statutes: genetically engineered crops under the Plant Pest Act and related authorities; animal vaccines under the Virus, Serum and Toxin Act; and engineered poultry and livestock under various meat inspection statutes. Under the Plant Pest Act, the USDA issues de facto commercial permits in the somewhat confusing form of determinations that the products are not pests and do not need further regulation. These determinations are accompanied by environmental assessments done under the National Environmental Policy Act (NEPA). The USDA Plant Pest Act program has overseen thousands of field tests of genetically engineered crops and issued about twenty de facto commercial permits. Crops approved for commercial use include engineered versions of most major commodity crops such as corn, cotton, and soybeans, as well as several fruits and vegetables.

In general, genetically engineered animals other than poultry and livestock are not regulated for environmental risks under US law. Engineered fish are a notable example. There is some indication that the FDA may regulate engineered fish as "animal drugs," but no official policy has been announced.

The Need for a New Regulatory Framework

The framework of regulations applied to genetic engineered organisms is weak because it leaves important categories of genetically engineered organisms uncovered and because it often lacks strong authority to require premarket review of genetically engineered products.

The current programs differ widely in the degree to which they allow the public to participate in decisions about engineered products. Most of the statutes grant companies broad privileges to withhold data and information, including health and safety information, from the public.

Making these statutes work requires active involvement by the public. The agencies mentioned above almost always hear from the regulated industry on pending policies and decisions. Unless agencies hear from the public too, their positions often coincide with those of industry. Decisions about genetic engineering should not be left to the multinational corporations developing these products. Letting the agencies know that the public cares about genetic engineering is the best way to positively influence their decisions.

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