

# Biotechnology: Regulatory Oversight

## The Basics

Tomatoes that fight cancer. Peanuts that are hypoallergenic. Potatoes that are pest-resistant. Corn that is more tolerant of crop protection products and high alkaline soils. These realities of modern agriculture are a direct result of biotechnology.

Since Gregor Mendel's first experimentation with cross-breeding peas, science has progressed fast and furiously toward new innovations in agriculture. Biotechnology takes Mendel's breeding principles one, precise step farther. By identifying a particular genetic trait (gene) in one organism, removing it and then placing it in another organism, the ability to immediately create a product with added benefits is possible. Some of these beneficial traits include:

- Longer shelf-life
- Increased flavor
- Products that are lower in saturated fat
- Products that have certain higher nutritional values (i.e., Vitamin A)
- Pest and disease resistance
- Higher tolerance for drought, poor soil conditions and application of crop protection products

But how, exactly, does today's plant breeding differ from that of the 19<sup>th</sup> century? The simple answer is precision. Biotechnology isolates the specific gene of a desired trait or characteristic and transfers it into an existing product. In traditional plant breeding, trying to achieve this specific characteristic/trait transfer could take years, sometimes with limited or no success (see below).

<b>Plant Breeding</b>	<b>Biotechnology</b>
Selection of two plants: one with desired characteristic and one without (i.e., flowers with purple versus white petals)	Same
Process of cross-breeding: fertilization of one plant with the pollen from the other	Identification and isolation of gene (i.e., specific to petal color purple)
Continued process of cross-breeding – as process is repeated, the likelihood of transferring the color increases (could take months, years)	Insertion of gene into existing product (i.e., flower with white petals)
Results are dependent upon likelihood of transfer over time	Results are immediate; little time, money is wasted on experimentation

But biotechnology is not limited to agriculture. Its promise is being applied to medicine, where proteins that can fight infection and disease are being replicated at a cheaper, faster rate, as well as helping clean up the environment. But how do consumers benefit from this?

One example is in the cost to create medicine from “scratch,” in a lab, and then recreate it for mass production. With biotechnology, the protein that is the basis for the medicine can be replicated within a plant, and, therefore, be created more efficiently. The result may mean that you have greater access to medicine and, perhaps, at a cheaper cost. Examples of ailments that currently or will benefit from pharmaceutical-based biotechnology include:

- Rheumatoid arthritis
- Cancer
- Paralysis
- Tooth decay
- Vaccinations
- Blood proteins
- Monoclonal antibodies
- Hormones

Science is also making it possible to apply biotechnology to environmental remediation. Work is currently being done on enhancing plants and their ability to store toxic, hazardous substances. The result may mean that plants could help in the cleanup of spills, leaks and other environmental contamination concerns.

### **How Is Biotech Regulated?**

Biotechnology is regulated in the United States by three, federal agencies: the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). Each agency works in cooperation with others to ensure oversight of biotechnology, from research lab to marketplace.

FDA focuses on the product’s changes and how it compares to a similar product already on the market. The agency requires that researchers clearly demonstrate that the biotech product is equally safe as its conventional counterpart. FDA assesses the crop and reviews whether the product possesses any undesirable traits (i.e., allergens). FDA testing includes:

- Assessment of the genetic material
- Allergenicity testing
- Comparison of the plant to its traditional counterpart

- Agronomic analysis – testing that compares how the product grows in the field
- Compositional analysis – what the plant contains, including nutrients, minerals, fatty acids, etc.

If there are ultimately no differences between the biotech plant and the conventional one, FDA deems the product “substantially equivalent” and “as safe as” its conventional counterpart. If there were any significant differences, such as nutritional content or allergenicity, the product would require special labeling.

EPA becomes involved when a plant contains a plant incorporated protectant, or PIP. A PIP is a genetically introduced material that helps the plant fight pests, fungi and/or diseases. In its review, EPA considers the following:

- Where the PIP is expressed and how, if at all, it would impact other organisms
- The PIP’s toxicity and allergenicity
- How the PIP would impact “non-target” organisms, such as plants and wildlife
- The long-term fate of the PIP and how it breaks down in the soil

Finally, the USDA studies the possibility of the biotech plant becoming a plant “pest” in the environment. Through the department’s Animal and Plant Health Inspection Service (APHIS), the agency reviews:

- Environmental consequences, including cross-pollination or “contamination” with other, non-biotech plants and what the impact might be
- Impact on wildlife, particularly if it feeds on the biotech crop
- How likely it is for the biotech crop to become a weed

## **In California**

California follows federal oversight of biotechnology in lieu of specific, state regulations on the issue. However, a Biotechnology Task Force and Advisory Committee were established in early 2002 to review the issue of biotech and develop a report for the state legislature. The Committee is organized through the California Department of Food and Agriculture and includes a variety of interests: the biotechnology industry, environmental groups, university researchers, state agency representatives, agricultural organizations and others. The Task Force expects to complete a report on the impact of biotechnology in California by the end of 2002.