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To: Members of the Legislature

Senate Bill 2065 (Costa, Chapter 589, Statutes of 2000) required the creation of the Food Biotechnology Task Force (comprised of the Secretaries of the Health and Welfare Agency, the Technology, Trade and Commerce Agency, and the Department of Food and Agriculture) in order to identify and analyze emerging food biotechnology issues considered of primary importance to the state.

As a first step in this process, the Department contracted with the California Council on Science and Technology, as encouraged by the legislation, to prepare a scientific overview assessing current research on food biotechnology. The Department submitted this manuscript to the Legislature in July 2002.

The recently completed final report builds upon the previous scientific overview and includes an analysis of the emerging food biotechnology issues of primary importance to Californians. This report includes input from the Food Biotechnology Advisory Committee, consisting of various industry and environmental representatives, policymakers, and academic experts. The principal concerns raised in the report center on food biotechnology's potential benefits and risks to human health, to the state's economy, and to the environment. These include:

- The need for further investigation of existing federal and state evaluation and oversight procedures;
- Domestic and international marketing issues;
- Agricultural production, sustainability, waste management, organic farming and other unique California issues, such as crops for which California is the nation's sole producer;
- The need for well-designed long-term studies on environmental and health effects; and
- The need for effective communication with consumers.

The purpose of the report is to identify issues and provide information, rather than offering policy recommendations. There is a range of competing considerations and interests that needs to be sorted in public processes. We hope that the report contributes to informed deliberations resulting in good public policy.

This report is available at <http://www.cdfa.ca.gov/exec/scienceadvisor/index.htm>. For a hard copy, please contact Legislative Policy Analyst John Moffatt at (916) 654-0321 or [jmoffatt@cdfa.ca.gov](mailto:jmoffatt@cdfa.ca.gov). If you have any questions, please contact me at (916) 654-0433 or [msen@cdfa.ca.gov](mailto:msen@cdfa.ca.gov).

Sincerely,

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# A FOOD FORESIGHT ANALYSIS OF

## AGRICULTURAL BIOTECHNOLOGY

*A Report to the Legislature*

January 1, 2003

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for the

**Food Biotechnology Task Force**

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## Methodology

Governor Gray Davis signed Senate Bill 2065 in September, 2000, giving three state agencies a stake in defining what California's role will be in food biotechnology. SB 2065 directed the creation of the Food Biotechnology Task Force (FBTF) consisting of the Secretary of the California Health and Welfare Agency (CHWA), the Secretary of the California Trade and Commerce Agency (CTCA) and the Secretary of the California Department of Food and Agriculture (CDFA). CDFA was designated the lead agency. The task force shall report issues studied, finds, basis for their findings and recommendations to the Governor and Legislature by January 1, 2003.

The legislation requires the California Department of Food and Agriculture to inform legislators of current food biotechnology acceptance issues (both pro and con). Nuffer, Smith, and Tucker was contracted to produce a broad-based analysis of issues relating to the growth of food biotechnology in the state, and a strategic analysis of key factors that are shaping the future of food biotechnology in California. The methodology used for this report is the *Food Foresight*\* process.

Research for this trends' report included:

- Review of multi-year *Food Foresight*\* analysis of biotech trend;
- Interviews with key influentials among the stakeholder universe (including representative sample of Food Biotechnology Task Force);
- Review of stakeholder Websites;
- A media search;
- Review of consumer perception research.

A trend is a compilation of multiple sources, therefore there is no single source cited in many cases.

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\**Food Foresight* is a trends analysis collaboration between Nuffer, Smith, Tucker, Inc and the California Institute of Food and Agricultural Research at University of California, Davis.

*Food Foresight* provides trends intelligence for anticipating, planning for, and managing trends/issues likely to impact the agri-food chain. Twice a year, information is collected across numerous data bases with implications drawn by a multidisciplinary blue ribbon panel of experts.

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## Executive Summary

### Agricultural Biotechnology – Now and the Near Future

It's still too early to tell how influential agricultural biotechnology will become in shaping the future of the world's food supply. Acceptance and adoption are likely to take longer than proponents originally envisioned with more consumer, regulatory, farm practice and trade strategies needed to meet new demands.

The National Academy of Sciences recently reported on new challenges for future biotechnology products. The current regulatory review processes will need to improve to deal with the risks of engineered crops that contain complicated genetic engineering as well as with crops engineered to produce substances for non-food uses, such as pharmaceutical products, industrial chemicals, or fuel.

In order to be successful, government's various regulatory roles and responsibilities will need to be coordinated. There is concern among industry about complying with a patchwork of laws state-by-state.

Across many stakeholder groups there are recommendations to reassess U.S. regulatory systems and processes and update them based on the realities of genetic engineering technologies. Pre-market regulation strategies are often cited. Gene flow and health issues, such as allergenicity, are cited as concerns, especially with regard to second and third generation GE\* products. "Biopharming"- producing crops for a wide variety of pharmaceuticals - and GE application to animals have heightened concerns.

There is less agreement on whether mandatory labeling is a strategy to fully meet consumer and industry needs. It's difficult to argue against a consumer's right to know but industry fears labels will be interpreted as warnings and is not prepared to handle the management and cost issues of a mandatory labeling system.

Expect trade disputes on the horizon. If the E.C. adopts its current GE proposals, billions of dollars could be lost in trade. Even though farmers see production benefits with GE crops, international pressure may lead more farmers to question planting GE crops for fear of lost markets. The current "holding position" for GE wheat is but one example.

The E.U.'s "precautionary principles", which require that a technology or technique be entirely safe, could become the norm in international markets. Although with the advent of countries with large populations - such as China and India - embracing GE research, some in the international community may soften their positions for fear of losing a competitive advantage.

\*Agricultural biotechnology products are described in this report as genetically engineered (GE) rather than genetically modified. Genetically modified can be defined as including traditional breeding methods.

Uncertainty and mistrust is pervasive. The success of agricultural biotechnology hinges on acceptance - of stakeholders and consumers - not only in the U.S. but also in the growing number of markets around the world raising roadblocks. Objective sources of information are critical. This is an opportunity for credible organizations and/or scientists.

In a major miscalculation, the industry counted on public recognition and acceptance of the "rich potential" of the science. Instead, most consumers in the U.S. are apathetic, while non-government organizations (NGOs) fill the void with a well-orchestrated opposition that has fueled resistance from governments around the world (with exponential growth for natural and organic segments).

Consumer opinion polls don't paint a clear picture of where the consumer will fall out on acceptance of agricultural biotechnology. Currently, it appears consumers want labeling but when questioned further, genetic engineering doesn't appear to be a top priority for most Americans. It is hard to judge whether this is a tinderbox waiting to be ignited. The questions in need of answers are not as much about science as they are about social acceptance.

Simply providing the facts is not the savior some hope it will be as knowledge doesn't necessarily correlate to public acceptance, particularly when there are so many unknowns. Education can demonstrate the benefits of agricultural biotechnology - better taste, optimal health and positive environmental benefits. But education also provides a platform for discussions about risk. Success will require careful listening – not for persuasion, but for understanding public anxieties and anger – and making adjustments to public concerns.

Most believe bioengineered products with nutritional benefits will not appear until later in the decade. So, describing this type of consumer benefit may be premature.

It's difficult to make predictions on how consumers will react in the next couple of years. Industry blunders have definitely set the time clock back. Since food creates such strong emotional ties, some question now whether medical breakthroughs will have the positive rub-off on agricultural biotechnology once assumed.

A likely scenario finds some products gaining acceptance while others do not, depending on their benefits and the strategies employed to satisfy public concerns. Niche markets will emerge for those who can segregate and label but, as described in this report, it is easier said than done. There are likely to be markets for second-and third-generation GE products with improved nutritional qualities and pharmaceutical applications.

## The Situation for Agricultural Biotechnology Today

The issue of agricultural genetic engineering involves a variety of stakeholders from gut-strong philosophical passion to apathy. The continuum of beliefs generally extends from "sound science holds all answers" at one end to "some things should be out of human control and hold unknown consequences" at the other. Those on the extreme poles find it difficult to understand each other and it's probably impossible to expect a change of heart or compromise in the name of consensus.

Those at the center of the belief continuum tend to be apathetic or asking "what if" questions but their opinions are not irreversible. That is, I lean this way today, but with this or that piece of information or the right amount of trust, I can modify my position.

The Food and Drug Administration (FDA) views current GE foods as "entirely safe." A Government Accounting Office study reports no difference in the inherent risks to human health between GE and conventional foods. According to the report, pre-market testing on GE foods is adequate to assess their safety.

Future products will pose new challenges, according to a recent report, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, issued by the National Academy of Sciences (NAS). NAS contends current regulatory review processes need to better address the risks of future GE crops containing more complicated gene modifications. Second-generation crops will be engineered to improve nutritional quality and to produce non-food uses like pharmaceutical products, industrial chemicals and fuel.

Proponents advocate that regulations for GE products should not be any more stringent than conventional foods. Critics think lack of adequate regulatory systems is at the core of current problems.

The first biotechnology-derived crops were commercialized in 1996. This first line of products – a series of pest repelling (*Bt*\* crops) and herbicide-resistant crops – clearly demonstrated benefit to farmers but not consumers.

The biotech industry counted on public recognition and acceptance of the "rich potential of the science." Instead, most consumers in the U.S. have remained rather apathetic while non-government organizations (NGOs) filled a void with well-orchestrated opposition. This resulted in resistance from some governments around the world (and exponential growth for natural and organic market segments).

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\**Bacillus thuringiensis* (*Bt*) is a naturally occurring microorganism producing a toxin that only kills insect larvae. The genetic information that represents the toxin has been identified and through biotechnology has been moved into plants to make them insect tolerant.

Last year, more than 100 million acres of the world's most fertile farmland were planted with bioengineered crops. The principal GE crops grown are soybean (63 percent), corn (19 percent), transgenic cotton (13 percent) and canola (5 percent). Only 4 countries account for 99 percent of the global GE acreage, with the U.S. occupying 68 percent, followed by Argentina (22 percent), Canada (6 percent) and China (3 percent).

More than 75 percent of this year's U.S. soybean harvest is expected to be bioengineered with herbicide-resistant varieties planted on 90 percent of farms producing soybeans.

California's highly diverse agriculture has limited experience with GE crops. The most extensive commercial GE crop produced is cotton. Cotton, the state's second largest cash crop, is an important domestic and export crop. In 2001, GE cotton accounted for 36 percent of California's cotton acreage.

California's research laboratories have developed and are field testing about 30 varieties of GE crops; however, the costs of registration and concerns regarding acceptance have delayed their entry into the market place.

The biotechnological expectations for California's fruit and vegetable industries lie in the creation of product engineered for better taste and more nutrition. Bioengineered produce lines reviewed by FDA in the last decade include corn, tomatoes, potatoes, squash, sugar beets, radicchio and cantaloupe.

One line of cantaloupe was reviewed for delayed ripening. Six lines of tomatoes were reviewed for delayed softening or delayed ripening. Zeneca Limited patented a method for the genetic engineering of fruit, especially bananas, to improve ripening characteristics. The cancer-fighting antioxidant lycopene content of tomatoes is being enriched.

Bioengineered fruits and vegetables from California produce industries are not likely to be seen until later this decade. According to reports from biotechnology companies, creating bioengineered specialty fruits and vegetables is too complex and costly in light of the public controversy and limited acreage. Staple crops – like corn and soybeans – were among the first targets because they are planted in very large quantities as ingredients for processed foods. Fresh fruits and vegetables, on the other hand, reflect smaller, more fragmented industries.

In the United States, approximately 70 percent of processed foods in grocery stores contain bioengineered ingredients, making them ubiquitous in the food supply here. Most U.S. food manufacturers continue to use GE crops insisting they are safe and far too pervasive to avoid with relatively few consumers concerned enough to stop purchases.

## The Situation for Agricultural Biotechnology Today *(continued)*

However, non-governmental organizations opposing biotechnology are targeting some of the more visible brands in an attempt to influence their policy on biotechnology. Under threats of protests, a number of companies have retreated from GE ingredients. Among them are Starbucks, Novartis (Gerber baby foods, Ovaltine, Wasa crackers), H.J. Heinz, McDonald's and Pepsi-Co's Frito Lay unit. Retailers Whole Foods, Wild Oats and Trader Joe's have also pledged to remove GE ingredients from store brands. The major chains are also targeted. Expect this pressure to continue and NGOs to become more powerful as marketing channels become more transparent and brands become more important to both manufacturers and retailers.

A number of companies are pulling back on research and development investments in GE foods until there is more evidence of public support for biotechnology. Monsanto, for example, is reportedly waiting until 2007 or 2008 before introducing high-protein soybeans and corn with no saturated fat and fewer calories. Getting a GE product to market can cost tens of millions of dollars and takes about seven years from field trials to application for FDA approval.

The primary concern for the U.S. agriculture is one of economics.

The primary concerns raised in the public debate on agricultural biotechnology include:

- Potential for allergenicity;
- Potential for development of *Bt*-resistant insects and herbicide resistant weeds;
- Potential for gene flow;
- Lack of systems to regulate safety (test, track, monitor, inform);
- Insufficient information to make comfortable choices;
- The impact of worldwide regulations on U.S. trade.

In the end, public acceptance of agricultural biotechnology will come down to perceived consumer benefit. Consumer benefit is yet to be clearly demonstrated.



## Analysis of Benefits of Agricultural Biotechnology

Fewer pesticides, better pest control and potential for improved nutritional traits are the most often cited benefits of agricultural biotechnology. "Biopharming" is just beginning to be viewed for its possible benefits. The improvement of agronomic traits and the ability to feed the hungry are also among the benefits cited.

### Reduction in use of pesticides, insecticides and herbicides

Biotechnology can create a production environment where fewer chemicals are needed to produce food. *Bt* crops reduce herbicide application for cleaner soil and water. The crops also help with no-till farming\*, which minimizes soil erosion. No tillage crop production methods can reduce modern agriculture's impact on global warming by 88 percent, according to research from Michigan State University.

A 2002 USDA report states that herbicide-tolerant crops do not increase dollar profits but do save significant amounts of farmer time and effort. *Bt* crops have effectively increased yields by reducing insect damage losses. The current generation of biotech crops was developed to decrease the use of insecticides and reduce the cost of production. *Bt* cotton use of chemical insecticides has decreased by 50 percent. *Bt* corn farmers report they often don't spray chemicals on *Bt* fields.

The National Center for Food and Agricultural Policy is a private non-profit, non-advocacy research organization. Its report on 40 case studies of 27 crops document that hardier crops, developed through biotechnology, can help Americans reap an additional 14 billion pounds of food and improve farm income by \$2.5 billion, while using 163 million fewer pounds of pesticides.

*Bt* cotton allows farmers to drastically reduce the amount of insecticides used. The USDA's Economic Research Service estimates a 2,000 ton reduction in the use of insecticides at a savings of \$178 million to cotton producers.

In an article in the "Food and the Future" supplement to the journal *Nature*, Anthony Trewavas writes, "the benefit of (GE) technology to the poorest farmers is palpable. To a cotton farmer working on a farm about a hectare in area, the use of *Bt* cotton has raised income by a quarter, cut costs by a third and slashed pesticide use by three-quarters."

One Nebraska farmer is planting 70 percent *Bt* corn because he doesn't have to monitor for evidence of corn borer infestations. This means that fuel costs are reduced. He also plants Round-Up Ready soybeans because it means fewer applications of herbicide and allows him to avoid clearing stubble off fields before planting, keeping more water in the ground and minimizing erosion.

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\*Undisturbed soil from harvest to planting

Researchers have field tested a herbicide-tolerant tomato that lets farmers use one general-purpose herbicide, rather than several chemicals to control weeds. The National Center for Food and Agricultural Policy estimates California farmers can cut pesticide use by 4.2 million pounds a year by adopting a bioengineered tomato.

According to an American Soybean Association report, farmers in the Midwest would have suffered more from the current drought had it not been for herbicide-resistant biotech crops allowing for more no-till farming.

### Pest control

Genetic engineering is being researched as a means to control agricultural pests. One example has the University of Florida patenting a way to implant a silkworm gene into grapevines to resist Pierce's Disease. The commercial availability of the vine will take five to 10 years. It's questionable whether California winegrowers will use GE applications since there is no industry consensus on its use and there are concerns over lack of consumer confidence.

### Nutritional value and taste

One strong biotechnology "promise" for consumers is the nutritional enhancement of food products. A Rockefeller Foundation report states that modern plant breeding and biotechnology offer new opportunities to increase the micronutrient content and enhance the nutritional value of staple foods for developing countries.

The hope is that phytochemicals can be enhanced through biotechnology to help prevent diseases and support optimal health. Researchers at Purdue University and the USDA's Agricultural Research Service developed a tomato with three times the amount of cancer-fighting antioxidant lycopene than conventional tomatoes. This is probably the first example of using biotechnology to increase the nutritional value of a fruit.

Golden rice is an example that has received much media attention. The rice, which has increased levels of beta-carotene and other carotenoids the body converts to Vitamin A, was to be distributed in developing countries such as India and the Philippines. Researchers believe the rice could help overcome Vitamin A deficiency affecting 124 million children. (These positive proclamations have been met with controversy. Critics say the rice doesn't contain enough vitamin-A precursor to make a difference and that diets of hungry children lack the fat and protein needed to convert it.)



## Analysis of Benefits of Agricultural Biotechnology *(continued)*

### Biopharming advantages

Some predict that future medicines will be made from GE foods. While the industries will overlap, pharmaceutical companies and food companies will likely go into different types of pharmaceuticals. Oral vaccines, produced in plants, for example, will decrease the need for needles and sophisticated health professionals to administer them. Potatoes, tomatoes and bananas are being tested.

The milk of transgenic cattle may provide an attractive vehicle for large-scale production of biopharmaceuticals such as the production of recombinant human lactoferrin.

It will be at least three to five years before these crops hit the market but ProdiGene, a company with a large number of drug and chemical-producing plants, says that 10 percent of the U.S. corn crop could be devoted to biopharming production by 2010.

A report by the Genetically Engineered Food Alert Coalition cites 300 locations now growing experimental pharmaceutical plants (including California). Experiments with corn, soy, rice and tobacco are producing drugs to act as vaccines and produce industrial and allergenic enzymes. USDA regulates these test plots while FDA monitors the manufacturing process. The two agencies are in the process of developing new guidance for these plants.

Senator Joe Lieberman sponsored legislation, SB 1764, that would offer biotechnology companies financial incentives to develop drugs, vaccines and diagnostic tests to fight bioterrorism.

### Biotechnology to feed hungry people around the world

Some experts see biotechnology as a key strategy to feeding the world's poor. Rockefeller Foundation statistics cite climbing numbers of chronically malnourished people and both biotechnology and ecologically sound agriculture as pieces of the solution.

In Asia, for example, some predict GE foods could increase the yields of wheat, rice and cereals by up to 20 percent. These crops can also grow in marginal soils and resist droughts. There is also a promise of food engineered to immunize people against infectious diseases and reduce vitamin deficiencies.

Researchers at University of California at Davis are developing crops to remove salt from the soil for storage in crop leaves. This kind of technology could make irrigated farming in the Arab world sustainable for the first time in history. Researchers at Cornell have developed several lines of GE rice that may be able to maintain their grain yields when grown in

cold, drought, or high salt conditions. If the GE rice were grown commercially, it could potentially increase rice yields by up to 20 percent.

African countries suffering famine recently refused U.S. aid because it included GE corn from the U.S. Three countries - Zimbabwe, Mozambique and Zambia - initially rejected the corn out of fear about safety and environmental implications. Following safety assurances from around the world, only Zambia continues to refuse shipments and South Africa and Japan have offered to supply them non-GE food.

### Altering survival agronomic traits

Biotech advances can improve overall food productivity by changing properties, such as salt tolerance or drought resistance, so plants can be grown productively in less-than-ideal soil conditions. Chinese scientists announced the use of seawater to successfully irrigate and grow GE crops of tomato, eggplant and hot pepper on beaches. Rice is the next target crop. Chinese scientists claim to have transferred genes from plants that can survive a salt-saturated environment into fresh-water crops. Some scientists are skeptical of the report. If the report is true and the crops are stable over time, it is estimated that saltwater-resistant crops could bring 40 million hectares of new land into cultivation - producing 150 million metric tons of agricultural products, about 30 percent of China's yearly output.

## Analysis of Concerns of Agricultural Biotechnology

Skeptics believe tampering with nature can alter species, harm wildlife and give rise to new problems, like herbicide-resistant "superweeds." They also worry about the long-term health consequences of eating foods with insecticides and foreign genes. Ethical-philosophical-religious considerations question whether humans should be engaged in genetic manipulations.

Among the specific concerns are gene flow or contamination of non-GE crops, regulatory processes for second- and third-generation products, allergens, antibiotic resistance and involvement by multi-national companies.

### Biotech pollution/ gene flow/ability to segregate crops

Concerns center on wind-blown pollen, commingled seeds and black-market plantings that have extended biotech products to the far corners of the globe – maybe irreversibly.

Most GE crops are soybean and corn planted in North and South America. But GE crops are being shipped to or experimented with in China, India, Australia and South Africa. They even turn up where people least expect them:

- In countries where they are banned but a black market has developed;
- In food supplies where they are forbidden or shunned, like organic products;
- In fields farmers believe are completely free of GE crops.

The September 2000 StarLink incident is the biggest illustration. StarLink, a GE yellow corn variety approved only for animal use, was discovered in 300 products ranging from taco shells to corn dogs. The corn is not approved for human consumption because of concerns about allergic reactions. A product recall cost food manufacturers \$1 billion. Many food manufacturers then switched to white corn. However, the FDA received a complaint about an allergic rash and found StarLink in corn chips made from white corn. While tests by the manufacturer could not duplicate the FDA's findings, the company now requires grain suppliers to perform extra tests on all white corn shipments.

This incident demonstrates the difficulty in keeping GE crops from spreading to other crops. It is proving all but impossible to prevent some commingling of conventional and GE ingredients. The mixing could happen at processing plants, during transportation or in the fields through cross-pollination.

Contamination is seen to be a widespread problem with non-GE farmers finding it hard to grow GE-free crops. U.S. maize exports to the European Union, for example, have all but disappeared because of the contamination issue.

Issues like crop-to-crop gene flow become more important as "identity preservation" and segregation of GE from non-GE crops become factors in marketing products.

Organic growers are very concerned about the "genetic pollution" of their crops. California is a national leader in organic agriculture. There are more than 2,000 organic producers in California representing more than 70 commodities.

The EPA took enforcement actions against two biotechnology companies whose plantings of experimental GE crops were found to violate the law. Mycogen Seeds, a unit of Dow AgroSciences, failed to isolate its experimental insect-resistant corn with a border crop of hybrid corn and failed to plant trees as windbreaks. Pioneer Hi-Bred International, a DuPont subsidiary, planted its experimental corn crop too close to other crops.

### Allergenic potential

Allergies have been the primary human health concern of agricultural biotechnology. It's a question of whether or not a novel protein produced through genetic engineering is allergenic. Extensive research on the current generation of GE foods approved for human use has shown these foods are safe. There are Codex guidelines for allergenicity testing. There is growing concern, however, that the second and third generations of GE foods that enhance nutritional quality, or have pharmaceutical properties may be more difficult to test for allergenicity.

A report from an EPA-, FDA- and NIH-sponsored conference *Assessment of the Allergenic Potential of Genetically Modified Foods* acknowledges the benefits of GE foods but recommends addressing allergenicity concerns. A report of the meeting from *Environmental Health Perspectives* calls for more validation of current methods of safety assessment and the need for developing alternative strategies, including animal models and immunoassays.

A Pew Initiative on Food and Biotechnology report, *A Snapshot of Federal Research on Food Allergy: Implications for Genetically Modified Foods*, found the science needed for government regulators to assess allergies in GE foods could be improved. Nine federal agencies or institutes currently supervise 33 food allergy research projects totaling between \$4.2 and \$7 million. The report found funds are spread thin with little coordination among federal agencies or between research teams. Most of the studies focus on known allergens, such as milk and peanuts, and few examine the allergenicity of novel proteins potentially introduced to foods through biotechnology.

## Analysis of Concerns of Agricultural Biotechnology *(continued)*

### GE animal concerns

Strong social, ethical and religious issues are raised with GE and cloned animals.

The future of GE and cloned animals is likely to be challenged for several reasons:

- Lack of scientific data;
- New novel biotechnology applications may not be adequately covered by current regulations and policies, which creates uncertainty for companies and consumers;
- More complex and more broadly applied technology may strain the technical and scientific capability of federal agencies;
- Costs and benefits associated with new biotechnology will put a strain on an already stressed agricultural production system.

There are fewer than 100 cloned animals on U.S. farms today. Each animal costs tens of thousands of dollars to produce. As cloning becomes more established and less costly, entire dairy herds may be cloned from the most prolific cows.

The *Washington Post* reports, "milk from cloned cows and meat from the offspring of cloned cows and pigs could show up on grocery shelves as early as next year under the plans of livestock breeders who are raising scores of clones on American farmsteads." The first cloned food products could include milk and veal from their first-generation offspring.

A National Academy of Sciences (NAS) report, *Animal Biotechnology: Science Based Concerns*, calls for additional studies but says the cloning technique is unlikely to affect the safety of the food supply. The FDA is reviewing whether clones, their byproducts or their offspring should be allowed into the food supply. The agency hopes to reach a decision by late 2002. There is concern for the welfare of cloned animals and their surrogate mothers, with some groups suggesting animal suffering.

An NAS report written for the FDA sees benefits if the technology is applied carefully but cites concerns about the risk of GE animals escaping into the wild and threatening native plants and animal species. According to the report, GE insects, shellfish, fish and other animals are mobile, escape easily and risk upsetting the delicate environmental balance. Concern is greatest for migratory animals (e.g., fish, mice, shellfish, insects) but not for domestic barnyard animals (e.g., poultry, dairy cattle).

The NAS panel reports no evidence of danger from cloned animals. More caution is urged for animals engineered to contain genes from other species. And there's a recommendation

that FDA examine safety concerns, such as new proteins prompting allergic reactions. The report cites the potential for producing meat with less fat or more protein, eggs with less cholesterol, or milk containing drugs or vaccines to fight disease. The panel recommends against allowing non-food products (e.g., drugs in milk) to enter the food supply but it is unclear whether or not there are adequate controls to prevent it.

The NAS panel raises concerns about the adequacy of regulations – now spanning several federal agencies – particularly the legal and technical capacity of the agencies to address potential environmental hazards. The panel recommends giving regulators the statutory tools needed to deal with non-traditional technology crossing traditional agency lines. The report addresses science-based but not psychological concerns.

### GE fish

Concerns about GE fish include health issues, environmental questions and considerations about what could happen to fish populations if GE fish make their way into the ocean. Britain has asked the U.S. to ban the fish or limit breeding to giant pens on land.

Aqua Bounty, a biotechnology company, is working to get FDA approval for GE fish. One FDA report concludes that GE fish escaping into the wild pose a risk to natural species, either through cross breeding or depleting food supplies.

A U.K. biotechnology commission called for new controls on GE and cloned animals, including a ban on GE fish. It fears GE animals could escape and interbreed with their wild counterparts. The commission also expressed caution about research that could lead to the release of GE insects.

Friends of the Earth opposes GE fish and supports grocers and restaurants that have pledged to avoid them. Well-known California restaurants and supermarkets such as Chez Panisse, the French Laundry, Citronelle, Babbo and Whole Foods Market are among 200 restaurants, grocers and seafood distributors boycotting bioengineered fish. The pledge was organized by the Center for Food Safety, Clean Water Action and Friends of the Earth.

While the California Department of Fish and Game is not formally prohibiting fish farmers from introducing GE fish into public waterways, it is not currently granting permits to use this biotechnology. It will not grant permits until the safety issues are resolved. The department is reviewing its regulations to determine whether they need updating.

## Analysis of Concerns of Agricultural Biotechnology *(continued)*

### Biopharming concerns

There are concerns that growing GE crops which produce pharmaceuticals in open fields raises the risk of novel proteins accidentally making their way into the food supply. This could happen through gene flow from cross-pollination between GE crops and other crops or from plants unintentionally mixing with commodity crops during harvesting, transport and processing. Problems could also occur from biopharming seed residues carried by farm equipment to conventional fields.

Although these novel proteins may be harmless if accidentally ingested, consumer groups and the food industry are concerned about public reactions. What would be the impact to the food chain if a mishap occurred? Would consumers question the safety of the food supply and avoid products? Some are concerned these proteins could cause harm to humans by causing medical reactions or allergies. And there are concerns that plants producing a high level of biologically active proteins could cause problems for soil organisms and any wildlife or livestock that inadvertently consumed crops.

Consumer advocates argue that the current federal regulatory system isn't up to the challenge of regulating plant-based pharmaceuticals. They want the process to be transparent to the public. Currently, companies can classify much of the information about crop development as confidential. There is concern that much of the experimental research is being conducted on corn, which is subject to cross-pollination issues.

In October 2002, the Biotechnology Industry Organization announced a plan by its member companies to limit growing areas for new GE pharmaceutical and industrial compound crops. It was a response to food processor concerns about GE crops contaminating the food supply. The plan caused an angry response from the governor of Iowa who fears it may stop Iowa farmers from producing certain value-added corn varieties. Concern heightened in mid-November when USDA ordered ProdiGene to destroy several thousand bushels of Iowa corn because the company had not followed stringent procedures to limit the spread of genes foreign to corn. In Nebraska, inspectors seized 500,000 bushels of soybean mistakenly mixed with a small amount of leaves and stalks from ProdiGene GE corn. The corn was engineered to grow a protein for a vaccine against a viral disease for pigs.

According to the Grocery Manufacturers Association (GMA), the incident represents a potential for unacceptable risk to the U.S. food supply. Concerned about the use of plant crops for pharmaceuticals, GMA wants the science and regulatory community to guarantee its separation from the food and feed supply. ProdiGene says its scientists are studying the possibility of growing these GE corn crops in parts of the

country where it will not contaminate the food supply. The company is working with USDA to design more rigorous procedures to contain its gene-altered grain.

### Release of new characteristics

Concerns are growing about the exchange of genetic material between GE foods and unaltered organisms within the environment. Potentially negative effects may include:

- Creating pests and pathogens with resistance to GE traits;
- Exacerbating the effects on existing pests through hybridization with related transgenic plants or animals;
- Harm to non-target species, such as soil organisms, non-pest insects, birds and other animals;
- Irreparable loss or changes in species diversity and genetic diversity within a species.

The successful adoption of *Bt* crops has led some to suggest the widespread use of *Bt* proteins in crops will lead to the development of insect populations resistant to these proteins. This means *Bt* crops and *Bt* sprays may be less effective in controlling these insects. As a safeguard, the U.S. Environmental Protection Agency requires registrants to implement science-based plans to minimize the potential for pest resistance to plant-expressed *Bt* proteins.

Some GE foods might possess genuinely new characteristics that may require much greater scrutiny in terms of scientific research than organisms produced by traditional techniques of plant and animal breeding.

### Antibiotic resistance

While research shows GE material in most GE foods poses no risk to human health, there is concern among some that GE crops with antibiotic-resistant marker genes inserted in them could compromise the ability to fight infection if such material passes to humans.

Research commissioned by Britain's Food Standards Agency (FSA) showed that DNA material from GE crops could find their way into the human gut bacteria of people whose lower bowel have been removed. An FSA spokeswoman acknowledged that low levels of DNA were detected but said there is no evidence affecting antibiotic resistance.

Although current research suggests no risk of antibiotic resistance, efforts are being made to remove the marker genes with support from organizations like the American Medical Association.

## **Analysis of Concerns of Agricultural Biotechnology** *(continued)*

### **Multinational company control**

Concern has been raised by some stakeholders about multinational companies and a fear that they will become "architects of life" for profit. There is concern that patenting GE seeds takes biotechnology out of the control of farmers.

### **Intellectual Property Rights**

In recent years, patents have become an important means of protecting innovations by crop breeders and producers of related technologies. To date, the bulk of private investment in biotechnology has focused on a small number of high-value crops. California's main crops have not been the prime targets of genetic engineering efforts by large agricultural biotechnology companies. If the development of GE crops for California's agriculture is left to the private sector, many applications of biotechnology to California crops are likely to be delayed or blocked altogether. Intellectual property rights favors well-financed private research companies and can limit collaborative private and public research efforts.



## Public Perceptions

### Opinion surveys

While public interest in labeling of GE foods and ingredients is high, when asked specifically about bioengineered foods, consumers tend to range from wariness to apathy -- although it is hard to judge whether public opinion is a tinderbox waiting to be ignited by an unexpected event.

### Consumers

A February 2002 survey by the Pew Initiative on Food and Biotechnology, which encourages balanced and objective dialogue on agricultural biotechnology, found 54 percent of Americans saying they've heard nothing or very little about GE foods. Nonetheless, 58 percent say they oppose modified ingredients in the food supply and 75 percent want to know whether their food has these ingredients. However, when told these ingredients are already in at least half the products on store shelves, almost 50 percent assume they must be safe.

The survey also found an American public evenly divided over whether GE foods help or hurt the environment. When asked to rank 13 environmental items (both risks and benefits), benefits score significantly higher than any risk listed, with the exception of affecting non-GE crops. Among Californians, all benefits outrank all risks.

"Initially, people tend to feel slightly more strongly about the risks of the technology, but react more positively when additional information is presented to them," says Michael Rodemeyer, executive director of the Initiative. "Simply put, it looks like the jury is still out."

When addressing this survey, the Pew publication, *Spotlight*, states that it isn't clear just how concerned people are about GE food crops, and polling data provides equivocal results. When asked directly whether they would like to have labels on GE foods, large majorities of consumers say yes. When asked open-ended questions about food safety, relatively few consumers mention GE ingredients.

An April 2001 survey from the Center for Science in the Public Interest (CSPI) found two-thirds of Americans want labels on bioengineered foods. Americans want to see labeling for unlabeled food processes. Examples cited include whether crops are sprayed with pesticides (76 percent) or imported (56 percent). Out of four choices, 17 percent rank GE labeling as a top priority. When told GE labeling will add \$50 or more to their annual food bill, only 28 percent continue to favor labeling.

An August 2002 poll by the International Food Information Council Foundation, an industry supported group, found 71 percent of Americans are likely to buy produce enhanced by biotechnology if it offers protection from insect damage and

requires fewer pesticide applications. Fifty-nine percent of those surveyed support FDA's labeling policy requiring disclosure on a food label only if biotechnology introduces an allergen or substantially changes the food's nutritional content.

A 2001 British NOP research group survey found consumers evenly split in their willingness to eat GE foods. Forty-eight percent say they will eat transgenic food and 44 percent say they won't. A similar survey, conducted last year, had 46 percent saying yes and 50 percent saying no.

Bioengineered animals evoke very deep emotions in people. A survey by sociologist Thomas Hoban of North Carolina State University found 26 percent of Americans saying it is morally wrong to genetically engineer plants and 53 percent saying it is wrong to engineer animals.

### Farmers

Farmers, for the most part, hold views similar to consumers while they continue to grow bioengineered crops.

An American Corn Growers Association July 2001 survey found 77 percent of farmers surveyed say they believe consumer and foreign market concerns about GE foods are very or somewhat important and 78 percent are willing to plant non-GE corn varieties to keep world markets open to U.S. corn. About half (56 percent) believe Congress should require labeling of GE foods and export cargoes. Yet the amount of transgenic corn varieties grown this year dipped by only 6 percent over last. Fifty-six percent say they are aware that competitor countries are capturing U.S. markets using non-GE marketing strategies. Japan decreased its imports of U.S. corn by 53 million bushels last year, replacing it with non-GE Brazilian and Chinese corn. Some 74 percent of survey respondents say they believe that rejection of GE corn by international markets is contributing to lower corn prices.

A 2001 Reuters farmer survey showed similar findings. Overall, it shows a 4 percent reduction in plantings of GE corn, soybeans and cotton with all declines coming from two varieties, Roundup Ready soybeans and *Bt* corn. Sixty percent of the farmers surveyed say the StarLink controversy had no influence on their planting intentions. Some say they believe StarLink frightened consumers and soured the appetites of some countries for U.S. grain exports at least in the short term. Eight of 10 farmers surveyed say they are not going to invest in segregating GE crops, despite growing demands around the world for testing of grain shipments.

## Trade Implications

U.S. exports of crops with a GE component face greater restrictions in foreign markets, according to a report from the General Accounting Office. This is a major concern for the export marketing of U.S. GE crops and products that contain GE ingredients. New regulations and guidelines that may further restrict exports of biotech products (e.g., labeling, traceability) are being enacted and considered by U.S. trading partners.

Currently, the trade impact to California cotton farmers has been minimal but it does pose a serious concern to the export of other California crops developed through biotechnology.

Some see consumer concerns about the safety of biotech as driving the trade issue. Others see obstacles raised as artificial trade barriers or a ploy to slow down biotechnology advances so countries not on the edge can catch up. Whatever the reason, there is concern that trade issues and foreign governments could derail agricultural biotechnology. On the other hand, countries with the world's largest populations, specifically China and India, are moving forward on the GE front and this could lead to more support for GE crops.

The U.S., as the single major producer of biotech food crops, has been relatively isolated in its efforts to maintain access to markets for these products. Corn, cotton and soybeans are major U.S. commodity exports and a large percentage of these crops are GE. Other GE crops grown in the U.S. include canola, squash and papaya. About 55 percent of U.S. canola in 2001 was GE. In 2000, 53 percent of papaya acreage in Hawaii was planted with GE varieties. Additional GE crops such as sugar beets, potatoes and sweet corn are commercially available but not accepted by growers.

### European Union

The U.S. and E.U. could be heading toward more severe trade disputes that could cost U.S. farmers billions of dollars. The disputes could also set precedence for how other countries view and regulate GE crops and ingredients.

In 1998, the E.U. blocked the approval of new agricultural biotech products and since 1997 has required mandatory labeling of GE foods. The U.S. has demanded that the E.U. lift its ban on new GE products, which costs U.S. corn growers about \$200 million a year in exports. The E.U. executive body did recommend lifting the ban, but six of the 15 E.U. governments (France, Italy, Denmark, Austria, Greece and Luxembourg) refuse to do so until labeling and traceability rules are in place.

The E.U. has banned GE foods on the basis of the "precautionary principle" under which regulators do not need to show scientifically that a biotech crop is unsafe before banning it; they need only show that it has not been proved harmless.

Some reasons that have been suggested for the E.U.'s reluctance to accept agricultural biotechnology include:

- Deep cultural connections to their food;
- Distrust of food-safety regulators and laws;
- Strong Green party.

In July 2001, the European Commission (E.C.) introduced a new set of stronger proposals to "restore confidence" in GE foods. The proposals call for strict labeling and tracing of all food and animal feed produced from GE crops. They do not call for labeling of meat or dairy products from animals fed GE crops or GE materials used in the manufacturing process.

On June 4, 2002, the Environment Committee of the European Parliament narrowly approved a stricter proposal. The Committee approved a measure to lower the threshold at which mandatory labeling would be required, from 1 percent (as proposed by the E.C. originally) to 0.5 percent per ingredient. Labeling is required of meat, eggs and dairy foods when the animals are fed GE crops. The proposal will probably be amended as it moves through the rest of the review and approval process.

As of early October 2002, the European Union governments had abandoned the idea of reaching an early agreement on the stringent biotech rules because of disagreements. For example, the British oppose labeling requirements for foods derived from biotech crops, such as highly processed corn oil, where the GE material is no longer scientifically detectable. Others want rules to go further, including meat and dairy products from animals fed GE feed, or question how much biotech material should be allowed to be present accidentally or unintentionally before a label is required.

On November 28, E.U. agriculture ministers agreed that food and animal feed containing more than 0.9 percent of any GE organism must be labeled. The agriculture ministers' decision still faces approval by the E.U. parliament, which may attempt to reduce the limit to 0.5 percent.

U.S. producers consider even 1 percent unworkable due in part to the cost of testing and **segregation**. Japan has set a 5 percent threshold.

A Pew Initiative on Food and Biotechnology report says the 2001 value of U.S. exports of agricultural products to the E.U. was \$6.3 billion. The main products exported were soybeans, tobacco and animal feed, including corn gluten. The value of E.U. exports of agricultural products to the U.S. was \$7.9 billion. The main products were wine and beer.



## Trade Implications *(continued)*

European Commission officials anticipate that the regulations could go into effect in 2002 or 2003. Once the proposals are put into action, the ban on approving new GE products will likely be lifted.

These stricter rules would further harm trade relations between the U.S. and the E.U. The U.S. has said it will probably take the E.U. to the World Trade Organization's dispute review board if these proposals are enacted.

U.S. government officials consider the E.C. proposals costly, unworkable, unnecessary and discriminatory against U.S. agricultural products. They believe they are discriminatory because E.U. exports like cheese and beer, produced using GE enzymes would not have to be labeled. The E.U. argues that when genetic engineering is not in the end product, consumers accept the product. The U.S. Economic, Business and Agricultural Affairs estimates these regulations will "effectively block \$4 billion of US exports to Europe" and that:

- U.S. farmers and food producers will have to segregate GE crops and foods derived from such crops at every step of the crop harvesting and food processing processes;
- Many foods cannot avoid labeling requirements of the proposed 1 percent threshold;
- Difficulty in accurately labeling all GE food products creates enormous liability and risk for U.S. exporters;
- Even if crops are segregated, some unintentional mixing of GE grains with non-GE grains is probable;
- Farmers will also need to prevent commingling during harvest, transport and storage by cleaning all equipment and on-farm storage facilities.

### Other countries

The picture of worldwide attitudes toward GE products is very complex. More than 30 countries require labeling of GE foods, including Japan, Korea, Thailand, China, Russia, South Korea, Indonesia, Australia and New Zealand. Ethiopia is wary of genetic engineering, while Kenya is pursuing the technology. Kenya has released a GE sweet potato. In South America, Argentina has embraced GE crops while they are yet to be approved in Brazil. China is pursuing its own GE crops and India has just approved GE cotton.

Mexico allows GE foods to be imported as long as they are labeled, but has not allowed GE corn to be planted there for fear of contamination of native corn. New Zealand recently banned GE imports. States in Australia have established zones where GE crops cannot be grown.

### Other trade issues

A Pew analysis reported the Codex Alimentarius Commission, established by the World Health Organization and the Food and Agriculture Organization of the United Nations, is in the process of developing international guidelines for countries that choose to establish mandatory labeling of GE food and food ingredients.

In March 2002, the Codex Intergovernmental Task Force of Foods Derived from Biotechnology adopted two standards for GE foods - principles of risk analysis and guidelines for conducting safety assessments. Traceability and food labeling were named as risk management tools. The Commission recommends testing and approval of GE food before release to the market. The potential for allergenicity is one of the safety characteristics it wants to assess.

The standards will be submitted to the next meeting of the Commission in July 2003 when countries will make further comments. The Commission will then adopt the standards or send them back to the task force for more debate. Some are concerned that Europeans are treating the Codex as an alternative forum for international trade agreements instead of a forum for setting international food safety and health standards.

In January 2000, the Cartagena Protocol on Biosafety aimed at providing a framework for assessing the environmental impact of bioengineered products that cross international borders, was adopted by more than 130 countries. It must be ratified by 50 countries before it goes into effect. Countries ratifying this protocol include India, Denmark, Austria with the 15 European Union nations joining in recent weeks.

## Regulatory Climate

A reoccurring theme in collecting data for this report suggests concerns about inadequate GE regulatory systems to ensure human health and environmental safety.

In the future, scientists expect genetic engineering to increasingly change the composition of GE foods to enhance their nutritional value. Current tests have been adequate for evaluating the few GE foods with relatively simple compositional changes. However, new testing technologies are being developed to evaluate the increasingly complex compositional changes expected.

At present, agricultural biotechnology products are regulated under a federal regulatory coordinating framework developed 15 years ago and based on laws that predate the advent of biotechnology.

California, like most states, follows federal oversight of biotechnology in lieu of specific state regulations on the issue. Food derived from GE sources is regulated under the same rules that govern conventional food. Some state agencies do request and review technical information regarding genetic engineering for research and experimental use permits. The state requires no special labeling, special permits, technical review of genetic engineering production methods or any special tracking of movement, sale or planted acreage. With the potential for more state regulatory involvement, it will be imperative that adequate laboratory capacity is available.

The White House is proposing new safety reviews to better protect consumers and to avoid the need for disruptive recalls. The Office of Science and Technology Policy suggests that crops undergo a preliminary safety assessment by FDA or EPA before field trials.

The voluntary assessment would look at whether the new protein introduced into the crop by gene splicing is toxic or will cause allergies. If a trait or protein presents an unacceptable risk or the risks cannot be determined adequately, then field-test-confinement requirements would be rigorous to restrict out-crossing and commingling of seed. The occurrence at any level of biotechnology-derived genes and gene products from these field tests would be prohibited in commercial seed, commodities, and processed food and feed. If crops are deemed not harmful, small amounts of contamination would not trigger health concerns or food recalls.

Field trials, now overseen by USDA, mainly look at environmental effects. The Office of Science and Technology Policy is asking USDA to amend criteria for allowing regulated materials into commercial seed and commodities if they pose no unacceptable environmental risk. The FDA and EPA look at the health aspects, but not until the crop moves closer to commercialization. Those assessments would still be made.

The Biotechnology Industry Organization, representing GE crop developers, supports the White House initiative as further assurance that the regulatory review process works. Dow AgroSciences supports third-party audits of their biopharming facilities. The Grocery Manufacturers of America prefers a mandatory safety assessment.

The Center for Food Safety, an opponent of GE foods, sees the proposal as a step in the right direction but too little too late. The group wants to make sure this is not a disguise to bail out companies if their experimental crops end up in food.

The National Research Council makes several recommendations similar to the White House initiative. The Council wants to strengthen various aspects of federal oversight and establish a coordinated regulatory approach to update field testing requirements of GE plants and to establish early food safety assessments for new proteins intended for food or feed use.

That National Academy of Sciences calls for more information and oversight in its report, *Environmental Effects of Transgenic Plants*. While the report complements improvements in the regulatory process, it asks USDA's Animal Plant Health Inspection Service (APHIS) to sharpen its watch on GE crops and look at potential effects of GE plants, above and beyond the direct effects tested by company developers. One way is to track them once they've been released to the public. The Biotechnology Regulatory Unit under APHIS was recently created to focus on GE crops.

In May 2002, several consumer advocacy groups (Center for Science in the Public Interest, Environmental Defense, Consumer Federation of America, the Union of Concerned Scientists, the Institute for Environment and Agriculture) and the Whole Foods Market grocery chain wrote Health and Human Services Secretary Tommy Thompson asking for finalization of a ruling to require premarket notification of bioengineered foods. The rule would not require government approval for GE foods.

A pre-market notification rule would improve the regulatory system, but advocacy groups want new legislation requiring a mandatory pre-market approval process for GE foods. Currently, the FDA only reviews safety data on biotech crops provided by seed companies on a voluntary basis. The FDA has a mandatory approval process for GE foods. The EPA has a mandatory approval process, including a food-safety component, for crops that have pesticides engineered into them.

In a paper presented to the National Agricultural Biotechnology Council's Food for Health conference on *How to Approach the Regulatory Conundrum?* Gregory Jaffe of Center for Science in the Public Interest said that without

## Regulatory Climate *(continued)*

additional legal authority and stronger oversight, the U.S. regulatory system cannot ensure that agricultural biotechnology products are safe for humans and the environment, especially as we move to commercialize the next generation of GE crops. These crops are trumpeted to be more nutritious foods and the plants will be used to produce pharmaceutical antibodies and industrial enzymes.

The U.S. Public Interest Research Group sees the USDA's regulation of GE crops as inadequate and that APHIS decisions lack scientific rigor in part because of the agency's lack of technical capacity. The group supports the need for a more transparent regulatory system. They also want systematic monitoring of the effect of GE crops on crop and soil ecology.

Consumer Federation of America's Carol Tucker Foreman says those who manufacture and sell food have a moral and legal responsibility to assure their products are safe to eat. When determining what is "safe," she thinks the adopted standard must be rooted in the best available scientific data and analysis and that the standard needs to reflect more than science.

"Science helps us estimate risks and the benefits, but determining what risk and how much risk is acceptable are value judgments," says Tucker Foreman. She says government officials chose speeding products to market over rigorous regulatory scrutiny and pre-market safety approval. This, she says, has undercut consumer confidence in these products.

"A new approach for the FDA would be a law that required the agency to conduct a comprehensive scientific evaluation of biotech products, approve them as safe before they go on the market and explain to the public the agency's reasoning in approving them," Tucker Foreman said.

"A formal statement verifying safety would advance public trust in the food safety system, public confidence in the safety of GE foods and, ultimately, public acceptance of agricultural biotechnology," said Tucker Foreman.

### Labeling

The FDA requires labeling of GE foods only if there is a significantly different nutritional property, or if a new food includes an unexpected allergen. FDA's position is that engineered food is no different than conventional food and needs no labels to reveal production details.

According to Health and Human Services Secretary Tommy Thompson, the Bush administration opposes the labeling of GE food because it "will only frighten the consumer." The administration would like to see more marketing done on the safety of biotechnology products.

Many within the food industry believe current FDA labeling requirements are adequate since mandatory labels might be perceived as a warning. This, they say, is inappropriate since GE foods don't represent a health or safety threat.

Other groups believe mandatory labeling will give consumers the information needed to make decisions about what to include in their diets. It's a consumer's "right to know" argument, acknowledging that people make food decisions based on factors other than safety. Some consumers want labeling because it helps them choose foods that they believe are a better product—more tasty, more nutritious, more environmentally friendly.

There are market mechanisms in place today to separate some GE foods. For example, conventionally-grown produce has a PLU bar code sticker with four numbers, organically-grown fruit has five numbers prefaced by the number 9 and GE fruit has a five-numbers PLU prefaced by the number 8.

In 2001, the FDA proposed voluntary guidelines for labeling food that does or does not contain GE ingredients. Companies that want to label food non-GE will have to wait until the FDA decides how to make sure a label is true. The food would have to be tested by the companies and checked periodically by federal inspectors. Food developers would have to notify FDA at least four months before putting a new GE food on the market, and the scientific description of the product would be posted on the Internet during this time.

FDA work to date suggests that a label might read something like:

- We do not use ingredients produced using biotechnology;
- This oil is made from soybeans that were not genetically engineered;
- Genetically engineered;
- This product contains cornmeal that was produced using biotechnology;
- This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat.

The FDA recently sent letters to several organic food companies warning them not to label their products GMO-free because it is misleading to suggest that GE ingredients are inferior. And traditional selective breeding methods – crops with ideal traits bred together — are also considered to be GE.

Accurate labeling requires an extensive identity preservation system from farmer to elevator to grain processor to food manufacturer to retailer. Testing would have to be done at various steps along the food supply chain. A recent study by

## Regulatory Climate *(continued)*

the Canadian government estimated mandatory labeling would cost that country's consumer \$700 million to \$950 million annually.

Impatient with labeling progress at the federal level, a group of stakeholders put a ballot proposition on the ballot in Oregon (fall 2002). An industry alliance (including Monsanto, Grocery Manufacturers Association and others) waged a multi-million dollar campaign to handily defeat the issue with the argument that GE ingredients were already in most foods and food costs would go up. More than 70% of the voters cast a no vote.

Some countries around the world already require labeling, including the European nations, Japan, Russia and Australia. The European Commission food-labeling proposal requires labels on all foods produced by genetic engineering, regardless of whether detectable DNA or proteins are in those products.

The Canadian Biotechnology Advisory Committee recommended voluntary labeling of GE foods saying that GE foods pose no risk to human health. The committee suggested the federal government institute clear guidelines for labeling, monitor the situation for five years and consider mandatory labeling if a voluntary system doesn't work.

Requiring labeling can create problems. In Australia, the *Daily Telegraph* reports thousands of GE foods remain free of labels despite a labeling law. Regulators and manufacturers admit it is impossible to know how many food items contain one of the approved GE products. The Australia and New Zealand Food Authority say labeling didn't go as far as some people wanted but tougher regulations would have encountered enforcement problems.

Colorado State University's Department of Soil and Crop Sciences cites a number of questions professors there would like to see answered prior to a mandatory labeling:

- What specific technologies for crop variety development would require a label? Most target GE, but some legislative efforts have defined the term "genetically modified" to include techniques used by plant breeders before genetic engineering.
- What percentage of a GE ingredient must be present in a food before a label is required? One percent is commonly proposed, but figures ranging from 0.1 to 5% have been suggested.
- Would meat and dairy products derived from livestock-fed transgenic crops require a label? Biological rationale for doing so has not been demonstrated since DNA or protein from inserted genes have not been found in livestock products.

## Legislative Climate

During May (2002), Congressman Dennis Kucinich and 23 of his colleagues introduced legislation governing GE food and crops which was referred to house subcommittees:

- Genetically Engineered Food Right to Know Act of 2002 (H.R. 4814) – requires food companies to label all foods containing ingredients from GE plants or animals;
- Genetically Engineered Food Safety Act of 2002 (H.R. 4813) – improves FDA oversight and testing of transgenic foods;
- Genetically Engineered Crop and Animal Farmer Protection Act of 2002 (H.R. 4812) – restores traditional farmer rights to save seed;
- Genetically Engineered Organism Liability Act of 2002 (H.R. 4816) – clarifies and reforms liability and other legal issues associated with GE crops and foods;
- Real Solutions to World Hunger Act of 2002 (H.R. 4815) – expands research to help developing nations better feed themselves.

The Sierra Club, National Farmers Organization, Center for Food Safety, Organic Trade Organization and American Corn Growers Association endorsed the legislation.

The Pew Initiative on Food and Biotechnology reports in 2001 that 22 governors signed 22 state bills regarding agricultural biotechnology, with nearly two-thirds of these laws increasing penalties for crop destruction. State legislatures also sought to protect farmers from economic losses arising when GE seed or pollen commingling with conventional crops. These GE liability bills were opposed by the Biotechnology Industry Organization.

Eleven states introduced labeling measures to identify foods containing any ingredient from a GE crop:

- Maine passed a law permitting the voluntary labeling of GE-free products;
- Several states considered bills placing a moratorium on planting GE crops. Montana, worried about GE wheat, wanted to ban growing it to ensure it would only become available when it was acceptable to foreign markets;
- Vermont and New York, with prominent organic farming industries, debated wide-reaching moratorium bills with a New York bill seeking a five-year moratorium on GE crops;
- Maryland enacted a law prohibiting the release of GE fish into the Chesapeake Bay;
- Massachusetts, North Carolina and Hawaii considered laws to regulate growing and marketing of certain GE crops;

- North Dakota Senator Bill Bowman plans to introduce legislation giving farmers in his state the right to sue biotech companies for damages if their wheat is contaminated by GE grain. The North Dakota Legislature's agricultural committee endorsed a bill to establish a state board to monitor the development of GE wheat.

Maine is considering a bill that would seek a three-year moratorium on growing GE crops. Several bills in California were introduced that would prohibit the import, transport, possession or release into California any live transgenic fish.

States enacting agricultural biotechnology legislation could result in a national patchwork of laws that vary from state to state.



## Resources

**A trends' synthesis report reviews many sources of information to investigate an issue. Some of the background information sources gathered in preparation of *A Food Foresight Analysis of Agricultural Biotechnology* include:**

## Reports

*A snapshot of federal research on food allergy: implications for genetically modified foods*  
Pew Initiative on Food and Biotechnology, Bloomberg School of Public Health, John Hopkins University

*Animal biotechnology: science based concerns*  
National Academy of Sciences

*Benefits and risks of food biotechnology*  
California Council on Science and Technology

*Biotech briefs*  
Office of the Agricultural and Environmental Science Advisor  
California Department of Food and Agriculture

*Biotech crop use benefits environment*  
The Council for Agricultural Science and Technology

*Biotechnology and globalization project*  
Harvard University, Center for International Development at Harvard University, Belfer Center for Science and International Affairs at Harvard University, Kennedy School of Government and Rockefeller Foundation

*Biotechnology communications workshop for food and agriculture*  
California Institute of Food and Agricultural Research  
UC Systemwide Biotechnology Program  
International Food Information Council

*Comparative environmental impacts of biotechnology-derived and traditional soybean, corn, and cotton crops*  
Council for Agricultural and Science Technology

*Environmental effects of transgenic plants: the scope and adequacy of regulation*  
National Academy of Sciences

*Let the facts speak for themselves: the contribution of agricultural crop biotechnology to American farming*  
American Soybean Association, American Agri-Women, National Chicken Council, National Corn Growers Association, National Cotton Council, National Milk Producers Federation, National Potato Council, National Turkey Association, United Soybean Board

*Seeds of doubt*  
Soil Association

*The safety of foods produced through biotechnology*  
Society of Toxicology

## Resources *(continued)*

### Websites

Ag Biotech InfoNet (search engine on scientific reports and technical analysis on emerging issues sponsored by Science and Environmental Health Network, Institute for Agricultural and Trade Policy, Consumer Policy Institute/Consumer Union, Council for Responsible Genetics, Benbrook Consulting Services)  
[www.biotech-info.net](http://www.biotech-info.net)

AgBioWorld Foundation (academics, independent scientists, non-profit researchers' foundation)  
[www.agbioworld.org](http://www.agbioworld.org)

AgricultureLaw (McLeod, Watkinson & Miller Attorneys at Law)  
[www.agriculturelaw.com](http://www.agriculturelaw.com)

Alliance for Better Foods (agriculture and food-related groups)  
[www.betterfoods.org](http://www.betterfoods.org)

American Enterprise Institute for Public Policy Research (think tank with resident scholars and fellows)  
[www.aei.org](http://www.aei.org)

Biotechnology Industry Organization (biotechnology trade organization)  
[www.bio.org](http://www.bio.org)

Brookings Institution (research, analysis, education, and publication focused on public policy issues)  
[www.brook.edu](http://www.brook.edu)

California Council on Science and Technology (partnership of industry, academia and government that identifies ways that science and technology can be used to improve California's economy and quality of life)  
[www.ccst.us](http://www.ccst.us)

California Department of Food and Agriculture  
[www.cdfa.ca.gov/exec/scienceadvisor](http://www.cdfa.ca.gov/exec/scienceadvisor)

Campaign to Label Genetically Engineered Foods (support legislation to require labeling of genetically engineered foods)  
[www.voteyes27.com](http://www.voteyes27.com)  
[www.thecampaign.org](http://www.thecampaign.org)

Center for Food Safety (promotes sustainable agriculture, organic food standards and protect consumers from hazards of genetically engineered foods)  
[www.centerforfoodsafety.com](http://www.centerforfoodsafety.com)

Center for Science in the Public Interest (nutrition advocacy organization)  
[www.cspinet.org](http://www.cspinet.org)

Centocor (biopharmaceutical company)  
[www.centocor.com](http://www.centocor.com)

Congress of the United States, House of Representatives  
[www.house.gov](http://www.house.gov)

Consumers Union (Consumer Policy Institute promotes consumer interest through research and education)  
[www.consumersunion.org](http://www.consumersunion.org)



## Resources *(continued)*

## Websites *(continued)*

Council for Agricultural Science and Technology (consortium of scientists)  
[www.cast-science.org](http://www.cast-science.org)

Council for Biotechnology Information (Council of biotechnology companies and trade associations)  
[www.whybiotech.com](http://www.whybiotech.com)

Cropchoice.com (alternative news and information source for American farmers and consumers)  
[www.cropchoice.com](http://www.cropchoice.com)

Environmental Defense (protecting the environmental rights of all people)  
[www.environmentaldefense.org](http://www.environmentaldefense.org)

Farm Progress (agricultural publishing)  
[www.farmprogress.com](http://www.farmprogress.com)

Food and Agriculture Organization of the United Nations  
[www.fao.org](http://www.fao.org)

Food and Drug Law Institute (manufacturers and suppliers of medicines (pharmaceuticals, biologics and biotechnologies), medical devices, food and cosmetics subject to regulation by FDA)  
[www.fdi.org](http://www.fdi.org)

FoodFirst (Institute for food and development policy – solutions to hunger and poverty around the world and to reform the global food system)  
[www.foodfirst.org](http://www.foodfirst.org)

Foodfuture (Food and Drink Federation – UK food and drink manufacturing industry)  
[www.foodfuture.org](http://www.foodfuture.org)

Friends of the Earth (federation of autonomous environmental organizations)  
[www.foei.org](http://www.foei.org)

Genetically Engineered Food Alert (coalition of seven organizations for testing and labeling genetically engineered food – Public Interest Research Group, National Environmental Trust, Institute for Agriculture and Trade Policy, Organic Consumers Association, Friends of the Earth, The Center for Food Safety, Pesticide Action Network of North America)  
[www.gefoodalert.org](http://www.gefoodalert.org)

GenomeWeb (online news and information covering the business and technology of genomics and bioinformatics)  
[www.genomeweb.com](http://www.genomeweb.com)

Grand Forks Herald (Grand Forks newspaper)  
[www.grandforks.com](http://www.grandforks.com)

Greenpeace (expose global environmental problems and force solutions)  
[www.truefoodnow.org](http://www.truefoodnow.org)

Grocery Manufacturers of America (association of food, beverage and consumer product companies)  
[www.gmabrands.com](http://www.gmabrands.com)

Initiative for Future Agriculture and Food Systems (address critical emerging agricultural issues)  
[www.reeusda.gov/ifafs](http://www.reeusda.gov/ifafs)

## Resources *(continued)*

## Websites *(continued)*

Institute for Agriculture and Trade Policy (promotes resilient family farms, rural communities and ecosystems)  
[www.iatp.org](http://www.iatp.org)

International Food Information Council Foundation (supported by broad-based food, beverage and agriculture industries)  
[www.ific.org](http://www.ific.org)

International Service for National Agricultural Research (fosters sustainable and equitable agricultural development in developing countries)  
[www.isnar.org](http://www.isnar.org)

Just Food (online portal for food industry)  
[www.just-food.com](http://www.just-food.com)

Keep Nature Natural (campaign for labeling and establishment of safety standards for genetically engineered foods)  
[www.keepnatural.org](http://www.keepnatural.org)

Life Sciences Network (Australian/New Zealand companies/associations to promote strategic economic opportunity from the application of biotechnology)  
[www.lifesciencesnetwork.com](http://www.lifesciencesnetwork.com)

MSNBC News  
[www.msnbc.com](http://www.msnbc.com)

National Post (Canadian newspaper)  
[www.nationalpost.com](http://www.nationalpost.com)

Nature Biotechnology (scientific publishing arm of Macmillan Publishers Ltd)  
[www.nature.com](http://www.nature.com)

New York Times  
[www.nytime.com](http://www.nytime.com)

Observe (Italian non-profit research center on scientific research, political decisions and public opinion)  
[www.observanet.it](http://www.observanet.it)

Office of Science and Technology Policy (federal interagency effort to develop and implement sound science and technology policies)  
[www.ostp.gov](http://www.ostp.gov)

Official California Legislative Information  
[www.leginfo.ca.gov](http://www.leginfo.ca.gov)

Organic Consumers Association (promotes food safety, organic farming and sustainable ag practices)  
[www.organicconsumers.org](http://www.organicconsumers.org)

PBS (public television stations)  
[www.pbs.org](http://www.pbs.org)

Pesticide.Net (pesticide related news and regulatory information maintained by Wright & Sielaty law firm consultants at ChemReg Int'l)  
[www.pesticide.net](http://www.pesticide.net)

## Resources *(continued)*

## Websites *(continued)*

Pew Charitable Trusts (nonprofit activities in culture, education, the environment, health and human services, public policy and religion)

[www.pewtrusts.com](http://www.pewtrusts.com)

Pew Initiative on Food and Biotechnology (Funded by grant from Pew Charitable Trusts to the University of Richmond. Advocates neither for, nor against, agricultural biotechnology. Encourages debate and dialogue.)

[www.pewagbiotech.org](http://www.pewagbiotech.org)

Progress Farmer (agricultural industry magazine)

[www.progressivefarmer.com](http://www.progressivefarmer.com)

Science Direct (web database of Elsevier Science journals)

[www.sciencedirect.com](http://www.sciencedirect.com)

Soil Association (UK organization for organic food and farming)

[www.soilassociation.org](http://www.soilassociation.org)

Union of Concerned Scientists (alliance of concerned citizens and scientists. Desire strengthened oversight, testing regulations and labeling of biotech foods)

[www.ucsusa.org](http://www.ucsusa.org)

University of Guelph

Food Safety Network (provides research, commentary, policy evaluation and public information on food safety issues from farm-to-fork)

[www.foodsafetynetwork.ca](http://www.foodsafetynetwork.ca)

University of Virginia

The Cavalier Daily (student newspaper)

[www.cavalierdaily.com](http://www.cavalierdaily.com)

Washington Post

[www.washingtonpost.com](http://www.washingtonpost.com)

## Resources *(continued)*

### Publications/Newspapers

Alternatives Journal  
American Journal of Agricultural Economics  
Bangor Daily News – Bangor, ME  
Birmingham Post – England  
Chemical Week  
Christian Science Monitor  
Consumer Policy Review  
Daily Free Press – Boston University  
Economist  
Environmental Health Perspectives  
Environmental News Service  
Environmental Science and Technology  
Eurofood  
Farmers Guardian  
Financial Times – World Media Service  
Food and Drink Weekly  
General Accounting Office & Testimony  
Independent – London  
Journal of Development Studies  
Journal of Nutrition  
Kiplinger Agriculture Letter  
Nation  
Nature Biotechnology Journal  
New Scientist  
New Zealand Herald  
Nutrition Today  
Oils & Fats International  
Rockefeller Foundation  
Sacramento Bee  
San Diego Union  
San Francisco Chronicle  
San Jose Mercury News  
Technology Review  
Time Magazine  
Washington Times  
Washington Trade Daily  
Wall Street Journal

### Groups

American Corn Growers Association  
American Seed Trade Association  
American Soybean Association  
Biotechnology and Life Sciences Informatics Program, University of California-Davis  
Biotechnology Industry Organization  
Campaign to Label Genetically Engineered Foods  
Center for Food Safety  
Consumer's Choice Council  
Consumer Federation of America

## Resources *(continued)*

## Groups *(continued)*

CropLife American  
Foundation on Economic Trends  
Greenpeace  
Grocery Manufacturers of America  
Hoover Institution  
Hudson Institute's Center for Global Food Issues  
Institute for Agriculture and Trade Policy  
Institute for Plant Research, Cornell University  
Pew Initiative on Food and Biotechnology  
U.S. Public Interest Research Group

## The Food Biotechnology Advisory Committee

Ted Batkin, President of the Citrus Research Board  
Kent Bradford, Director of the Seed Biotechnology Center at the University of California, Davis  
Christine Bruhn, Director of the Center for Consumer Research at the University of California, Davis  
Henry Chin, Vice President of the Center for Technical Assistance of the National Food Processors Association  
Maarten Chrispeels, Professor of Biology and Director of the Center for Molecular Agriculture at the University of California, San Diego  
Cynthia Cory, Director of Environmental Affairs for the California Farm Bureau Federation  
Norman Ellstrand, Professor of Genetics in the Department of Botany and Plant Sciences at the University of California, Riverside  
Steve Forsberg, Senior Vice President of the California Plant Health Association  
Rebecca Goldberg, Senior Scientist at Environmental Defense in New York, NY  
Michael Hanson, Research Associate at Consumers Union/Consumer Policy Institute  
Lance Hastings, Vice President of Government Relations at the California Grocers Association  
Leslie Krasny, attorney at Keller and Heckman LLP  
Sharan Lanini, private agricultural consultant  
Brian Leahy, Executive Director of California Certified Organic Farmers  
Peggy Lemaux, Cooperative Extension Specialist in the Department of Plant and Microbial Biology at the University of California, Berkeley  
Martin Lemon, Biotechnology Science Coordinator for Monsanto Company  
John Maas, veterinarian and Chair of the California Cattlemen's Association's Cattle Health Committee  
Pamela Marrone, President and CEO of AgraQuest, Inc.  
Danila Oder, representative for Organic Consumers Association  
Joe Panetta, President and CEO of BIOCOM/San Diego  
Kristin Power, Director of State Affairs for the Grocery Manufacturers of America  
Jane Rissler, Senior Staff Scientist and Deputy Director for the Food and Environment Program of the Union of Concerned Scientists  
Barbara Schneeman, Professor of Nutrition at the University of California, Davis  
Sharon Shoemaker, Executive Director of the California Institute of Food and Agricultural Research at the University of California, Davis  
Suzanne Teuber, Associate Professor of Internal Medicine at the School of Medicine of the University of California, Davis  
James Tillison, Executive Director and CEO of the Alliance of Western Milk Producers  
Cynthia Wagner Weick, Associate Professor of Management at the University of the Pacific  
Kimberly Wilson, national campaigner for Greenpeace