California Agriculture

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Fruits of biotechnology struggle to emerge

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News departments

Editor's note

This issue of *California Agriculture* examines the significant hurdles to commercial development for genetically engineered horticultural crops. In a future issue, *California Agriculture* will look at the benefits and risks of agricultural biotechnology.

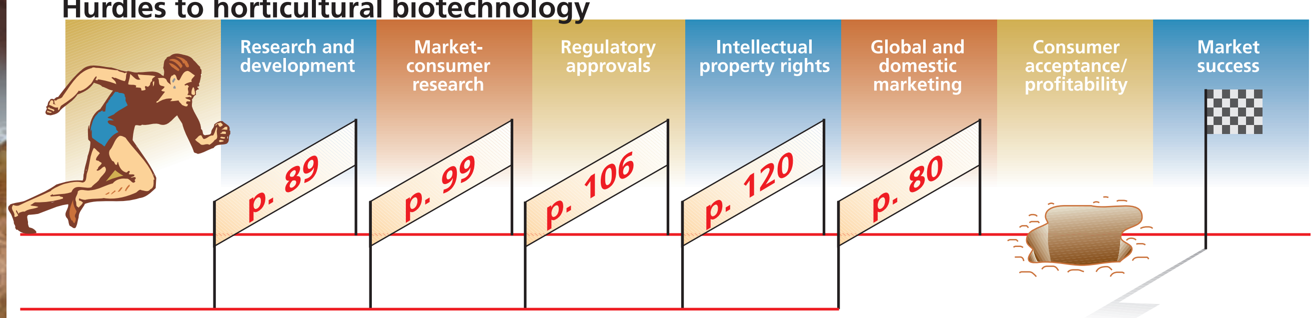
We gratefully acknowledge the contributions of the chairs and editors for this issue. The chairs were Julian M. Alston, Professor of Agricultural and Resource Economics, UC Davis, and Associate Director, UC Agricultural Issues Center: and Kent J. Bradford, Director, Seed Biotechnology Center, and Professor of Vegetable Crops, UC Davis. Associate editors for the peer-reviewed articles were Steven A. Fennimore, Richard J. Sexton, Sheri Zidenberg-Cherr and David Zilberman.

Due to cutbacks related to the state's budget deficit, *California Agriculture* will be publishing four issues in 2004 instead of six.

Cover: While vast acreages of transgenic row crops (such as soy, corn and cotton) are grown in the United States, few such horticultural crops (such as fruits and vegetables, nuts and ornamentals) are available to consumers.

Research articles

Hurdles to horticultural biotechnology



U.S. field tests of genetically engineered crops, 1997-2003

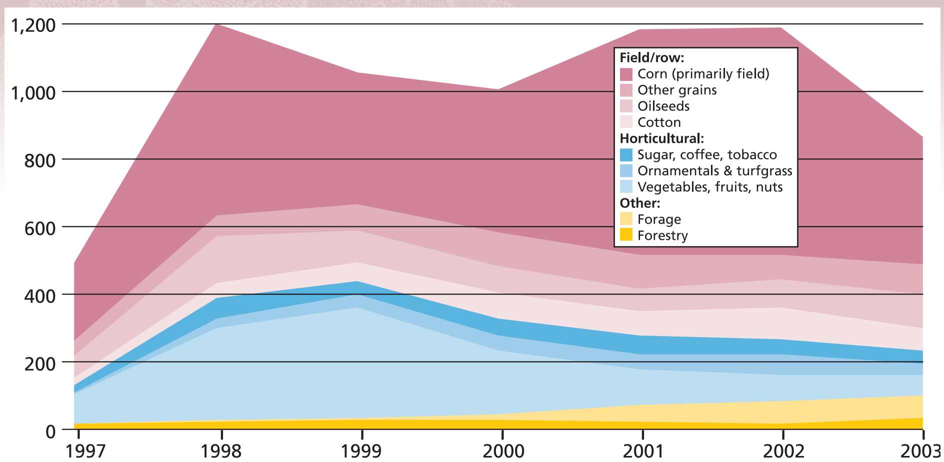


Figure courtesy of Gregory D. Graff. Sources: http://www.isb.vt.edu/cfdocs/fieldtests1.cfm; http://usbiotechreg.nbii.gov.

Despite the initial development and introduction of bioengineered horticultural crops (such as tomatoes, potatoes, sweet corn, squash and papayas), little acreage of these is currently in commercial production. There has been a marked reduction in research and investment in biotechnology for horticultural crops. In the peak year of 1999, there were 374 field test notifications or permits filed for biotech horticultural crops; in 2003, the total number had fallen to 97.

This contrasts with continued research in biotech corn, cotton and soybean, for which 506 permits or notifications were recorded in 1999 versus 520 for these three crops in 2003. Even corrected for differences in crop value, horticultural crops are receiving less research investment per dollar of crop production, and no biotech horticultural variety has been deregulated since 1999, with only one since 1997.

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Editorial overview

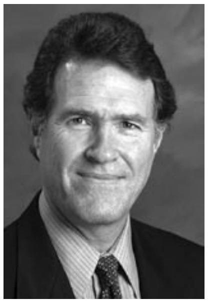
Challenges and opportunities for horticultural biotechnology

The term "biotechnology" encompasses a wide array of techniques through which humans employ biological processes to provide useful products. In the broadest sense, it includes the use of yeast in brewing and baking, and the breeding of plants and animals. More recently, the term has come to mean the collection of techniques that allow the direct manipulation of specific pieces of genetic material within and between organisms. Although there are many applications of biotechnology in crop and livestock improvement that do not include gene transfer, it is the ability to transfer genes among different species that has attracted the most controversy.

The application of biotechnology to crops has transformed the landscape of American agriculture for soybeans, corn, cotton and canola by providing genetic resistance to herbicides and insects. Since the first large-scale introduction in 1996, the global area planted to transgenic crops has grown to 167 million acres in 2003, of which 106 million acres (63%) were in the United States. In 2003, biotech varieties providing herbicide or insect resistance represented 81% of soybeans, 73% of cotton and 40% of corn grown in the United States.

It is evident from these adoption rates that the traits provided through biotechnology are benefiting some farmers. However, biotechnology has had limited commercial success to date in horticultural crops, including fruits, vegetables, flowers and landscape plants — the crops that comprise 60% of California's agricultural production value. Even though the first transgenic crop to reach the market was the Flavr Savr tomato, and sweet corn, potato, squash and papaya varieties engineered to resist insects and viruses have been approved for commercial use and marketed, papaya is the only horticultural crop for which transgenic varieties have achieved a significant market share (about 70% of the Hawaiian crop shipped to the continental United States is transgenic).

This issue of *California Agriculture* examines the challenges and opportunities for commercializa-


Kent J. Bradford


Julian M. Alston


Peggy G. Lemaux


Daniel A. Sumner

tion of biotech horticultural crops. A number of technical, economic, regulatory and market factors have combined to create hurdles for the utilization of biotechnology in horticultural crops, which are more diverse than field crops. Horticulture includes hundreds of distinct plants, the majority of which are grown on small acreages and which individually represent relatively small market values. Even the vegetable crops with the largest gross revenues, such as lettuce and tomatoes, are minor crops compared to major field crops like corn or soybeans. Their limited acreage makes it more difficult to recover the research and development costs of any new technology specific to these crops. Because of the limited size of the individual markets, the costs of gaining access to patented genetic-engineering methods and meeting the regulatory requirements for testing and registration of biotech crops represent substantial economic hurdles for horticultural products.

At the same time, consumer concerns and the related reluctance of food processors and marketers to accept new biotech commodities are delaying the introduction of horticultural products already developed. These barriers are exacerbated by the globalization of fresh produce markets and the growing dominance of large supermarket chains, as exporters must meet diverse regulatory requirements in different countries and specific standards set by multinational food marketers. Due to the disappointing past commercial results and current market outlook, many horticultural seed and nursery companies are reducing their investments in genetic engineering research. However, they are continuing to apply biotechnology to support traditional breeding activities.

In March 2002, a workshop was convened in Monterey, Calif. Its purpose was to bring together the spectrum of disciplines and industries involved in horticulture — including development, production, processing and marketing — to assess the current situation with respect to horticultural applications of biotechnology and identify avenues for future progress. Experts considered potential biotech products that would be desired by growers and consumers; identified hurdles limiting the application of biotechnology in horticultural crops; discussed priorities for future research and development; and explored the implications for public and regulatory policy. At the conclusion of the workshop, selected participants were asked to develop the papers that are presented in this issue of *California Agriculture*.

The themes explored here parallel those of the workshop, beginning with an assessment of the current status of horticultural biotechnology in terms of both the economic "state of the market" (page 80) and the technical "state of the art" (page 89). Sidebars to these articles explore specific issues with respect to changes in the market environment for fresh produce (page 82) and current and potential biotech products (pages 84, 92, 94, 96). The key issue of consumer acceptance of biotech crops is analyzed (page 99), with specific cases illustrating the difficulties in accurately assessing consumer preferences (pages 100, 103). These articles demonstrate the potential benefits that biotechnology could provide to horticultural crops as well as the significant challenges to bring them to the marketplace. Prominent among the latter are regulations specific to transgenic crops that significantly increase the cost of development and commercialization (page 106). Meanwhile, with commercialization stymied in the United States, China, already a major and rapidly growing competitor of California in Asian horticultural markets, is moving forward with the application of biotechnology to improve the efficiency of production and the quality of its horticultural products (page 112).

Public institutions have traditionally played a major research role in horticultural crops, and this is also true of horticultural biotechnology. How should they respond to the declining private interest in biotechnology research? It may be appropriate to increase research support in cases where there is a compelling public interest, such as the development of nutritionally enhanced food products or when a devastating disease threatens a horticultural industry and a biotech-based solution is the most viable option for developing resistant va-

Cauliflower and broccoli are derived from the same genetic ancestor, *Brassica oleracea,* but were developed over many years into individual and very different vegetables through selection and breeding. Biotech-nology can make this process more precise and less time-consuming.

rieties. However, public institutions generally do not have access to the full range of enabling technologies and trait genes, nor the resources to satisfy the regulatory and stewardship requirements needed to develop a commercial biotech variety, making public-private partnerships an attractive avenue for development (page 116).

New licensing structures for enabling technologies developed in universities and public research institutions may be particularly helpful for small-revenue crops as well as for developing countries (page 120). The Public Intellectual Property Resource for Agriculture (PIPRA) soon to be headquartered at

Objectives for horticultural biotechnology

A set of key research and policy objectives were developed out of discussions at the Workshop on Biotechnology for Horticultural Crops in Monterey.

Research

New technologies and products

- Develop efficient transformation technologies for many specialty crops.
- Develop promoters for tissue-, development-, disease- and environment-specific gene expression.
- Develop targeted gene-insertion techniques to control the site of integration.
- Develop a Generally Recognized As Safe (GRAS) set of methodologies that would not require characterization and registration of individual genetic-insertion "events."
- Develop products with clear and significant benefits for consumers.

Regulatory process

- Develop methods to quantify potential risks associated with individual species-trait combinations.
- Test product safety, potential for gene transfer to noncrop organisms, and the biological and environmental consequences of any such transfers.
- Quantify full economic costs of regulatory policies.
- Compare potential benefits and risks of biotech products to current practices.

Marketing and adoption

- Continue market research to determine consumer attitudes and how these change over time.
- Model and measure the roles of food processors and marketers in affecting farmer adoption and market acceptance of biotech products.
- Project the market potential of specific trait-crop combinations.
- Project consumer responses to altered nutritional content and associated labeling.

Policy

New technologies and products

- Develop a collaborative public-technology and intellectual-property resource.
- Develop technology and trait-licensing packages to enable public and entrepreneurial commercial-ization of specialty and subsistence crops.
- Target increased public research funding toward the application of genomics and biotechnology in horticultural crops, including methods that support traditional breeding.

Regulatory process

- Examine current regulations in light of accumulated experience and reduce redundant regulatory requirements when appropriate and justified.
- Replace regulation based on a single gene-insertion "event" with a more general approval of species-trait combinations.
- Create or extend governmental programs to assist small-market crops in data collection required for the regulatory process.

Marketing and adoption

- Establish identity-preservation and channeling programs to allow the coexistence of diverse market segments.
- Establish practical thresholds for adventitious (accidental) presence of approved biotech products to facilitate international trade.
- Provide documented scientific information on the relative risks and benefits of biotechnology for horticultural crops.

UC Davis represents a significant development in this area (page 127).

Public research agendas can also be targeted toward developing new methods for lowering intellectual-property and regulatory barriers and providing access to modern biotechnologies for specialty crops. In addition, the government can play a role in encouraging private research and development and facilitating the adoption of new technologies. For instance, the U.S. Department of Agriculture's IR-4 program, which assists in the registration of agricultural chemicals for specialty crops, could be broadened to support the registration of biotech varieties (page 110).

While recognizing that there are alternative viewpoints, we do not question the potential value that biotechnology can bring to horticulture. The acreage of biotech crops grown worldwide continues to increase annually, and growers clearly recognize the benefits of reduced pesticide use and conservation tillage enabled by these first-generation products. Regulation and monitoring are needed to ensure that novel traits are assessed for both food and environmental safety prior to commercialization. However, such prudent precautions should not be so restrictive as to present insurmountable barriers to the commercialization of horticultural products that could provide significant benefits to producers and consumers as well as to the environment. We believe that the responsible application of biotechnology is compatible with and has much to contribute to agricultural and environmental sustainability while helping to maintain the competitiveness of U.S. horticultural products in the global marketplace. With that view in mind, we have summarized some of the key research and policy objectives that emerged from the Monterey Workshop and that are elaborated in the articles of this special issue (see box, page 70).

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GLOSSARY

BIOTECHNOLOGY

Agricultural technology: technology based on the domestication of wild plants to create crops. Humans invented agriculture approximately 10,000 years ago; primitive crop cultivars, also known as **land races,** were adapted to local growing conditions and preferences. Today's crops are the result of thousands of years of gradual selection.

Agronomic/field/row crops: agricultural crops grown on larger acreages for food or nonfood products, including grains, alfalfa, field corn, oils, soybeans, canola (rapeseed) and cotton.

Allele: single transformation event which contains the genetic trait of interest and expresses the desired phenotype.

Biotech foods: those produced with genetically engineered crops or ingredients.

Biotechnology: the use of living organisms or their vital processes or components to provide new products. In modern usage, biotechnology refers to genetically engineered (GE) crop plants.

In this issue, ***Biotech, GE, genetically modified (GM)*** *and* ***transgenic*** *are used interchangeably.*

Chromosome: the organized structure containing DNA and genetic information.

Conventional/traditional breeding: genetic modification of plants through sexual crosses using parents selected for desirable traits.

Cultivar: a particular cultivated variety of a domesticated plant species.

Deregulation: the governmental approval of a biotech cultivar for commercial release in the United States without further regulatory restrictions on its production or utilization.

DNA (deoxyribonucleic acid): carrier of primary genetic information in most organisms.

Expression: the manifestation of a characteristic specified by a gene; also refers to the production of proteins by a genetically engineered organism.

Gene: the basic unit of informational inheritance consisting of a sequence of DNA and generally occupying a specific position within the genome.

Genetically engineered (GE)/genetically modified organisms (GMO): organisms with new combinations of genetic material. DNA from another organism is modified in the laboratory and transformed into an organism in which the specific sequence does not naturally occur.

Genetics: the science of the transmission of characteristics between generations.

Genotype: the total of all genetic information contained in an organism.

Germplasm: genetically distinct variants of a species that can represent a valuable natural resource of plant diversity.

Graft: a plant bud, shoot or scion that is inserted into the stem or stock of another plant, where it continues to grow.

Horticultural crops: fruits, vegetables, sweet corn, nuts, ornamental and landscape plants that are generally grown on smaller acreages than agronomic/field crops.

Hybrid: the offspring of a specific cross between two genetically distinct (usually inbred) parents

Intellectual property rights (IPR): the legal rights to the use of the results from research, invention, and other creative activity, such as the rights provided by patents or copyrights.

Marker (genetic): a distinguishing feature that can be used to identify a particular gene location on a chromosome.

Phenotype: appearance or other characteristics of an organism, which result from interactions of its genetic constitution with the environment.

Protein: a molecule composed of a chain of many amino acids that acquires a particular folded shape due to the amino acid sequence. Both the sequence of the amino acids and the pattern of folding are involved in the specific function of the protein.

Recombinant DNA: DNA formed external to a living cell by joining DNA from two or more different sources in the laboratory.

Sexual crosses: the transfer of pollen from one plant to the pistil of another closely related plant to result in seeds that carry traits derived from both parents.

Tissue culture (in plant biotechnology): the process of regeneration of a plant from single cells, isolated embryos or small bits of plant tissue on liquid or solid media.

Trait: a phenotypic characteristic associated with the expression of a single gene.

Transformation: the process of introducing a cloned gene into an organism.

Transgenic: an organism containing genetic material from other species introduced via the process of transformation.

Portions of this glossary were adapted from ANR Publication 8043, Biotechnology Provides New Tools for Plant Breeding *by Trevor Suslow, Bruce Thomas and Kent Bradford.*

Transgenic acreage grows amid changing regulation

Acreage in genetically engineered (GE) crops has increased steadily since their introduction in 1996, to 167 million acres worldwide in 2003. However, these crops remain controversial: advocates say they will help people and the environment but opponents fear they will hurt both. Regulations for producing, trading and labeling GE organisms are still evolving at the international, national and even local levels. Most recently, on March 2 California's Mendocino County became the first in the nation to ban production of GE plants and animals.

"New technology needs to be reviewed case-by-case until we're comfortable with it," says Norman Ellstrand, a UC Riverside geneticist and director of the UC Biotechnology Impacts Center.

Virtually all commercial GE crops are either herbicide-tolerant or pest-resistant. The United States is the largest producer of the 18 countries that grow GE crops, followed by Argentina, Canada and China. In 2003, significant portions of the worldwide harvest in four commodities were genetically engineered: 55% of soybeans, 21% of cotton, 16% of canola and 11% of corn, according to a 2003 report by ISAAA (International Service for the Acquisition of Agri-biotech Applications).

Photos: Monsanto

The United States requires permits for field-testing new genetically engineered varieties; before they are marketed they must be "deregulated" by three federal agencies. *Above,* soybeans resistant to the herbicide glyphosate (Roundup).

Three-part regulatory process

New technologies bring new regulations. The United States currently requires permits for field-testing GE varieties during their development; then, companies wishing to commercialize GE crops must pass a three-part regulatory-approval process that involves the U.S. Environmental Protection Agency, U.S. Department of Agriculture (USDA) and U.S. Food and Drug Administration (page 106).

"People need to know that there is oversight," says Christine Bruhn, director of the Center for Consumer Research at UC Davis. "The risks need to be acknowledged and controlled. Public education on the benefits is also key."

However, regulations can also hamper the development of GE crops. "Regulations can make it too expensive for the smaller market crops," says Kent Bradford, director of the Seed Biotechnology Center at UC Davis. Many of these (primarily horticultural) crops require dozens of varieties to match growing seasons and market preferences. U.S. regulations stipulate that a GE version of each variety must be registered separately. Alternatively, a single GE version may be registered and then the trait can be crossed into each of the varieties, but this is also time-consuming and expensive, Bradford says.

"By contrast, Canadian regulations focus on the safety and impact of the trait itself rather than on where it came from," Bradford notes. "No distinction is made between genetic engineering and conventional breeding in evaluating whether a novel trait may be introduced into the marketplace."

USDA to revise rules. On Jan. 22, the USDA announced plans to update and strengthen U.S. biotechnology regulations, which cover the importation, interstate movement and environmental release of GE organisms. "The science of biotechnology is continually evolving, so we must ensure that our regulatory framework remains robust by anticipating and keeping pace with those changes," U.S. Agriculture Secretary Ann Veneman said.

Since 1987, more than 10,000 GE organisms have been field-tested and more than 60 have been "deregulated." Currently, GE crops are no longer regulated once they have been approved for commercial production.

The move to update U.S. regulations coincided with the release of a National Research Council report on "bioconfinement" (see box, page 73). USDA sponsored the report because a number of GE organisms (such as transgenic fish) now exist that had not yet been developed when the current biotechnology regulations were established in 1986.

The proposed regulatory changes would include a requirement for ongoing monitoring of GE organisms after deregulation, and the development of a multitiered permitting system that both streamlines the approval of crops for commercial production and provides more oversight for the riskiest GE organisms.

Mendocino County ban. On March 2, Mendocino County passed Measure H with 56% of the vote, making it the first county nationwide to ban growing GE plants and animals. The measure's supporters included the owners of an organic brewpub in Ukiah, who wanted to protect the county's organic produce industry from genetic contamination. Organic producers are prohibited from using GE organisms or ingredients.

The new ban has little immediate practical significance because no GE crops are currently grown in Mendocino County. "The measure and the vote were largely symbolic," Bradford says. However, he added, the ban does set a precedent. "If similar measures pass in counties where GE crops such as herbicide-tolerant or insect-resistant (Bt) cotton are grown, that could increase the costs of pesticide use and labor and make California farmers less competitive."

Groups in other California counties, including Humboldt and possibly Sonoma, Santa Cruz and El Dorado, are expected to start trying to qualify similar initiatives for the November 2004 ballot. In addition, Measure H opponents are considering challenging the Mendocino initiative in court.

U.S. labeling movement. The U.S. currently does not require labeling for foods that contain GE ingredients. In July 2003, U.S. Representative Dennis Kucinich (D-Ohio) introduced a House bill that would require food companies to label all foods containing GE material. In addition, Barbara Boxer (D-Calif.) is expected to introduce this bill to the Senate by the end of the year.

International trade

After biotech crops are developed, approved and planted in the United States, they cannot be shipped to other nations without approval from each importing country. These rules can vary significantly from country to country. Some major trade partners of the United States have taken a precautionary approach toward allowing new biotech crops: Europe has had a moratorium for 5 years, while Japan approves them on a case-by-case basis.

Cartagena Protocol on Biosafety. This global treaty helps member countries regulate the movement of GE organisms across national borders. The protocol established a biosafety clearinghouse that allows member nations to ban GE products that lack safety information, and requires labeling for international shipments. Effective in September 2003, the protocol is a supplement to the 1992 U.N. Convention on Biological Diversity.

As of March, 87 parties, including the European Community, India and the United Kingdom, had ratified the Cartagena Protocol. Countries that have not ratified it include the United States, China and the Russian Federation. Countries that are not members must still adhere to the protocol's provisions when shipping GE products to participating nations. In February, protocol members adopted two new documentation requirements for bulk agricultural shipments.

Barbara Alonso

Left, **in March 2004, Mendocino County passed Measure H, which bans the growing of genetically engineered plants and animals. Proponents were concerned about cross-contamination of organic crops by biotech seeds and crops.**

European Union and Britain. In January, the European Commission ended its 5-year moratorium on new GE foods by approving the sale of canned, frozen and fresh GE sweet corn. (These corn products are already approved in the United States, Canada, Australia and Switzerland.) E.U. members have 3 months to endorse or reject the commission's approval. Britain is currently considering allowing the cultivation of GE corn; Germany and Spain are the only E.U. countries that grow GE crops.

— Robin Meadows

NRC recommends "bioconfinement" measures

On Jan. 20, a committee of the National Research Council (NRC) released "Biological Confinement of Genetically Engineered Organisms," a USDA-sponsored report calling for measures to prevent genetically engineered (GE) organisms from escaping into ecosystems or from passing engineered traits to other species.

The NRC committee's concerns included that GE crops could pass pesticide or disease resistance to weedy relatives, making them invasive; GE organisms could breed with or out-compete their wild relatives; and species engineered to produce pharmaceuticals could harm people or animals that eat them by mistake.

"Some things, such as future pharmaceutical crops, will need to be grown under regulation," says UC Riverside geneticist Norman Ellstrand, director of the UC Biotechnology Impacts Center and a member of the NRC committee.

Bioconfinement methods for plants include inserting genes that make them sterile or that keep them from producing pollen. "Confinement won't be warranted in most cases, but when it is, worst-case scenarios and their probabilities should be considered," said NRC committee chair Kent Kirk, professor emeritus of the University of Wisconsin, Madison.

The NRC committee's recommendations included:

- More research should be conducted about how bioconfinement methods work.
- More than one bioconfinement method should be used, because no single method is likely to be completely effective.
- Combinations of bioconfinement methods should be tested on representative organisms in a variety of environments.

— R.M.

Conventionally bred papaya still possible, even in California

At a Mexican farm, Honorio Fernández explains how papaya is grown as an annual crop in order to manage the papaya ringspot virus. Thousands of seedlings are started in a screen house, *above*, and the survivors are transplanted to the field.

Commercial papaya production worldwide has been hurt by the plants' high susceptibility to papaya ringspot virus (PRSV), a disease transmitted by aphids that has swept through the tropics, beginning in India and Puerto Rico in the 1940s, moving to the main Hawaiian growing area in the 1970s, and Australia in the 1990s.

In the mid-1990s, scientists took a single gene from the virus itself and inserted it into the papaya's genetic code. That tiny change prevents the virus from making copies of itself and stops the disease from damaging fruit and killing the plants. Papayas are often held up as a classic success story for agricultural biotechnology (page 92). However, planting genetically engineered papayas is not the only way to skirt PRSV.

Last year, six UC Cooperative Extension farm advisors traveled to the Mexican state of Veracruz to gain a better understanding of Mexican production techniques, insect- and disease-control methods, and import-export issues in the tropical region. They found farmers using an unconventional papaya-production practice to successfully grow fruit that has not been genetically engineered.

At Rancho Neveria, a small farm near the city of Cardel, papaya is grown as an annual crop rather than a perennial tree, to manage the virus. Agronomist Honorio Fernández described the ranch's annual papaya-production system, from the soil mix for seedlings to plant spacing in the field. The plants are started in a screen house (an enclosure to screen out insects) to protect them from disease-transmitting aphids. About 1,225 seedlings are transplanted per acre in the field, he said. Before harvest, a quarter of the plants are pulled due to viral infection. Nevertheless, the approximately 900 remaining plants produce a profitable crop before succumbing to disease.

UC researchers believe there may be a market for papayas grown as an annual crop in California.

Although California lies well outside the papaya's favored climate zone — between the Tropics of Cancer and Capricorn — this approach to papaya production could be profitable for the state's small-scale farmers.

UC Cooperative Extension farm advisor Manuel Jimenez is studying papaya production at the UC Kearney Research and Extension Center near Parlier. A typical San Joaquin Valley winter will kill the unprotected plant, squeezing the growing season between February and November. That time frame only allows the fruit to reach unripe maturity, but unripe papayas are suitable for cooking and popular with consumers of Asian descent. The unripe fruit may be baked like winter squash or pumpkin, or used for chutney. A group of marketers who visited KREC last year thought the locally grown fruit was good quality for the "green" market.

"We had Hmong, Burmese, Mexican, Japanese and Laotian papaya marketers prepare green papaya salads," Jimenez says. "They all prepared the papayas differently, but they were all delicious."

Jimenez grew several varieties of nongenetically engineered seed, and lost nearly all of the cultivars from Hawaii to PRSV. He said the Chinese plants showed more natural resistance. He was only able to harvest the green papayas for 3 weeks, not long enough for a fruit marketer to abandon the tropical papaya provider.

"Papaya is very inexpensive to grow," Jimenez says. "We can plant an acre for $20 of seed, compared to several hundred dollars an acre for traditional vegetables. Papayas may be a crop for growers who direct-market their produce."

In fall 2004, Jimenez will try to protect the plants from cold weather under movable "hoop houses." If they survive the winter, the papaya fruit on those plants might ripen the following season, giving potential growers greater harvest flexibility and, perhaps, making papayas commercially viable for California small-scale farmers.

— Jeannette Warnert

UC researchers evaluating genetically engineered alfalfa

UC Cooperative Extension farm (UCCE) advisors and researchers are growing genetically engineered (GE) alfalfa in small experimental plots to determine whether the technology will be beneficial to California farmers.

"We would like to be ready with research-based answers when this technology is introduced," says Steve Orloff, Siskiyou County farm advisor. "It's somewhat controversial, but providing unbiased research results will enable growers to make intelligent decisions about it for themselves."

Although final results are not yet in, the UC scientists believe that the new varieties, which have been genetically engineered for resistance to the herbicide glyphosate (Roundup), could be an important new tool for alfalfa growers.

"It won't be a silver bullet for all farmers," says Kurt Hembree, Fresno County weed science advisor. "Glyphosate is weak on some important alfalfa weeds, like malva, nettle, hairy fleabane and filaree. Successful weed control with this technology will depend a great deal on the ability of the growers and pest control advisers to accurately identify their specific weed problems before treating."

Alfalfa is grown on more acres in California than any other crop and is the third most valuable crop in the United States. But because it is used primarily for dairy feed and is a few steps removed from the dinner plate, the general public does not often recognize its importance." Alfalfa is ice cream in the making," quips UC Davis alfalfa specialist Dan Putnam.

In anticipation of a possible 2005 commercial release of gyphosate-resistant (Roundup Ready) alfalfa, UCCE farm advisors and specialists are evaluating it in the Intermountain Region and throughout the Central Valley. "We rate the trials blind," Orloff says. "We don't favor one approach over others."


Steve Orloff

When the herbicide glyphosate is sprayed over the top of Roundup Ready alfalfa, it kills the weeds but not the crop.

Weed control a challenge

Weed control is a major challenge for alfalfa growers. Alfalfa contaminated with too many weeds may be unpalatable to livestock and less nutritious. In California, lower-quality alfalfa hay is worth an average of about $44 per ton less than premium hay. With the Roundup Ready alfalfa plant, growers can spray glyphosate over the crop after the alfalfa and weeds have emerged, eliminating nearly all the weeds. Later herbicide sprays may be unnecessary as the alfalfa grows vigorously and shades later-emerging weeds.

Left, **in field-test plots, the untreated control (right, foreground) is clearly weedy; a plot treated with conventional herbicides (left, foreground) is better; and the glyphosate-resistant alfalfa (back) is the least weedy.** ***Right,*** **UC Cooperative Extension farm advisor Steve Orloff and student assistant Josh McCollam (on tractor) inspect alfalfa at the Intermountain Research and Extension Center.**

Reducing pesticide use in alfalfa could provide environmental benefits. "Alfalfa growers are working closely with state agencies to prevent runoff of insecticides and herbicides into streams and rivers," says Mick Canevari, San Joaquin County farm advisor. "This new technology may reduce the amount of pesticides that are needed to grow the crop, and thereby reduce the risk of pesticide runoff with some of our winter-applied herbicides."

Larry R. Teuber

Honeybees, *above*, pollinate alfalfa crops grown for seed.

Pollinating honeybees studied

In addition to evaluating glyphosate-resistant alfalfa, UC scientists are studying the movement of pollen by honeybees used to pollinate alfalfa crops grown for seed.

"It is important to know how far honey bees and leafcutter bees will travel to pollinate alfalfa in order to produce Roundup Ready alfalfa seed with greater than 90% trait purity and to allow growers of seed of nongenetically engineered varieties to maintain their purity standards also," says Kent Bradford, director of the UC Davis Seed Biotechnology Center.

Field studies were conducted in 2003 by UC Davis professor Larry R. Teuber and Fresno County farm advisor Shannon Mueller, along with Allen Van Deynze of the UC Davis Seed Biotechnology Center. The studies looked at gene flow, which occurs when pollen from an outside source unites with the ovule from a plant in another field and produces a viable seed. The plots were isolated by at least 6 miles from other alfalfa crops to prevent any accidental movement of pollen from the test site.

Preliminary results showed trace levels of gene flow via honeybees moving pollen from genetically engineered alfalfa beyond 1,500 feet from a marker source; the current foundation seed-isolation standard is 900 feet from a marker source.

"These studies are confirming what we have suspected for years about honeybee movement of pollen," Teuber says. "We expect to evaluate and perhaps combine a number strategies — including isolation distances, pollinator species and blocking cultivars by type — for maintaining the genetic purity of cultivars," Teuber says.

However, concerns remain. Canevari has seen a "weed shift" in his experimental plots in Stockton, where glyphosate-resistant alfalfa has been grown for 3 years. "When we started this study, there were four or five stinging nettle plants on this end of the field," Canevari says. "Now you can see nettle all along the field. We're seeing more and more nettle each year."

Another worry is the development of herbicide-resistant weeds. Certain weeds — such as ryegrass — over the years have developed resistance to glyphosate. "At this point, we already have glyphosate-resistant corn and cotton. Alfalfa is being studied and I have a project with Roundup Ready wheat. If you were to rotate between these crops, I wouldn't recommend growing Roundup Ready crops successively," says Ron Vargas, Madera County farm advisor. "That's really setting yourself up for weed resistance."

Financial viability unknown

The economic feasibility of growing glyphosate-resistant alfalfa has not yet been studied because Monsanto has not announced the pricing formula for the alfalfa seed. Unlike most other Roundup Ready crops, alfalfa is perennial and does not need to be reseeded each year. An annual lease on the glyphosate-resistant trait or a price premium for the seed that takes into consideration multiple years are being considered. The UC field trials should assist growers in making an economic evaluation of the technology, since comparative yields, application rates and weed-control efficacy are being studied.

UC researchers are also considering the potential market acceptance, since growers will want to know whether buyers will purchase GE alfalfa hay. Putnam says he does not expect much resistance from the dairy industry, since it has already absorbed a number of similar technologies. Most cheese, he points out, is currently made from rennin from GE microorganisms. However, he says, there might be some consumer resistance to the GE alfalfa in markets that import California hay, such as Japan.

"In my discussions with exporters, there will likely be initial resistance from the export market, since some Japanese consumers are reluctant to purchase genetically engineered foods. That will likely moderate over time and will be price dependent," Putnam says. "Organic producers will reject the technology, as they do all herbicides. Some horse owners may also initially balk at the use of genetically engineered alfalfa, but they may also quickly realize the benefits, since a number of horses die each year from poisonous weeds that could be easily removed through this technology."

For more information, go to: http://alfalfa.ucdavis.edu. — *Jeannette Warnert*

World trade rules affect horticultural biotechnology

Daniel A. Sumner
Director, UC Agricultural Issues Center

1997 IFPRI/Philippe Berry

Global markets are critical to reap the full benefits of investments in agricultural research, including in biotechnology. *Above*, a produce market in Vietnam.

Agricultural biotechnology and globalization seem to go hand-in-hand in the popular press, and protesters condemn both in the same breath. This perceived bond is puzzling to those involved in the international agricultural trade, much of which has little connection to biotechnology. The development and marketing of biotech-related products have no more international linkage than any other area of agriculture.

However, globalization and biotechnology do affect each other. Global relationships between businesses and governments shape markets for biotech crops, which in turn affect rates of scientific innovation and adoption. Agricultural biotechnology has important implications for hunger and nutrition, intellectual property protection, food safety and environmental quality, all with international dimensions.

Innovations developed in one country may be adapted and applied elsewhere. In addition to trade in biotech-related foods and inputs (such as seed), the science itself is traded. Firms export biotech seeds and plant materials for research, planting them where the technology will be applied. Rules facilitate trade by protecting the intellectual property of exporters while securing the human, agricultural and environmental safety of importers. These rules foster widespread benefits from research and development (R&D) investments, while creating research incentives. Global markets are crucial to reap the benefits from scientific investments, reduce global hunger and improve the diets of the poor.

A major promise of horticultural biotechnology is reducing the cost of delivering higher quality fruits and vegetables to malnourished and hungry people. However, today some of this research is being diverted or delayed by international restrictions on trade or use of biotech inputs such as seeds. Some consumers and whole parts of the world have opted out. For example, the European Union banned imports of all new transgenic crops and products beginning in 1998; Japan approves such imports on a case-by-case basis. Several African countries have refused shipments of unmilled genetically engineered grain in spite of widespread hunger and malnutrition.

Despite the controversy, biotech products are subject to the same international trade rules as other agricultural products. The General Agreement on Tariffs and Trade (GATT), administered by the World Trade Organization (WTO), sets rules for all traded biotech goods. The WTO is a voluntary "club" of nations, with no enforcement mechanism. It relies on members to voluntarily comply with agreements. Three overriding principles of the WTO are that members' regulations regarding trade must be transparent, not discriminate among WTO members, and not favor domestic sellers relative to imports.

The Agreement on Sanitary and Phytosanitary (SPS) Measures of the GATT recognizes that members establish their own rules for food safety and environmental protection. The WTO Web site notes that SPS regulations "must be based on science; they should be applied only to the extent necessary to protect human, animal or plant life or health; and they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail." The Cartagena Protocol also deals with some aspects of cross-border shipments of biotech-related materials. However, major agricultural exporters, such as the United States, Australia, Canada, Argentina and New Zealand have not ratified the protocol and it does not exempt any nation from GATT obligations.

Although WTO members have wide latitude in specifying trade rules to ensure food and environmental safety, they have nonetheless been subject to formal dispute. The United States and other nations have filed formal proceedings with the WTO concerning the European Communities' "Measures Affecting the Approval and Marketing of Biotech Products." Their argument is that the European Union has erected barriers that are not based on the sound application of science and thereby inappropriately block importation of safe products. Related issues concerning, for example, specifics of product labeling, have not yet reached formal WTO disputes, but may be on the horizon.

The dispute has important implications for horticultural biotechnology. The initial costs of ap-

For more info:

World Trade Organization:
www.wto.org/english/thewto_e/whatis_e/whatis_e.htm

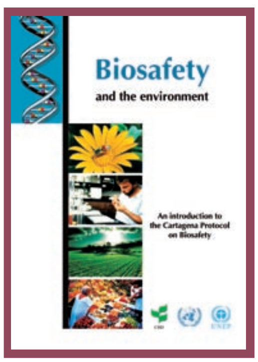
The Agreement on Sanitary and Phytosanitary (SPS) Measures:
www.wto.org/english/tratop_e/sps_e/sps_e.htm

More on the SPS agreement:
www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm

Related issues:
www.agecon.ucdavis.edu/outreach/areupdatepdfs/UpdateV6N1/N1_1.pdf

Monsanto

Members of the World Trade Organization have wide latitude in specifying trade rules related to food safety and the environment. *Left,* a Monsanto scientist prepares materials for an experiment. *Right,* agricultural products are often shipped by sea.



The Cartagena Protocol on Biosafety addresses the international movement of biotech-related materials.

plied biotech R&D are substantial, in part because governments require costly procedures to assure that the research and testing are safe. Most markets for horticultural crops are quite small relative to major field crops, and the markets for biotech horticultural seeds and other materials are small. When international trade restrictions artificially limit their geographic scope, firms are reluctant to invest in bringing new varieties to the market.

In addition, firms that market horticultural products internationally may be hesitant to support biotech varieties if they believe the market for the final products will be limited to a few countries — especially if the introduction of biotech crop products results in a loss of international markets for conventional varieties. For example, tree nuts and some tree fruits have substantial shares of their sales in Europe, Japan and Korea. Maintaining access to these markets discourages firms from using biotechnology to develop new cultivars.

If trade restrictions and limited market prospects continue to discourage horticultural biotech in developed countries, future investments and planting may occur mainly in developing countries, such as China. However, if major biotech investments were limited to poorer countries, the pace of science would slow and technological benefits would be limited. Further, farms and firms in developed countries, such as the United States, would lose some of their long-held technological edge.

Government restrictions on trade in biotech-related products reflect political choices and are designed to limit the choices of farmers, marketers and consumers. So, for example, if consumers simply did not wish to purchase biotech products or marketers simply did not wish to sell such products no import barriers would be needed to keep the products out of the market.

Trade regulations for biotech products have evolved for several reasons. Policymakers may think the products could be unsafe and believe they should therefore restrict their availability to consumers. Domestic forces determine such policies; however, when the policies affect trade, core WTO principles apply. Policymakers may also believe that importation is likely to spread diseases, weeds or other contaminants. This environmental argument applies more to seeds or plant materials than to food. Trade rules similar to those regulating invasive species may apply. For example, governments concerned about potential drift of biotech-derived seeds to native habitat must show that regulations do not harm trade partners disproportionately.

Finally, the pressure to insulate and protect domestic markets is pervasive. Often these pressures come from producers of competing products, but increasingly the pressure comes from groups claiming to oppose globalization *per se*, or oppose certain technologies, *per se*. Accepted trade rules, however, require that WTO members have credible scientific evidence that imports pose a significant potential hazard before trade may be restricted.

Labeling is one way that governments and market participants respond to demands for information about products, including those related to biotech. Private labels are used to encourage consumers to buy products and to enhance profitability. GATT principles apply only to government regulations that surround such private labels. For example, when governments require that label claims have an objective verifiable basis, they must apply the same standard to claims about the safety of imported biotech-related products. Label specifications that are required by governments themselves are more contentious because they can more easily discriminate against imports. In the GATT, governments set label specifications that do not discriminate against imports and have science-based environmental, health or safety foundations. Nonetheless, wealthy countries apply many rules for labeling consumer products and have wide latitude about how they are applied.

Global controversy over agricultural biotechnology has led to a bifurcated market for new technologies. Trade restrictions have reduced adoption and slowed the pace of scientific investment. It is unclear if this bifurcated market will continue or if governments will gradually allow farmers and consumers to make their own purchasing decisions. Government trade restrictions seem unlikely to block the long-term global spread of biotechnology, unless new science reveals some major new concerns. However, for horticultural biotechnology, the most immediate issue is not trade barriers, but market acceptance by consumers and producers in countries that are already open to agricultural biotechnology more generally.

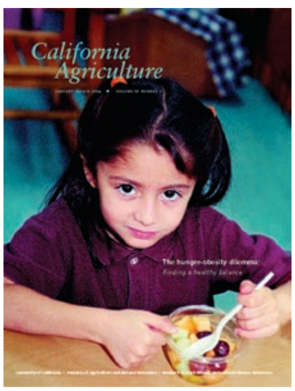
WHAT DO YOU THINK? The editorial staff of *California Agriculture* welcomes your letters, comments and suggestions. Please write to us at calag@ucop.edu or 1111 Franklin St., 6th fl., Oakland, CA 94607. Include your full name and address. Letters may be edited for space and clarity.

Sell produce locally to fight fat

The January-March 2004 issue, with its focus on hunger and obesity, caught my interest. I grew up in a lower-middle class family. Both of my parents weigh over 200 pounds. My brothers and I would fill up on snack food after school because dinner was usually unpalatable. Lunch in the school cafeteria was the best meal of the day, and my brothers and I rejoiced when our school district started serving breakfast as well.

If any lasting change is to be made, acquiring and eating healthy foods must become convenient. A few examples:

In Pittsburg, Kansas, when the economy began its slump, Wal-Mart, which is the largest grocer in town, started giving local farmers first option on business. This helped guarantee that the population had enough money to buy the foods they needed.



I recently visited India for the first time, and I noticed that there was a vegetable market just outside my apartment. Vegetable markets in India are a convenient walk — usually within half a mile — from nearly every residential area. Instead of people going to the market, the market goes to the people, even in the middle of winter when temperatures drop as low as 40°F.

Here's an idea. The larger grocers can take a few boxes of a variety of fruits and vegetables to these residential areas where the working poor live, either when they would pass the vendors on the way home or be at home (and able to go to the vendors easily). The vendors sell the produce for an honest profit, and the families get the foods they want.

People are forced into bad eating habits for convenience, but for convenience they will change those habits. The people will have healthier, better-tasting food, and they will feel better. Also, the grocers willing to risk doing business in this new way will reap many benefits. They will enjoy increased sales and cash flow for the mere cost of labor — one person to man the vegetable stand. The grocers who do this will also earn the high opinion of their customers. Imagine the gratitude of a mother who can feed her children foods they really want — oranges, salads and fresh juices — because the grocer does the traveling.

The crucial point is to determine the areas where this service is most needed and the times during which people living in those areas will be free to shop; increasing service would increase the bottom line for grocers.

Michelle Jain
Kansas City, Missouri

Interesting for nonfarmer

It's so rare to find an agriculture publication of any kind that can be read with interest by a nonfarmer. What I like about *California Agriculture* is that it gets me beyond a view of agriculture as just a production process with inputs and outputs. It shows me many of the ways that agriculture fits interdependently with the earthly (land/water/air) resources that sustain it and the people who live on that earth.

What got me really thinking in the January-March 2004 issue was the package on the connections between food insecurity and obesity. This was something I have been thinking about since I taught junior-high kids in Bakersfield 25 years ago and watched how they acted. I am really glad this research was done, because I think it speaks to a key public-health issue. But I am especially grateful that your team of authors and editors managed to explain the research in ways that I could understand and that stayed true to the complexity of the issue. Maybe it was just that sweet picture of a kid eating fruit salad on the cover. If only I could get my 6-year-old to eat *her* veggies!

That was just one of the articles in the last issue that put agriculture in a larger social context — the people connection that includes labor, nutrition, immigration, economics, health...you name it. So it's not just the great writing and graphics that make *California Agriculture* interesting; it's the fact that you are telling me about agriculture in a way that really matters to people.

Joseph A. Davis, Writer-Editor
Bethesda, Maryland

RESEARCH ARTICLE

Horticultural biotechnology faces significant economic and market barriers

Julian M. Alston

Technological change has driven economic progress in agriculture and will continue to play a crucial role in the 21st century. The latest wave of technological change in agriculture is based in molecular biology. Will horticulture participate? Genetically engineered crop varieties have been adopted on a wide scale in some agronomic crops, but horticultural crops face larger hurdles. High costs for research, development and regulatory approval combined with the small acreages planted and the diversity of varieties, will limit the potential for profitable applications of biotechnology to many fruits and vegetables, tree fruits and nuts, and nursery crops. In addition, there are market barriers. Like most important changes in agriculture, modern biotechnology has met with spirited political opposition from some quarters. Threats of political action may discourage food manufacturers and retailers from adopting biotech products that are wanted by some consumers and may be profitable for growers.

Agriculture has been an important engine of economic development, and the mainspring of economic progress in agriculture has been productivity improvements driven by technological change that is fueled by research and development (R&D). Since World War II, agricultural productivity has more than doubled in the United States, as in many other countries. California agriculture today produces more than twice the output of 1950, using roughly the same total input — although with less labor and land, and more capital and purchased inputs.

These gains can be attributed to new biological, mechanical and chemical technologies, including improved genetic material, machines, fertilizers and pesticides, and knowledge. The current wave of technological progress continues this pattern, while emphasizing information technologies and biotechnology — in particular genetically modified (GM) crops. For many, GM crops represent the hope for a future with less hunger and malnutrition, and for a more sustainable agriculture with more varied, cheaper and safer food. For others they are cause for serious concern about the environment and food safety. Regardless of how we may feel about it, the juggernaut of technological change continues and the biotechnology revolution is well under way in the United States and other countries.

The challenge for public policy is to determine what regulations should be applied to govern the development and use of these technologies, and what other types of intervention may be necessary, such as public investments in research to correct for private-sector underinvestment. In the case of horticulture — the cultivation of fruits and vegetables, tree fruits and nuts, turfgrass, flowers and ornamental crops — these issues are sharply drawn because the private sector has not found it profitable to develop or commercialize many GM crops in the current political, legal and market environment.

What will happen in biotechnology applied to horticultural crops is up to the government, for a variety of economic reasons. Some of these aspects may be unique to GM horticultural crops but many are common to GM crops generally, and similar issues arise with some new non-GM technologies.

Courtesy of USDA-ARS

While agricultural biotechnology has revolutionized agronomic crops such as soybeans, corn and cotton in the United States, thus far virtually none of the produce on supermarket shelves is genetically engineered. The reasons for this disparity are complex.

For many, [transgenic] crops represent the hope for a future with less hunger and malnutrition, and for a more sustainable agriculture with more varied, cheaper and safer food. For others they are cause for serious concern about the environment and food safety.

Public, private roles in ag science

Without government intervention, the rate of innovation will be too slow, reflecting both underinvestment in research and underadoption of some research results. Both problems are related to the nature of property rights for research results. "Free-rider problems" occur when property rights are incomplete, and private investors can capture only part of the returns to their investments in certain types of research (such as developing new crop varieties); as a result, their incentives to invest are reduced. On the other hand, when the rights to research results are protected, such as by patents or trade secrets, the owner of a new variety can charge monopoly prices, unduly limiting the use of that variety. Intellectual property rights (IPRs) are a double-edged sword: to the extent that they provide a greater incentive for investing in research they are also likely to result in lower adoption rates.

Jack Dykinga/USDA-ARS

Large corporations have found it profitable to invest in research on genetically engineered agronomic crops, but smaller firms and public institutions such as the U.S. Department of Agriculture and land-grant universities undertake much of the research on horticultural crops. *Above*, Peter Quail of UC Berkeley inspects mutant *Arabidopsis* plants at the Plant Gene Expression Center, a joint venture of UC and USDA in Albany, Calif.

Governments have addressed the incentive problems in agricultural research in several ways. Federal and state governments (as well as industry) have funded agricultural research at public institutions such as the U.S. Department of Agriculture (USDA) and state agricultural experiment stations associated with land-grant colleges. This approach allows an increase in total research without the problems associated with monopoly pricing of inventions. However, even though the investment has paid handsome dividends, it is increasingly difficult to sustain the past levels of funding for public agricultural R&D, in the face of general budget problems and declining political support for public science funding, including agricultural science (Alston et al. 2000). Governments have also acted to strengthen IPRs applied to plants and animals as well as mechanical technologies; and changes in IPRs, especially in the 1980s, were crucial for the agricultural biotechnology development that followed. Partly as a reflection of enhanced IPRs, in the United States, private-sector funding of agricultural research has been growing faster than public-sector funding and now exceeds it.

The balance in agricultural R&D between the private and public sectors varies among types of research. For instance, until recently the private sector emphasized agricultural R&D pertaining to mechanical and chemical technologies, especially pesticides, where IPRs are effective; and the government was more important in other areas such as improving crop varieties. Private involvement was dominant in crop-variety research only in hybrid corn, where the returns were well protected by technical restrictions on copying or reusing saved seed, trade secrets and other legal rights. Changes in the institutional environment and the form of new IPRs, combined with new scientific possibilities associated with modern biotechnology, resulted in a shift in the private-public balance in research to improve crop varieties. As the balance shifts toward private research, new attention must be paid to old questions about whether the private investment in crop research will be sufficient, whether the allocation of those resources (say, among crops) will be optimal, whether the results will be adopted rapidly and widely, and what role the government should play.

Economic and market aspects

The development of new technologies through R&D is only one element of the picture. The technologies must also be approved for commercial application and economically attractive enough to be adopted by farmers. The experience with other biotech crops has lessons for horticultural biotechnology.

Biotech crops have been a commercial reality only for a few years but they have made very rapid inroads in some parts of the market. In particular, pest-resistant and herbicide-tolerant corn, soybeans, canola and cotton were rapidly developed and adopted in the United States and to a lesser extent in other countries (James 2000). To date, the successful GM crop varieties have emphasized "input traits," related to reducing the use of chemical pesticides or making them more effective, rather than "output traits," related to product quality. Why has there been rapid development and adoption of GM cropping technologies for these crops and not other important crops, such as wheat and rice? The likely reasons relate to the nature of supply and demand for new technology, and the economics of adoption.

— *continued on page 84*

Transgenic produce slow to enter evolving global marketplace

Roberta L. Cook

IF and when genetically engineered (GE) horticultural products become more widely available and adopted, they will enter an expanding marketplace that is becoming globally integrated and more consolidated. Fewer, larger firms will control access to a rising share of the world's population, including rapidly growing middle-income consumers in the developing world. Consumers everywhere will be increasingly focused on convenient, ready-to-eat and value-added products. In order to compete on a global scale, GE produce must meet the challenges of the quickly evolving market for fruits and vegetables.

In the United States alone, the estimated final value of fresh produce sold through retail and food-service channels surpassed $81 billion in 2002. Europe-wide fresh produce sales through supermarket channels alone (excluding green grocers and food service) were estimated to exceed $73 billion in 2002, and total final sales to exceed $100 billion.

Worldwide, consumption and cultivation of fruits and vegetables is increasing. Between 1990 and 2002, global fruit and vegetable production grew from 0.89 billion tons to 1.3 billion tons, and per capita availability expanded from 342 pounds to 426 pounds (FAO 2003). Much of this growth has occurred in China, which is aggressively pursuing agricultural biotechnology (see page 112).

The global fresh fruit-and-vegetable marketing system is increasingly focused on adding value and decreasing costs by streamlining distribution and understanding customer demands. In the United States and Europe this dynamic system has evolved toward predominantly direct sales from shippers to supermarket chains, reducing the use of intermediaries. Food-service channels (hotels, restaurants and institutions) are absorbing a growing share of total food volume and are also developing more direct buying practices. The year-round availability of fresh produce is now seen as a necessity by both food service and retail buyers.

Product form and packaging are also changing as more firms introduce value-added products, such as fresh-cut produce, salad greens and related products in consumer-ready packages. Estimated U.S. sales of fresh-cut produce were over $12 billion in 2002. Fresh-cut sales are even higher in Europe and beginning to develop in Latin America and Asia as well. The implications of this trend may become as important to the biotechnology industry as the changes in market structure, since fresh-cut processors are increasingly demanding specific varieties bred with attributes beneficial to processing quality.

International trade

The streamlining of marketing channels poses both challenges and opportunities for horticultural biotechnology. A smaller number of larger firms, controlling more of world food volume, now act as food-safety gatekeepers for their consumers, reflecting the diversity of consumer preferences in their buying practices. Where consumers perceive products utilizing biotechnology to be beneficial, retail and food-service firms will provide them. Products with specialized input traits valued by consumers, such as unique color, flavor, size or extended shelf-life, are the most likely to succeed in today's marketplace.

While large food-service and retail buying firms and international traders may offer easy access to consumer markets, if major buyers adopt policies unfavorable to GE foods, distribution obstacles could become insurmountable. Such policies are common among European food retailers, reflecting strong consumer concern there over GE products.

The challenge to supply seasonal, perishable products year-round has favored imports, and increased horizontal and vertical coordination and integration among shippers regionally, nationally and internationally. Seasonality in the production and consumption of perishable commodities, due to natural climatic conditions, causes much horticultural trade to be counter-seasonal, such as the shipment of Southern Hemisphere grapes and stone fruits from Chile to the United States and Europe in order to meet consumer demand during the Northern Hemisphere's winter, when domestic supplies are low.

Integration among international traders and grower-shippers allows them to position themselves as consistent year-round suppliers of differentiated products; these firms increasingly seek out varieties that offer superior flavor and other attributes. For example, Sun-World, a California fresh fruit shipper is pursuing a strategy of marketing differentiated, proprietary varieties where possible. These varieties must be provided from multiple locations in the Northern and Southern Hemispheres so that shippers can provide customers around the world with a year-round supply of consistent quality. Long-term, breeding a set of attributes into a particular fruit or veg-

Syngenta

Global consumption of fruits and vegetables is on the rise, but important markets for California produce growers such as Europe and Japan, *above*, have taken a cautious approach toward imports of transgenic foods.

etable variety in one location will be insufficient to meet these goals.

The United States is the world's largest importer and exporter of fruits and vegetables. U.S. imports of fruits and vegetables grew from $6.7 billion in 1990 to $10.8 billion in 2001, while imports by E.U. countries (including intra-E.U. trade) grew slightly to about $36 billion. Germany has long been the most important import market within Europe, accounting for 12% of world fruit and vegetable imports in 2001. However, a declining import share for Germany is largely responsible for a drop in the E.U.'s share of world imports from 56% in 1990 to 48% in 2001. Japan imported $5.9 billion worth of fruits and vegetables in 2001, accounting for about 8% of world imports since 1993.

With store locations in 10 countries, Wal-Mart is the one U.S. firm with a global presence, and it is also the world's largest grocery retailer.

While the influence of the European Union and Japan on world horticultural markets has not been growing, they will remain vitally important. Leading and emerging fruit and vegetable suppliers will continue to vie for these lucrative markets and will respond to market signals conveying evolving European and Japanese preferences regarding the use of biotechnology. Furthermore, in the case of Japan, declining domestic horticultural production over time and economic recovery are expected to eventually cause imports to rebound.

The importance to the United States of European and Japanese preferences regarding GE foods is evident. In 2001, the United States exported $1.1 billion of fresh and processed fruit, vegetables and nuts to the European Union and had a $300 million trade surplus with the European Union in these products (USDA 2002). Nuts, raisins and fruit juices are most important, with about two-thirds of the trade in those categories, while fruits such as table grapes, stone fruit and citrus are also important. In 2001, the United States also shipped fresh fruit worth $537 million to Japan, accounting for 40% of the market (USDA 2003). On the other hand, the United States is now a minor player in the Japanese vegetable import market, shipping $278.3 million worth of vegetables in 2001, a 14% share. China has become the leading (and still growing) supplier of fresh vegetables to Japan, with a 57% share. Hence, Japanese consumer preferences regarding GE foods will affect the U.S. fruit industry more than the vegetable industry.

Countries well known for their fruit exports, such as Chile, Brazil, Argentina and Ecuador, have market shares of 2.3% or less, and Australia and New Zealand hover at the 1% level. While some countries may hold important market shares in certain individual products, in general, there is still great geographic diversification in the world fruit and vegetable trade. For fresh vegetables, the world's top five exporters (the Netherlands, Spain, Mexico, United States and China) contributed 59% of total export value in 2001. Only the United States was ranked within the top five both as an importer and exporter, making decisions in the United States regarding biotechnology especially important to vegetable breeders.

Retail markets

Over the past decade the world has experienced a high rate of mergers and acquisitions in the grocery retailing industry, both in home country markets and across borders via foreign direct investment. Over the past decade this trend led to an estimated 30 firms accounting for 10% of global grocery sales (M+M PlanetRetail 2003). Many of these chains are European and Asian, but with store locations in numerous countries, enhancing their global buying power.

Latin America and Asia have experienced striking growth in the role of supermarkets in food retailing over the past decade, with southern and eastern Africa engaged in the same transformation process (Weatherspoon and Reardon 2003). Over the next decade the rapid evolution of supermarkets should induce more direct linkages between suppliers and retailers on a global scale, gradually eroding the dominant role of traditional wholesalers, open street markets and small-scale fruit and vegetable vendors, following the trend occurring in the latter half of the 20th century in the United States and Europe.

With store locations in 10 countries, Wal-Mart is the one U.S. firm with a global presence, and it is also the world's largest grocery retailer. Approximately 30% of Wal-Mart's $259 billion in global 2003 sales were estimated as grocery-equivalent, generating impressive new buying power in the food industry. To date, Wal-Mart's policy is to market GE food products.

As the food distribution system consolidates, retailers are seeking larger suppliers that come closer to matching their scale, as well as suppliers offering more services and marketing support, tailored to their specific needs. This movement toward account-based marketing is making the food system more technology-intensive, including the introduction of demand-based information management practices to stimulate sales and profits for retailers. To compete effectively, both suppliers and buyers must be consumer-driven, utilizing modern information management practices in all aspects of the vertical food system. The adoption (or not) of GE foods will depend on consumer response as measured by commercial buyers acting as food safety gatekeepers.

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Benefits to farmers and others. The total benefits from farmers adopting any new cropping technology are approximately equal to the benefits per acre times the number of acres affected. With pest-resistant crop varieties, these benefits come primarily from reduced costs for applying chemical pesticides and increased yields, after an allowance for regulatory requirements for refugia to manage resistance. The distribution of these total benefits between farmers (and ultimately food and fiber consumers) on the one hand, and the technology suppliers on the other, is determined by the size of the premium charged for the use of the new technology, but this premium also affects the incentives for farmers to adopt the technology.

Economic studies suggest that farmers and biotech companies have shared in the benefits of biotech crops and that the net benefits have been large. Gianessi et al. (2002) conducted 40 detailed U.S. case studies of biotech cultivars. They estimated that in 2001, eight biotech cultivars adopted by U.S. growers provided a net value of $1.5 billion to growers, reflecting increased crop values and cost savings. They further estimated that the 32 other case-study cultivars would have generated an additional $1 billion in benefits to growers if they had been adopted, bringing the total potential benefit in 2001 to $2.5 billion. Of this annual total, the lion's share was for herbicide-tolerant crops ($1.5 billion per year), followed by insect-resistant crops ($370 million per year). These estimates do not represent the total economic impact because the geographic analysis was limited in scope, and they do not include any benefits to the seed companies and biotech firms that produced the technology.

Environmental concerns. Private benefits and costs from biotech crops accrue to growers and consumers of the products, along with seed companies and biotech firms. If the new technology involves environmental risks (as some fear may be the case with biotech crops) or replaces technology that involves environmental risks, there will

Diversity of horticultural biotech crops contributes to market hurdles

Kent J. Bradford
Julian M. Alston

Why is the acreage of biotech agronomic crops continuing to increase while commercialization of horticultural biotech products stagnates? Representatives of the horticultural industry offered a variety of explanations at a workshop in Monterey in March 2002 (see acknowledgments below).

Species diversity. Virtually all of the biotech crops currently grown are in four species (soybean, corn, cotton and canola). This contrasts with the hundreds of horticultural species and thousands of fruit, vegetable and ornamental crop varieties. In most cases, specific procedures are required to genetically transform each species, and the ease with which different varieties can be transformed varies widely. Introducing a trait into a specific crop and variety may require considerable research and development. The diversity of propagation and marketing mechanisms also presents challenges, as many horticultural crops are vegetatively propagated from cuttings or grafting rather than by seed, or are perennial, bringing different issues for containment, stewardship and value.

Multiple niche markets. Unlike the commodity agronomic crops, horticultural markets are highly segmented by factors such as location, season and consumer preferences. The horticultural market is composed of many niche markets, and any single product may be successful in just a few of those niches. People in different countries or regions prefer different colors, shapes, sizes and flavors of melons, for example. Diseases vary by location, so the types of resistant varieties required also vary. Diverse growing conditions and seasons require multiple adapted varieties — even if the product, such as broccoli, appears virtually identical — to assure availability in the market every day of the year. Consumers often prefer different colors of their favorite flower. Introducing a trait into a horticultural species likely requires its introduction into multiple varieties to achieve market success.

Limited market windows. The niche market for horticultural crops also means that any single variety is likely to be successful in only a small fraction of the crop's total market. In California lettuce production, a given variety may have a market window of only a few weeks in a specific location as production moves seasonally around the state. The potential acreage (and sales) of a variety is limited, and unless development and regulatory costs can be spread over multiple varieties, the potential returns on a biotech trait are often too small to be economically feasible (see page 106).

Many processed products are marketed internationally and regulatory approval is required in each importing country, possibly with each having different testing or labeling requirements.

Processor requirements. For most processed crops, the processor specifies the varieties grown and the raw-product standards. While existing biotech traits would be beneficial to processors, such as high viscosity in tomatoes or insect resistance in sweet corn, processors are also highly sensitive to consumer preferences and often have recognizable brand names that are much more valuable than any single product. Processors are wary of jeopardizing their overall market position by risking pickets or protests from anti-biotech activists. For example, Dole would have little interest in helping its lettuce growers control weeds with herbicide-tolerant lettuce if that would put its global pineapple and banana markets at risk.

Edwin Remsberg/CSREES-USDA

With regard to horticultural crops, consumer preferences vary. They may want several different melon varieties or flower colors, *left.* Garden and lawn-care products such as turfgrass, *right*, could provide inroads for genetically engineered varieties.

In addition, many processed products are marketed internationally and regulatory approval is required in each importing country, possibly with each having different testing or labeling requirements. Segregating or channeling processed products for different markets is possible, but requires extensive (and expensive) changes in current production and distribution systems.

Distribution requirements. The distribution and retailing of horticultural products is increasingly global and concentrated (see page 82). Large distribution firms can dictate standards independent of any regulatory system, so whether they agree to market a particular product can mean the difference between success and failure. Labeling on the basis of whether recombinant DNA techniques were used is not required in the United States, but it is in many other countries. There is still no consistency among countries about what should be on such a label, how much information it should provide or whether it should be voluntary or mandatory.

Traceability is the ability to track a product from the market back to the field or greenhouse where it was produced. While this is possible with some items, such as fresh flowers, fruits and vegetables, it is more difficult with products commingled during processing such as canned vegetables and fruits. Segregation of products is possible, as for organic foods, but associated costs often require higher prices for profitability.

Liability is a critical issue, as demonstrated by recalls following the discovery of Starlink corn in tortilla chips, when the transgenic variety had not been approved for human consumption. The food industry is leery of any situation where its products might be considered adulterated and require a recall. Without practical thresholds for adventitious (unexpected or accidental) presence of biotech DNA or protein in the processed product (as there are for things like insects found in agricultural products), the risk is high with little benefit to the distributor.

Consumer benefits. While the first wave of biotech products was targeted primarily to growers, incentives are needed throughout the marketing chain to share both the risks and the benefits. Products with clear benefits for consumers may be needed to develop demand; these will also likely require a premium price to compensate for the tracking and segregation needed to ensure that the promised quality is delivered. As biotechnology moves beyond the initial phase of input traits and begins to develop output and consumer traits, its developers must pay attention to the interests, concerns and requirements of all participants in the production, processing, distribution and marketing chain.

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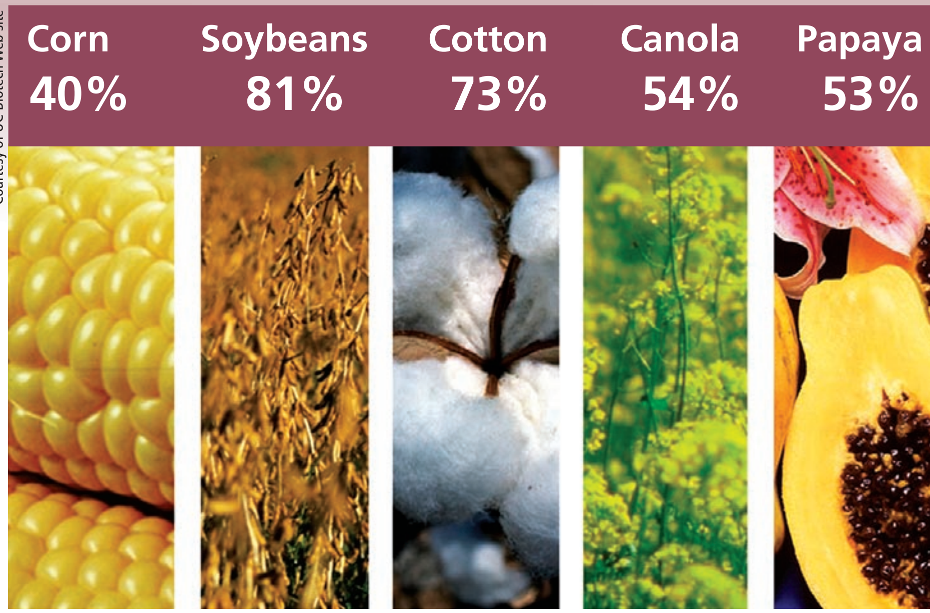
"The Workshop on Biotechnology for Horticultural Crops: Challenges and Opportunities," held in Monterey in March 2002, was sponsored by the Giannini Foundation, UC BioStar Project, UC Davis College of Agricultural and Environmental Sciences, UC Division of Agriculture and Natural Resources, UC Agricultural Issues Center and UC Davis Seed Biotechnology Center. Presenters included Ted Batkin (California Commodities Committee and Citrus Research Board), Fred Bliss (Seminis Vegetable Seeds), Neal Gutterson (formerly of DNA Plant Technology), Susan Harlander (BioRational Consultants), Kathy Means (Produce Marketing Association), Irvin Mettler (formerly of Seminis Vegetable Seeds), Carlos Reyes (Monsanto), Chuck Rivara (California Tomato Research Institute), David Schmidt (International Food Information Council), Terry Stone (Monsanto), Larry Stults (Syngenta) and Mary Zischke (Dole Fresh Vegetables).

Courtesy of UC Biotech Web site



Significant percentages of acres planted to major U.S. row crops and one minor horticultural crop (papaya) were genetically engineered varieties in 2002 (canola) and 2003. These crops were transformed to provide traits attractive to growers rather than consumer-oriented traits like taste or nutritional value.

be additional environmental costs and benefits to take into account as an element of national costs and benefits. For instance, pest-resistant crops can reduce the application of broad-spectrum chemical pesticides, which are hazardous to farmworkers, compromise food safety and impose a burden on the environment. The economic studies to date have not assessed these environmental costs and benefits. However, Gianessi et al. (2002) estimated that adoption of the eight current cultivars allowed a reduction in pesticide use of 46 million pounds in 2001, and the 32 potential cultivars could have allowed a further reduction of 117 million pounds. The relevant comparison then is between the environmental risks associated with these biotech crops and those associated with the annual burden on the environment of 163 million pounds of chemical pesticides that could be avoided by growing biotech crops instead – 66 million pounds in California alone, where 185.5 million pounds of pesticides were used in 1999 (Mullen et al. 2003)

Market acceptance. On the demand side, farmers will adopt biotech varieties if the perceived net benefits to them are large enough, and this depends on the perceived market acceptance of GM crops. Concerns have been raised about the possibility that GM crops may be unsafe for consumers because of allergens or other, as yet unidentified risk factors, about risks to the environment and to the economy from uncontrolled genetic drift, and about the moral ethics of tampering with nature. The GM varieties that have been developed and adopted extensively to date have not experienced significant price discounts because of buyer resistance. This can probably be attributed to the nature of the crops. For feed grains, the buyers are other farmers who are comfortable with the technology, and for fiber crops such as cotton the food safety concerns do not apply. For the major food grains, wheat and rice, even if the farm-production economics potential of GM varieties is as large as for feed grains, market acceptance may differ sufficiently to limit their adoption. Rather than another farmer, the relevant buyer for these crops is a food processor, manufacturer or retailer who may be reluctant to risk negative publicity or to risk losing consumers who would prefer a biotech-free label or who may not be confident that the biotech and nonbiotech grain can be segregated.

Processors and retailers. It is not sufficient that farmers and consumers perceive net benefits from GM crop varieties. The adoption of biotechnology must provide net benefits to other participants in the marketing chain, such as food processors and retailers. Pricing of the technology may be a critical factor. Even if the new technology is more cost-effective than the traditional alternative, monopolistic pricing could mean that the technology supplier retains a large share of the benefits. The cost savings passed on to processors and consumers may be a small fraction of the total benefits, rendering incentives for processors, retailers and consumers to accept the technology comparatively small. Processors and retailers can effectively block a new technology if it does not clearly benefit them, even if there would be net benefits to the general public.

Fixed costs. The size of the market matters. The cost to develop a new variety is essentially the same whether it is adopted on one acre or a million acres, but the benefits are directly proportional to the number of acres on which the variety is adopted. This is why biotech companies have focused on developing technologies for more widely planted agronomic crops, especially feed-grain and fiber crops for which market barriers are lower.

The technology developer must also obtain regulatory approvals. It is difficult to obtain precise information on costs of regulatory approval for biotech crops and chemical pesticides, but according to available estimates, the total cost of R&D — from "discovery" to commercial release of a single new pesticide or herbicide product — exceeds $100 million, and regulatory approval alone costs more than $10 million. A new technology must generate enough revenue for the developer over its lifetime to cover these costs, and for some crops the total acreage is simply not sufficient. Given the large fixed costs associated with regulatory approvals for specific uses, agricultural chemical companies have concluded that the potential market is too small to warrant the development of pesticides for many of California's specialty crops, which have become technological orphans.

It does not follow that the government should invest in developing new conventional or GM pest-control technologies for these orphan crops. If the current regulatory policy and process is appropriate and efficiently

To date, the successful GM crop varieties have emphasized "input traits," related to reducing the use of chemical pesticides or making them more effective, rather than "output traits," related to product quality.

implemented then the high cost is not excessive; if a new technology cannot generate benefits sufficient to pay those costs, then it is simply not economical to develop that technology. The question for technology orphan crops is whether it is possible to reduce the costs of R&D and regulatory approval sufficiently to make it profitable for the nation and the private sector to change their orphan status.

Markets for horticultural biotech

On the supply side, "horticulture" includes an enormous diversity of fruit and vegetable crops, but it also includes many nonfood species, such as ornamentals, flowers and recreational turfgrass. Collectively these horticultural crops compare well with major agronomic crops in terms of total value in the United States. However, they use much less acreage, and the market size for some biotech products depends on both acreage and production value. In 2000, the United States produced fruits, nuts and vegetables with a total value of more than $28 billion, of which California contributed about $14 billion (table 1). In addition, horticulture includes a small number of larger-scale crops (such as potatoes and onions, apples and wine grapes) as well as a large number of smaller-scale crops (such as Brussels sprouts and persimmons). At current costs for R&D and regulatory approval, it is unlikely that biotechnology products will be developed and achieve market acceptance for many of these smaller-scale crops in the near future (see sidebar, page 84). Further, experimentation with perennials such as grapes, nuts and fruit trees is comparatively expensive (because the experimental unit is larger and takes more time), and it is costly to bring new acreage into production or replace an existing vineyard or orchard with a new variety.

On the demand side, the market for horticultural products, especially fresh fruits and vegetables, is undergoing important changes associated with the changing structure of the global food industry (see sidebar, page 82). Increasingly fewer and larger supermarket chains have been taking over the global market for fruits and vegetables, especially fresh produce, and changing the way these products are marketed. Because fresh produce is perishable and subject to fluctuations in availability, quality and price, it presents special problems for supermarket managers compared with packaged goods. Supply-chain management, and the increasing use of contracts that specify production parameters as well as characteristics and price, is replacing spot markets for many fresh products. A desire for standardized products, regardless of where they are sourced around the world, could limit the development and adoption of products targeting smaller market segments, unless retailers perceive benefits and provide shelf space for diversified products — such as biotech and nonbiotech varieties of particular fruits and vegetables.

On the other hand, an increasingly wealthy and discriminating consuming public can be expected to continue to demand increasingly differentiated products — with an ever-evolving list of characteristics such as organic, low-fat, low-carbohydrate and farm-fresh. Hence retailers will have to balance the cost savings and convenience as-

TABLE 1. Value of production and acreage for selected commodities, 2000

	Value of production		Area grown		
Commodity	**California**	**U.S.**	**California**	**U.S.**	**World**
Fruits and tree nuts	*million $*		*thousands of acres*		
Almond	655	655	500	500	4,136
Apple	142	1,326	31	445	13,517
Apricot	27	32	19	20	951
Avocado	310	326	59	65	827
Grapefruit	55	285	15	145	620
Grape, all types	2,804	3,072	827	946	18,503
Kiwi	14	14	5	5	136
Orange	514	1,683	196	815	8,930
Peach/nectarine	358	595	103	191	5,114
Strawberry	840	1,086	28	48	575
Total*	7,285	12,626	2,464	4,092	NA
Vegetables and melons					
Artichoke	71	61	9	9	307
Asparagus	144	221	37	77	2,645
Bell pepper	172	527	21	62	969
Carrot	322	438	85	123	2,357
Cauliflower	212	249	42	47	2,259
Garlic	140	155	29	35	2,660
Lettuce	1,581	1,872	211	284	2,079
Melon	372	704	90	290	10,175
Onion	189	736	50	166	557
Potato	209	2,591	44	1,348	49,490
Tomato	948	1,809	311	432	9,745
Total*	6,718	15,560	1,734	2,820	NA
Field crops					
Corn for grain	65	18,499	205	72,440	340,580
Cotton	807	4,260	914	13,053	82,000
Rice	217	1,050	548	3,039	380,019
Soybeans	0	12,467	0	72,408	183,804
Wheat	104	5,782	487	53,133	532,545
Total*	1,586	47,514	4,738	328,449	NA

*Totals include many other crops in addition to those listed.

NA = not available.

Sources: USDA National Agricultural Statistical Service and California Agricultural Statistics Service for California and U.S. data; United Nations Food and Agricultural Organization for world data; Cotton Incorporated for world acreage of cotton.

Supporters of agricultural biotechnology believe it can help to reduce pesticide use and provide more abundant food for an ever-increasing global population. Government can play a role in guaranteeing safety while ensuring that unreasonable hurdles are not preventing its broader distribution. *Far right,* aerial spraying of pesticides; *right,* a produce market in Ethiopia.

IFPRI/Klaus von Grebmer

Jack Kelly Clark

sociated with global standardization against the benefits from providing a greater range of products, which will include GM products when retailers begin to perceive benefits from stocking them. Unlike other types of foods, fruits and vegetables are often consumed fresh and in clearly identifiable and recognizable form. This has implications for perceptions of quality and food safety that may influence consumer acceptance — perhaps favorably, for instance, if a genetically modified sweet-corn could be marketed as reduced-pesticide (see page 99).

Other elements of GM horticulture — such as nonfood products, ornamentals or turfgrass — have advantages in terms of potential market acceptance. GM trap crops, which provide pesticide protection for other crops, and GM sentinel crops, which signal the presence of pests or provide other agronomic indicators — may be used in food production without overcoming barriers of acceptability to market middlemen or consumers (see page 89). Biotechnology products designed for home gardeners may be more readily accepted because the grower is the final consumer.

Market acceptance in the United States is also linked to continued access to export markets, particularly in the European Union and Japan where restrictions have been applied to biotech foods. The relative importance of the domestic market could help to account for the success of the GM feed-grain technologies in the United States, and it may also help to account for the success of these and other GM technologies in China. China is comparatively important in horticultural biotechnology — its investment in agricultural biotechnology is second only to the United States, but with a different emphasis, including significant investment in horticultural biotechnology (see page 112).

Implications for government policy

The technological potential for GM horticultural crops appears great, particularly when we look beyond the "input" traits that have dominated commercial applications to date, to opportunities in "output" traits, such as pharmaceuticals and shelf-life enhancements. Because delays in socially beneficial technologies mean forgone benefits, there may be a legitimate role for the government in facilitating a faster rate of development and adoption of horticultural biotechnology products. For instance, the government could reform property-rights institutions to increase efficiency and reduce R&D costs. IPRs apply to research processes as well as products, and limited access to enabling technology or simply the high cost of identifying all of the relevant parties and negotiating with them, may be retarding some lines of research — a type of technological gridlock (Binenbaum et al. 2003). Nottenburg et al. (2002) suggest a government role in improving access to enabling technologies. Similarly, the government could revise its regulations to increase efficiency and reduce costs for regulatory approvals. Instead of requiring a completely separate approval for each genetic transformation "event," it may be feasible to approve classes of technologies with more modest specific requirements for individual varieties.

The government could also reduce some barriers to adoption, especially market acceptance of biotech food products, by providing information about their food safety and environmental implications. The biotech industry and agriculture can have an influence here, too. The general education of consumers and market intermediaries about biotech products may be facilitated in a process of learning by experience with products — such as nonfood applications, or home garden applications — that have good odds of near-term success because of low barriers to market acceptance and good total benefits.

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Despite benefits, commercialization of transgenic horticultural crops lags

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The acreage of agronomic crops (soybean, cotton, corn and canola) developed using recombinant DNA technology has expanded dramatically since their introduction in 1996, while the commercialization of biotech horticultural crops (vegetables, fruits, nuts and ornamentals) has languished. This is not due to a lack of both current and potential traits that could be utilized in horticultural crops, as ongoing research is identifying a diverse array of applications. However, commercialization is stalled by market reluctance to accept biotech products, particularly in the absence of clear benefits to consumers. High regulatory costs and restricted access to intellectual property create additional hurdles for specialty crops. These challenges are causing the horticultural industry to forego a number of current benefits. New products with clear advantages for producers, marketers and consumers may be required before the potential of biotechnology can be realized.

IN 2003, nearly 106 million acres of transgenic or genetically engineered (GE) crops was planted in the United States, part of 167 million acres of such crops grown worldwide (James 2003). Despite the fact that the first commercialized transgenic food crop was the Flavr Savr tomato, four agronomic crops (corn, soy, cotton and canola) account for virtually all of the current acreage. Last year, only four horticultural crops developed using recombinant DNA technology were available in the United States: papaya, sweet corn, squash and a carnation. Except for transgenic papaya, which accounts for approximately 50% of the Hawaiian crop (HASS 2001), the fraction of the total horticultural commodities represented by transgenic varieties is miniscule.

The absence of significant commercialization of transgenic varieties in horticulture is not due to lack of potential products or value (Dandekar and Gutterson 2000; see sidebar, page 94). The basic techniques of molecular biology have become routine, and considerable research is being conducted on horticultural crops. For example, herbicide resistance has been transferred into bentgrass and bluegrass to make weed control in municipal and highly managed turf environments such as golf courses more efficient. However, they have not been commercialized. Similarly, some horticultural crops, including lettuce and tomato, have been engineered with herbicide resistance and tested in field trials but remain uncommercialized. Disease resistance, particularly to viruses, can be developed using biotechnology, and potato and papaya cultivars engineered for virus resistance have been commercialized, but many potential applications are currently underutilized. Improving traits that directly benefit consumers, such as nutritional or aesthetic quality, is also technically feasible now in many horticultural crops, but only a few products have reached the market.

Approved traits and technologies

The major technologies that have been approved and widely adopted by the industry focus on input traits, or those affecting production of the crop rather than the qualities of the final product. Although most approved genes confer insect resistance and herbicide tolerance, a range of genetic traits has been approved by the U.S. regulatory system (table 1).

Insect resistance. Insect resistance has been engineered primarily by using

Florigene

Florigene, of Melbourne, Australia, markets transgenic carnations engineered for blue-violet color under the variety name 'Moonshadow'.

TABLE 1. Approved transgenic traits for U.S. crops

Trait	Examples
Herbicide tolerance	Bromoxynil, glufosinate, glyphosate, sulfonylurea
Insect resistance	Bt kurstaki, Bt tenebrionis
Virus resistance	Papaya ringspot virus, cucumber mosaic virus, zucchini yellow mosaic virus, watermelon mosaic virus, potato leaf roll virus, potato virus Y
Male sterility	Barnase/barstar
Modified ripening	ACC synthase, ACC deaminase, SAM hydrolase, polygalacturonase
Modified oils	High lauric, myristic, oleic acids

two classes of bacterial genes derived from *Bacillus thuringiensis* (Bt) ssp. *kurstaki* and ssp. *tenebrionis* (de Maagd et al. 2003). These Bt genes control a broad spectrum of lepidopteran and coleopteran insects, respectively. The genes have been approved for use in major row crops (feed corn and cotton) and some horticultural crops (sweet corn and potato). Potato and sweet corn varieties engineered for resistance to Colorado potato beetle and corn earworm, respectively, were in commercial production for several years and were technically and agronomically successful, allowing significant reductions in insecticide use (Shelton et al. 2002). However, the transgenic potato varieties were withdrawn from the market after major processors and distributors chose not to purchase and market them. Bt sweet corn, while still available, is not widely grown for the same reason (Cornell Cooperative Extension 2003).

Herbicide tolerance. Several herbicide-tolerance genes are registered for use. The most widely commercialized gene is a bacterial enzyme conferring tolerance to glyphosate, the active ingredient of Roundup herbicide. Transgenes conferring tolerance to bromoxynil (Buctril), glufosinate (Liberty) and sulfonylurea (Glean) herbicides are also approved for use in a wide variety of crops. In addition, crops tolerant to imidizolinone (Clearfield) and sulfonylurea herbicides have been developed through nontransgenic methods based on natural or induced mutations. However, no horticultural crops engineered for herbicide resistance have been commercialized, although several have been developed and tested.

Virus resistance. The use of viral coat protein genes to confer resistance has been approved for several virus-crop combinations (table 1). The most commercially successful has been papayas engineered for resistance to the papaya ringspot virus. This product has revived the Hawaiian papaya industry, which was devastated by the virus in the 1990s (see sidebar, page 92). Small acreages of transgenic squash resistant to mosaic viruses are also grown. Virus-resistant potato varieties were formerly commercialized but are not currently being marketed. Newer technologies, such as RNA interference or RNA silencing (Waterhouse et al. 2001), offer promise for developing resistance to other damaging diseases, such as those caused by geminiviruses (Gilbertson et al. 1998).

Courtesy of USDA-ARS

Doug Wilson/USDA-ARS

Left, **scientists are investigating ways to prevent Pierce's disease in grapes by genetically engineering genes from a naturally resistant variety, *Muscadinia rotundifolia,* into susceptible varieties. In a peer-reviewed study, a parasitoid wasp that controls the diamondback moth, *right*, a canola pest, was not affected by Bt canola.**

Flavr Savr tomato. Transgenic horticultural crops providing direct benefits to the consumer have also been developed. Calgene's Flavr Savr tomato silenced the gene encoding polygalacturonase, an enzyme implicated in fruit softening. The expectation was that the tomato would soften and spoil more slowly and could be picked at a later stage of maturity. This later harvest, in principle, would permit greater development of flavor compounds and better taste. This product, first marketed in 1994, was a success with consumers but failed economically for a variety of reasons (Martineau 2001). This same gene was also used in a tomato variety processed for paste and marketed by Zeneca in the United Kingdom. The trait reduced processing costs and consumers accepted the clearly labeled product, until the European uproar over biotech foods forced it off the supermarket shelves.

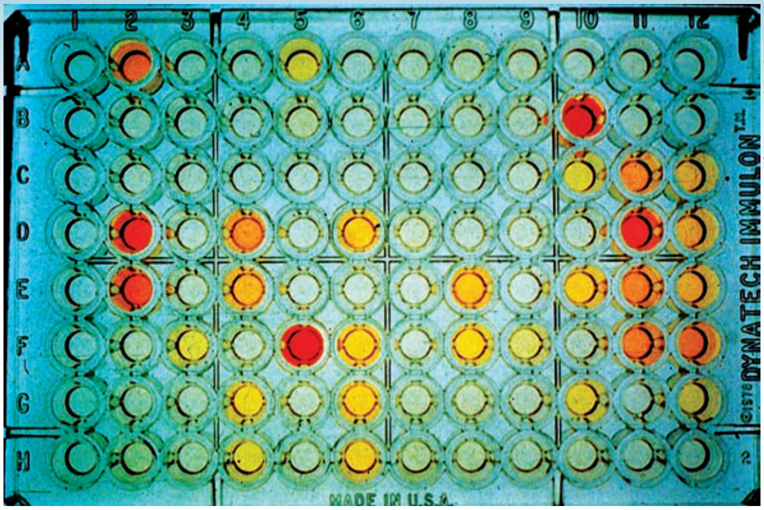
U.S. regulatory agencies also approved several other delayed-ripening tomato varieties based on strategies targeted to block the ethylene biosynthetic pathway (ACC deaminase and antisense/cosuppressed ACC synthase) that is essential for ripening. None of these products is currently marketed, despite their technical feasibility and potential consumer benefits. Rather, they were preempted by a nonbiotech approach utilizing the naturally occurring *rin* mutant of tomato that delays fruit ripening. Heterozygous plants produce fruits that ripen at a significantly slower rate than normal fruits. A nontransgenic approach achieved essentially the same objective, and aggressive breeding and marketing of the long-shelf-life *rin* hybrid tomatoes made the transgenic approach redundant.

Lengthening postharvest time. Similarly, virtually all bananas marketed in the United States are naturally deficient in their ability to initiate ethylene synthesis, allowing them to be shipped green and ripened by exposure to ethylene gas prior to sale. However, where natural mutants are not available, the general approach of manipulating ethylene synthesis has great potential for application in other climacteric fruits (whose ripening is mediated by ethylene), particularly tropical fruits with short postharvest lives such as mango, papaya and banana. A higher quality fruit bringing tangible value to the consumer could improve the market acceptance of biotech crops.

Despite their early introduction and initial market success, and in contrast to what many consumers may believe, the only biotech horticultural commodities currently marketed in the United States are Hawaiian papayas, a small amount of squash and sweet corn, and a few carnation varieties. The commonly cited estimate that as much as 70% of food products in U.S. supermarkets contain ingredients from GE crops is not attributable to fruits and vegetables, but rather to the widespread use of corn, canola and soybean oil, soybean protein, corn starch and related products in virtually all processed foods.

Opportunities for biotechnology

As global acreage of biotech agronomic crops sustains its eighth consecutive year of double-digit growth rates (increasing 15% from 2002 to 2003) (James 2003), it is paradoxical that the trend in horticultural crops is exactly the opposite, particularly as many of the approved genes fit naturally with the needs of horticultural crops. Fear of consumer rejection on the part of both producers and marketers of horticultural products is a major impediment to wider utilization of biotechnology, even though many consumer polls do not find a majority negative opinion about it (see page 99). Many food companies are unwilling to risk the consequences of alienating even a small fraction of their potential market (Gillis 2000). Clearly, growers, distributors and consumers must all see biotech crops as in their best interests for commercialization to be successful. Products offering compelling value could alter the economic forces influencing producer choices and could create consumer demand to pull such products through the marketplace.



Courtesy of UC Biotech Web site

Biotechnology is contributing to the development of sensitive diagnostic techniques. *Above,* plant samples are placed in wells and subjected to a color-based detection system; yellow shows evidence of disease.

Loss of pesticides. One factor that may significantly alter grower economics is the loss of currently registered pesticides due to environmental and health concerns. For example, methyl bromide is scheduled to be withdrawn from use in the United States in 2005 because it contributes to depletion of the ozone layer. Methyl bromide is widely used in horticultural crops to control soilborne diseases and weeds and to fumigate harvested crops to eliminate insects. The majority of this use is in horticultural crops (primarily strawberries, tomatoes, peppers, ornamentals and nurseries, and tree crops) with California and Florida together accounting for 80% of the 35 million pounds applied each year for preplant fumigation (Economic Research Service 2000). Many genes are available that potentially could be used to enable alternative weed-control strategies.

Horticultural crops are also limited in the numbers of herbicides registered for use. Loss of registration for a few key chemicals could markedly limit grower options, making crop resistance to broad-spectrum herbicides more critical. Resistance to fungal and bacterial diseases would also be desirable, as in some areas extensive use of pesticides is currently undertaken for their control. As for herbicides, it is also difficult to maintain registrations for minor crops grown on smaller acreages, which are primarily horticultural. Biotech strategies are being developed that could provide broader spectrum disease control and reduced dependence upon chemical pesticides (Lincoln et al. 2002). Resistance to viral diseases would be valuable in many horticultural crops, as there are few other options for control, and methods for engineering virus resistance are well established.

Tree fruit, nuts and grapes. Research is well under-way to build a robust platform of technologies to utilize genomics in the discovery of useful traits for trees (Dandekar et al. 2002). Transformation technology has been developed and trait evaluation is under way on apple, almond, peach, citrus, walnut, pear, plum, grapevine and persimmon. Good progress has been made in developing resistance to codling moth and fireblight in apple, plum pox virus in plum/*Prunus*, crown gall and codling moth in walnut, citrus tristeza virus (CTV) in citrus and Pierce's disease in grapevine.

Engineering of resistance to codling moth in apple to reduce the use of chemical pesticides has advanced to the point of commercial interest in product development. Work is also under way to develop productivity and quality traits such as modified sugar metabolism and ripening in apple and regulation of self-incompatibility in almond and other *Prunus* species. Some deployment strategies for transgenic trees are also being developed, such as the use of transgenic trees as "trap crops" to control insects in conventional orchards and the use of transgenic rootstocks to control diseases and pests in nontransgenic scion variet-

Virus-resistant transgenic papaya helps save Hawaiian industry

Dennis Gonsalves

The pivotal year in the history of Hawaii's papaya industry was 1992. In May 1992, papaya ringspot virus (PRSV) was discovered in Puna on Hawaii Island, where 95% of Hawaii's papaya was being grown. Just one month earlier, a small field trial to test the resistance of a transgenic papaya line had been started on Oahu Island, where papaya production had previously been devastated by PRSV. The timely commercialization of PRSV-resistant transgenic papaya trees has revived Hawaii's papaya industry and provides an example of the challenges and opportunities for horticultural biotechnology.

In 1945, D.D. Jensen made the first report in Hawaii of PRSV, a potyvirus that is transmitted nonpersistently by aphids (Gonsalves 1998). PRSV was first discovered on Oahu and caused such severe damage that the papaya industry was relocated to Puna in the late 1950s and early 1960s. The papaya industry expanded and prospered in Puna, primarily because PRSV was absent. However, by the 1970s PRSV was found only about 19 miles away in Hilo, and the Hawaii Department of Agriculture (HDOA) took rouging (the removal of infected trees) and quarantine actions to prevent its spread to Puna. In 1986, efforts were initiated to develop a virus-resistant transgenic papaya by transforming commercial lines of Hawaiian papaya with the coat protein gene of PRSV from Hawaii.

By 1991, the team of Maureen Fitch, Jerry Slightom, Richard Manshardt and Dennis Gonsalves identified a transgenic line (55-1) that showed resistance under greenhouse inoculations. These plants were micropagated and established in a field trial in Waimanalo on Oahu in April 1992. By December 1992, it was evident that line 55-1 was resistant under field conditions. From the 1992 field trial, two cultivars were developed and designated 'SunUp' and 'Rainbow'. 'SunUp' is homozygous for the coat protein gene while 'Rainbow' is an Fl hybrid of 'SunUp' and the nontransgenic 'Kapoho'. Unfortunately, by October 1994, PRSV had spread throughout much of Puna, causing HDOA to abandon rouging efforts to slow the spread of PRSV. The race was on to move the transgenic papaya line to commercialization. A 1995 field trial in Puna conclusively showed that 'SunUp' and 'Rainbow' were resistant under prolonged and heavy disease pressure.

Courtesy of R. Manshardt

Two varieties of papaya resistant to papaya ringspot virus have been developed using biotechnology: SunUp, *left,* and Rainbow, *right.* They have performed well for Hawaiian growers, even under prolonged and heavy disease pressure.

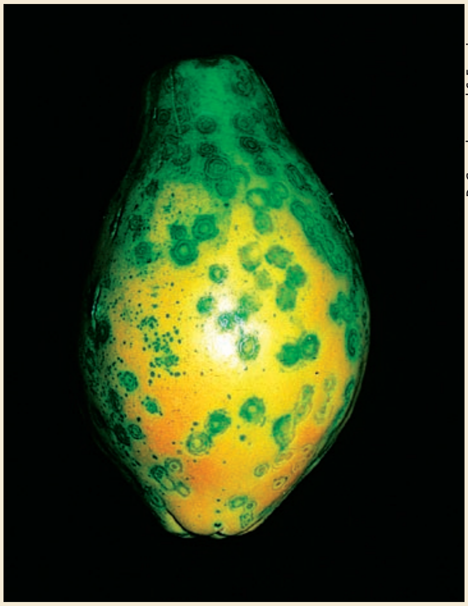
The experience in Hawaii shows that transgenic virus resistance is an excellent approach for controlling viral diseases in horticultural crops.

The U.S. Department of Agriculture's Animal Plant Health Inspection Service (APHIS) deregulated transgenic line 55-1 in November 1996, and the U.S. Environmental Protection Agency deregulated it in August 1997. The consultation process with the U.S. Food and Drug Administration was completed in September 1997. Licenses to commercialize the transgenic papaya were obtained by the Papaya Administrative Committee in Hawaii by April 1998. A celebration was held to mark the debut of the transgenic papaya on May 1, 6 years after PRSV was discovered in Puna and after the first field trial of line 55-1 was initiated. The transgenic fruit is currently sold throughout the United States.

In 1992, Puna produced 53 million pounds of papaya, but by 1998 production had dropped to only 26 million pounds as PRSV spread throughout the region. Since then, the transgenic varieties have enabled farmers to reclaim infected areas and in 2001, Puna produced 40 million pounds of papaya. The resistance has held up remarkably well and remains stable after 5 years of extensive plantings.

Hawaii also exports papaya to Canada and Japan. The transgenic papaya was recently deregulated in Canada, which is a relatively small market for Hawaii. The main challenge is deregulation of transgenic papaya in Japan, where Hawaii sells about 30% of its papaya. Presently, nontransgenic papaya must also be produced in Hawaii to satisfy the Japanese market, but this is increasingly difficult due to the disease pressure. Exporters face added expenses to guard against the accidental shipment of transgenic papaya to Japan. In December 2000, Japan's Ministry of Agriculture, Forestry and Fisheries approved line 55-1, and the Ministry of Health, Labor and Welfare is reviewing a recently submitted petition for deregulation. Anticipated approval of transgenic papaya in Japan will allow Hawai-

Simply the diversity of crops utilized in horticulture slows the adoption of new technologies. For example, as many as 60 distinct cultivars of iceberg lettuce alone may be grown throughout the year.


D. Gonsalves and S. Ferreira

Papaya ringspot virus causes small, darkened rings on the surface of fruit, as well as foliar damage.

ian growers to expand their transgenic papaya markets and will eliminate excessive costs associated with segregating trans-genic and nontransgenic fruits.

The experience in Hawaii shows that transgenic virus resistance is an excellent approach for controlling viral diseases in horticultural crops. This industry was fortunate to have a potential product already under development when PRSV was discovered in the main growing area of Puna. There are many reports that virus-resistant transgenic plants are being developed in diverse crops, but few have been commercialized. The papaya story shows that this approach can provide a stable and safe option for virus protection that can be essential for the success of specific horticultural crops.

D. Gonsalves is Director, Pacific Basin Agricultural Research Center, USDA-ARS, Hilo, Hawaii.

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ies (see sidebar, page 96). The latter approach avoids the task of transforming many varieties of a particular tree crop and in the future may be used to regulate quality and productivity traits.

Nutrients, consumer qualities. Although more difficult technically and therefore not close to market, there are many potential opportunities for enhancing the nutritional value or consumer appeal of horticultural products through biotechnology. In addition to modification of ripening, projects to increase the content of vitamins, minerals or nutraceuticals in horticultural products are in progress (Grusak and Della Penna 1999). The development of Golden Rice with enhanced beta-carotene (pro-vitamin A) in the grain (Ye et al. 2000) demonstrated the potential for biotechnology to increase nutritional value. Whether such products will have sufficient consumer appeal in fully developed markets to drive their commercialization remains to be seen.

Floriculture, ornamental plants

Since floricultural and ornamental plants are grown for aesthetic or other nonedible purposes, there may be less potential for public concern about GE varieties than there has been with biotech food crops.

Flower color. Several ornamental plants, including carnation, rose and gerbera, have been engineered for modified flower color. Research has focused on the manipulation of either anthocyanins (red and blue colors) or carotenoids (yellow and orange colors), with the intent of creating a wider range of flower colors than occurs naturally, as well as to produce natural dyes for industrial purposes (Lu et al. 2003). Florigene is selling Transgenic Moon series carnations engineered for dark violet-purple color around the world. The varieties are developed in Australia and flowers are produced primarily in South America for marketing in the United States and Japan.

Floral scent. Putting the scent back into flowers that have "lost" this trait over years of traditional hybridization and selection, or creating new fragrances in plants, has considerable potential and appeal. Research on genes controlling the different biochemical pathways for various floral fragrances is being conducted on wild plants and on crops such as snapdragon, petunia and rose (Vainstein et al. 2001).

Plant size. Currently, growth-regulating chemicals are applied to ornamental plants to inhibit gibberellic acid (GA) synthesis and reduce plant height during crop production. Many newly introduced ornamental species are receiving particular attention via conventional breeding for dwarf plants because their natural habits do not fit into marketing systems requiring compact plants. The manipulation of GA metabolism via biotechnology has the potential to produce ornamental and flowering plants with reduced-height phenotypes (Clark et al. 2003). The development of lawn grasses that require significantly less frequent mowing is another obvious application. Early experiments suggest that expression of genes controlling height can be applied to many plant species.

Leaf life. Engineering of plants to delay leaf senescence (yellowing) is also being pursued in ornamental crops. For years, ornamental breeders have selected new cultivars of plants with more attractive "stay green" phenotypes. Cytokinins are plant hormones well known to delay the loss of chlorophyll in leaves; using biotechnology, targeted expression of genes involved in cytokinin synthesis is now possible. When a gene promoting cytokinin biosynthesis is inserted into plants in conjunction with a regulator (promoter) that turns the gene on only when the leaf starts to senesce, leaf life is extended in transgenic plants exposed to drought, nutrition and pathogen stress (Gan and Amasino 1995; Clark et al. 2004).

Ethylene sensitivity. As in fruit ripening, manipulation of ethylene synthesis or sensitivity has applications in the ornamental plant industry. Ethylene accelerates floral and foliar senescence, and chemical methods have been developed to miti-

Biotechnology expands pest-management options for horticulture

Leonard Gianessi


Scott Bauer/USDA-ARS

Plums resistant to the plum pox virus have been developed by scientists with the U.S. Department of Agriculture but are not yet available to growers.

Fruit and vegetable crops are under constant pressure from pests such as weeds, viruses, fungi, bacteria, insects and nematodes. If not controlled, many of these pests substantially lower yields. Successful agricultural production has depended on the use of pesticides for 100 years, and, yet, losses still occur due to certain pests that are poorly controlled. Some crops incur high costs for hiring laborers to hoe weeds because there are no effective herbicides. In addition, new pests routinely arrive for which effective controls have not yet been developed.

Agricultural researchers continuously seek out new methods to control pests, including biological agents, new chemicals and plant resistance through classical breeding. Biotechnology also offers a solution in some situations where traditional methods are ineffective or costly. Numerous researchers around the world are investigating biotechnological solutions to pest problems of horticultural crops. In 2002, the National Center for Food and Agricultural Policy released a study of current and potential biotechnological approaches to pest management in a wide array of crops (Gianessi et al. 2002).

If plum pox virus reaches California, the transgenic plum could help prevent losses to the state's multibillion dollar stone-fruit industry.

Current plantings. The study identified three varieties of transgenic fruits and vegetables that are currently planted on small acreages in the United States: virus-resistant squash is grown on 5,000 acres in the Southeast, to prevent late-season losses to mosaic viruses; virus-resistant papaya is widely planted in Hawaii (2,000 acres)(see sidebar, page 92); and insect-resistant sweet corn is planted on a small number of acres and has reduced use of insecticide sprays.

Withdrawn varieties. Two transgenic horticultural varieties were available for a short time in the United States but were withdrawn due to marketing concerns. Insect- and virus-resistant New Leaf potatoes were planted on 4% of the nation's acreage in 1999 and were credited with reducing insecticide use. If the transgenic varieties had not been withdrawn due to processor resistance they could have been planted extensively in the Northwest, reducing insecticide use by 1.4 million pounds.

In 1999, the U.S. Environmental Protection Agency (EPA) granted Wisconsin sweet-corn growers emergency permission to spray herbicide-tolerant varieties (see sidebar, page 110). The transgenic varieties were not widely planted due to marketing concerns and growers have not reapplied for the use despite continued production losses.

Crops currently being tested. Numerous fruits and vegetables have been transformed through genetic engineering and are being tested for their potential role in improving pest management. For example, University of Florida researchers are testing virus-resistant tomatoes as a substitute for the extensive insecticide spraying currently utilized to control insects vectoring geminiviruses. In California, herbicide-tolerant processing tomatoes have been tested and have the potential to reduce grower costs by $30 million and replace the use of 4.2 million pounds of fumigants.

UC researchers have tested herbicide-tolerant lettuce that could reduce herbicide use by 140,000 pounds a year. Herbicide-tolerant strawberries could save Eastern growers several hundred dollars per acre in weed-control costs. Nematode-resistant pineapple is being developed at the University of Hawaii to replace 1.4 million pounds of fumigants. Insect-resistant broccoli developed at Cornell University could improve yields in years of heavy insect pressure. Virus-resistant raspberries developed by U.S. Department of Agriculture (USDA) researchers in the Northwest could help combat bushy dwarf virus, which is present in 80% of Northwest plantings. And transgenic apples resistant to fire blight bacteria have been developed and tested at Cornell University; the transgenic varieties would replace the use of antibiotics, which are used to kill the bacteria on 25% of U.S. apple acreage.

Emerging pests. Several research programs are focused on biotechnological approaches to control emerging pest problems. Plum pox virus was detected in the United States for the first time in Pennsylvania, where efforts are under way to eradicate it by destroying infected trees. USDA researchers have developed a virus-resistant plum that is being tested in Europe. If plum pox virus reaches California, the trans-genic plum could help prevent losses to the state's multibillion dollar stone-fruit industry.

Pierce's disease threatens California vineyards, and insecticide spraying has occurred to control the disease carrier, the glassy-winged sharpshooter. A researcher at the University of Florida (a state where Pierce's disease has been a problem for 80 years) has transformed grape tissue by inserting an antibacterial protein from another species into the grape genome. As a result, the transformed grape plant can destroy the bacteria without the need for insecticide sprays targeting the carrier.

Tristeza virus has killed 45 million citrus trees in Latin America and threatens the Texas citrus industry. Researchers at Texas A&M University have developed and are field testing virus-resistant trees.

Bacterial canker is present in Florida citrus orchards, and the state is trying to eradicate the disease by destroying infected trees, including millions of orchard and backyard citrus trees. A University of Florida researcher has developed and is testing a canker-resistant citrus tree.

L. Gianessi is Director, Crop Protection Research Institute, CropLife Foundation, Washington, D.C. The foundation is an independent, nonprofit research organization.

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Monsanto

Cotton has been genetically engineered to express a protein from a naturally occurring bacterium, *Bacillus thuringiensis*, which is toxic to insect pests such as bollworm and budworm. This cotton is widely planted in California and elsewhere in the United States.

gate its effects (Sisler and Serek 2003). Ethylene sensitivity can be reduced in floriculture crops through applications of the ethylene antagonist silver thiosulfate (STS), but unfavorable environmental aspects such as metal contamination of groundwater restrict its commercial use. Another compound, 1-methylcyclopropene, also blocks the ethylene receptor protein and makes plant tissues insensitive to ethylene, delaying ripening or senescence. Although this compound is effective in many crops, its action decreases with time after treatment as the tissues synthesize new ethylene receptor proteins during postharvest transit. By expressing a mutant form of the ethylene receptor protein or by blocking expression of components of the ethylene-signaling pathway, petunia plants with longer lasting floral displays have been produced (Wilkinson et al. 1997). Unfortunately, negative side effects, such as higher susceptibility to fungal pathogens and decreased rooting of vegetative cuttings, have limited the commercial use of these technologies. The key to effective manipulation of ethylene sensitivity will be the use of promoters limiting transgene expression to the target tissue, leading ultimately to plants that have longer lasting flowers with no negative side effects.

Hurdles to commercialization

The lag in commercialization of transgenic horticultural crops clearly is not due to a lack of useful genes or valuable applications. However, several fundamental issues inherent to horticultural crops create significant hurdles (see sidebar, page 84).

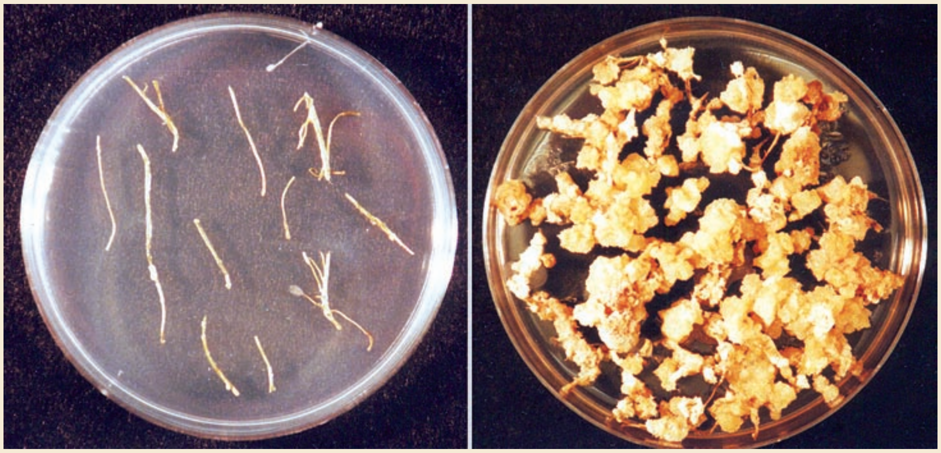
Biological diversity. Simply the diversity of crops utilized in horticulture slows the adoption of new technologies. For any given crop, there may be several different species and dozens of cultivars that are currently marketed, and the turnover of new cultivars from year to year is tremendous. For example, as many as 60 distinct cultivars of iceberg lettuce alone may be grown throughout the year as production locations shift seasonally. Add to this the dozens of additional varieties for romaine, leafy, red and other specialty types, and it is evident that introducing a new biotech trait for lettuce requires developing not just one but many new varieties. In perennials such as trees and vines, on the other hand, the choice of a variety is a long-term commitment, making growers cautious in selecting novel varieties.

Market acceptance. Currently, the largest impediment to adoption of at least some biotech horticultural products is the lack of market acceptance. Biotech products having documented agronomic, economic and environmental advantages have been removed from the market due to the concerns of processors and distributors about potential consumer rejection.

Intellectual property. Large corporations focused on the major agronomic crops own the majority of patents on

Transgenic trap crops and rootstocks show potential

John Driver
Javier Castillón
Abhaya Dandekar



Left, apple roots engineered to silence bacterial genes are resistant to crown gall formation. *Right,* control (nontransgenic) roots infected with the same bacterial strain show extensive gall proliferation.

Biotechnology may offer unique opportunities for pest control in perennial tree and vine crops (Dandekar et al. 2002). Trap crops — plants that an insect pest prefers to the commercial crop — have been tested in a number of agricultural settings, but in most cases have not achieved control levels high enough to completely replace chemical pesticides. Insects are attracted to the trap plant, but they multiply there and can spread to the adjacent crop. A variant on this concept is to incorporate expression of the *Bacillus thuringiensis* (Bt) insecticidal protein into the trap plant. When the insect feeds on the transgenic trap plant, it dies and the insect population is reduced, thereby protecting the nearby commercial crop.

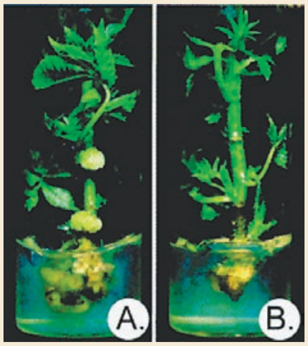
Dry Creek Laboratories of Hughson, Calif., demonstrated this concept with codling moth *(Cydia pomonella)*, a major pest of apples, pears, walnuts and other fruits. The female moth lays eggs on the leaves or fruit, which then hatch into larvae that burrow into the fruits, making them unmarketable. Pesticide sprays and pheromone disruption are generally used to control this pest. However, the female moth prefers to lay its eggs on apple trees. Under license from Monsanto, Dry Creek Laboratories developed apple trees capable of expressing a Bt protein that was toxic to the codling moth larvae, with the intention of using these plants as trap crops in and adjacent to walnut orchards.

A 90-acre field trial was established in 1997, and in the 4 subsequent years worm damage to the walnuts was almost completely controlled without pesticide applications, equivalent to that in the plots sprayed three times per season with pesticides. While walnuts have also been transformed to express the Bt protein directly (Dandekar et al. 2002), an attractive feature of this scheme is that the walnuts themselves are not transgenic and the method could be used to protect existing orchards by interplanting the Bt-expressing apple or crabapple trees. Broader application of this approach could result in more effective trap crops for a number of annual and perennial crops. Unfortunately, Dry Creek Laboratories is unable to move forward at this time with commercialization of the Bt apple plants due to the costs associated with the regulatory process required for biotech crops (see page 106).

When the insect feeds on the transgenic trap plant, it dies and the insect population is reduced, thereby protecting the nearby commercial crop.

Another opportunity for biotechnology in perennial crops that are normally grafted is to engineer only the rootstock for desirable traits. Commercial tree cultivars grafted onto transgenic rootstocks could benefit from increased rootstock productivity or disease resistance while producing nontransgenic pollen and fruit. For example, such applications in grapes could offer new solutions to Pierce's disease or *Phylloxera* by grafting traditional varieties onto resistant transgenic rootstocks. The feasibility of this approach was recently demonstrated for resistance to crown gall disease *(Agrobacterium tumefaciens)*. Infections by the bacterium result in the formation of a gall, an unorganized mass of plant cells that results from overproduction of two plant hormones. The bacterium has the natural ability to transfer some of its genes into the host plant's genome following infection. The transferred genes code for three specific enzymes. When the plant expresses these genes, the enzymes synthesize the two hormones that induce the plant to form the tumor, or gall, on which the bacteria live. Eventually, the galls can girdle the stems and reduce the vigor of the tree or vine.

A biotechnology tool called "gene silencing" has been used to generate resistance to crown gall. This method involves transforming plants with DNA that, when expressed, produces signals that block the expression of any genes with the same sequence as the inserted DNA. Plants transformed with these interfering versions of the three enzyme genes would be primed to block the function of the corresponding bacterial genes in infected plants. This would prevent the formation of the damaging galls without even needing to kill the bacterium itself. The feasibility of this approach was demonstrated in tomato and *Arabidopsis* plants (Escobar et al. 2001). Furthermore, both walnut (see photo; Escobar et al. 2002) and apple (see photo; J. Driver et al., un-



Crown gall formation was suppressed in walnut plants engineered to turn off specific bacterial genes. (A) The control shoot exhibits a large, undifferentiated tumor at 5 weeks after inoculation with a virulent *A. tumefaciens* strain, while (B) a shoot engineered for resistance exhibits no tumor. Source: Escobar et al. 2002.

published results) plants resistant to crown gall have been produced. As most crown gall infections occur in the rootstock, nontransgenic scions grafted on resistant transgenic rootstocks would be protected from the disease. Rootstock engineering holds great promise for the improvement of tree and vine crops by preserving the horticultural characteristics of existing varieties used as scions while incorporating beneficial traits into the rootstocks.

J. Driver is former President and J. Castillón is Director of Research, Dry Creek Laboratories, Hughson, Calif.; and A. Dandekar is Professor, Department of Pomology, UC Davis.

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the genes and enabling technologies (such as transformation protocols and promoters) required for genetically engineering plants. They are generally not interested in the smaller horticultural markets, and may not want to license their technologies, depending on the impact it could have on their other approved crops (see page 120).

Post-commercialization. Post-commercialization stewardship is also an increasingly important consideration to technology owners in deciding whether to license their intellectual property. In Bt crops, for example, insect-resistance management programs must be developed and monitored after commercialization. Identity preservation programs and segregation of products in the distribution channels may be required when marketing in locations where they are not approved. Herbicide applications to diverse horticultural crops have the potential to increase the Average Daily Intake (ADI) over the maximum permitted level for the pesticide active ingredient. (ADI is the total residues of a pesticide that a consumer can be exposed to, considering all sources; the government sets limits for each pesticide.) An agrochemical company will not approve the use of its herbicide-resistance trait in a small acreage crop if it endangers the registration of that herbicide for millions of acres of field crops.

Regulatory requirements. Extensive safety testing is required for regulatory approval (deregulation) of biotech crops beyond what is required for varieties bred using traditional methods (see page 106). If the trait has already been approved in other crops, the costs are lower as prior data can be used to support an application. However, for novel traits likely to be of interest for horticultural crops, the costs could be millions of dollars. For example, by some estimates it will cost $20 million to achieve deregulation of Golden Rice for humanitarian purposes in six developing countries (I. Potrykus, UC Davis seminar, Jan. 22, 2003). Since each transgenic event (each insertion of a gene in a genome) must be separately tested and approved, it is not feasible to transform multiple varieties with a given trait to amortize the research and technology investment across a given crop. Instead, a single insertion event is approved for commercialization and then must be transferred via standard backcrossing to other varieties. This is highly inefficient and often makes it difficult to regain the unique properties of all the diverse varieties. Public-private partnerships are one way to reduce the costs of commercialization (see page 116). The IR-4


Syngenta

"Golden Rice" has been genetically engineered to produce beta-carotene, the precursor to vitamin A. However, for a variety of reasons it is not yet available to farmers in developing countries, where vitamin A deficiencies are common.

program could also assist with chemical residue testing and with other aspects of meeting the regulatory requirements for release of transgenic horticultural crops (see sidebar, page 110).

Compelling benefits key

The commercial applications of biotechnology to horticultural crops lag far behind those of agronomic crops. In some respects this is to be expected, since the majority of research and investment has been directed to commodities with the greatest commercial value. For consumer and quality traits, however, many of the most interesting applications will be in horticultural crops. Intellectual-property issues must be resolved and regulatory costs reduced before significant progress can be made toward commercialization of transgenic products. However, the major impediment to horticultural biotechnology is the reluctance of the market to accept and actively promote these products. The development of products having compelling benefits for producers, marketers and consumers may be required to overcome this situation.

The first transgenic crop to receive U.S. government approval was a tomato engineered to soften more slowly than conventional tomatoes, allowing it to be picked later for improved flavor and taste. Bioengineered horticultural crops with clear benefits to consumers may be needed to overcome market reluctance. *Above,* conventional tomatoes.

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RESEARCH ARTICLE

Consumer knowledge and acceptance of agricultural biotechnology vary

Jennifer S. James

Results from consumer surveys reveal some basic conclusions about consumer attitudes toward agricultural biotechnology. First, consumers do not agree about whether biotech foods are good or bad. Second, a small group of people strongly opposes them. Third, the majority of consumers are uninformed about the technology and how food is produced. Relatively small but vocal anti-biotechnology activist groups are successful at influencing public opinion because of consumers' lack of knowledge, creating a role for universities and government agencies to provide clear, objective and accessible information.

The food system is often described as increasingly consumer-driven, but this does not seem to be the case with food products derived from modern biotechnology. Genetically engineered (GE) crops have been commercially available since 1996, but most consumers are unaware that they have probably been consuming them. Consumer acceptance or rejection of food made from biotech crops can have important economic implications at all levels of the food system (see page 80).

Consumer acceptance (or apathy) would imply that segregation, identity preservation and labeling of biotech foods are not necessary, at least from the consumer's perspective. On the other hand, consumer concerns or reluctance may mean that markets will be lost, ultimately causing adoption rates to decline. In the extreme, consumer concerns may drive policy decisions (as some argue has occurred in the European Union), with the resulting policies imposing costs on producers as well as consumers. Consumer willingness to purchase biotech products also affects the incentives for food retailers to carry them, for food manufacturers to use biotech crops as ingredients, for growers to adopt them, and for life-sciences companies to develop new applications. Furthermore, uncertainty about consumer willingness to purchase biotech products increases risks associated with the adoption, use of and investments in GE crops.

Although consumer preferences could potentially play an important role in the future of agricultural biotechnology, little is known about them. Because biotech products are not labeled in the United States, consumers have not had the opportunity to reveal their preferences. The only way for consumers to avoid biotech foods is to purchase certified organic products, but it is difficult to isolate consumer demand for the nonbiotech trait from the demand for other traits of certified organic foods.

While market data is not available, a fairly extensive body of survey research has been conducted to assess consumer awareness and knowledge of, and attitudes toward biotech products. Stated attitudes are usually used to infer how consumers might respond to, for instance, food labels indicating whether they contain biotech ingredients. This article describes and interprets results from the large and growing number of U.S. national telephone surveys and a few studies using alternative methods, and discusses possible implications for biotech product markets.

Consumer preferences could play an important role in the future of agricultural biotechnology in the United States.

While some consumers are uninformed or indifferent, the rest are split in favor and against biotech products, with a small share strongly opposed. When asked, most U.S. consumers say biotech products should be labeled.

A caution regarding survey results

The survey method has some shortcomings, which serve as a reminder not to read too much into any individual

Words matter

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Responses to survey questions can be affected by assumptions embedded in the question. A 1994 national survey conducted at Pennsylvania State University demonstrated the effects of such suppositions. The survey asked 1,000 respondents about their food safety concerns; they were divided into four groups of 250 and each group was asked different questions.

Consumers in group 1 were asked "How concerned are you about IMS in seafood?" Fifty-three percent said that they were either somewhat or very concerned, and 30% said they did not know. The wording of this question implies several underlying assumptions. In particular, this question assumed that the respondent is concerned about IMS, the only question being the degree of concern. Questions posed to the other three groups included filters designed to reduce the effects of such assumptions.

In group 2, consumers were asked "Are you concerned about IMS in seafood?" If they said yes, they were asked about their level of concern. When this concern filter was used, the proportion of respondents expressing concern decreased to 32%, with 25% saying they did not know. For groups 1 and 2, the questions assumed that respondents know what IMS is, or have at least heard of it.

In group 3, consumers were asked "Have you ever heard of any health problems associated with IMS in seafood?" When this awareness filter was used, only 24% of the respondents said that they had heard of health problems, with 65% saying they had not, and 11% saying they did not know or weren't sure. Comparing the 24% who said they had heard of IMS to the 53% and 32% expressing concern in groups 1 and 2 suggests that several people who expressed concern in groups 1 and 2 had not heard of IMS.

The wording of questions posed to groups 1, 2 and 3 all assumed that IMS exists. Group 4 combined the awareness and concern filters in order to minimize the effects of the suppositional wording in groups 1, 2 and 3. In group 4, consumers were asked if they had heard about health problems associated with IMS in seafood. Those who said they had heard of it were asked if they were concerned, and those who were concerned were asked their degree of concern. Even after applying both filters, 18% of the respondents in group 4 said they were somewhat or very concerned about IMS, a *food safety issue that does not exist*.

Filters help minimize the tendency for survey respondents to overstate their concerns, but they are seldom used because they slow down questioning and respondents may find them tedious.

The varying proportions of respondents expressing concern about IMS in the four groups shows how results can be affected by question wording. Filters help minimize the tendency for survey respondents to overstate their concerns, but they are seldom used because they slow down questioning and respondents may find them tedious.

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Further reading

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result. To a skeptic, a notable problem in survey results is the degree to which they can be influenced by how questions are worded. Compounding this problem is the fact that the exact wording of questions often is not presented with the results (especially in the popular press), so that it is easy to misinterpret findings or put them in an inappropriate context.

Suppositional wording is a way of asking a question that implies particular assumptions, which in turn affects responses; it has been shown to influence the level of concern expressed by respondents (see sidebar, page 100). In addition, imbedded assumptions can be seen in other types of questions. Information is often provided to respondents along with the questions, and its content and wording can influence responses. In some recent surveys, a definition of biotechnology or genetic engineering was read to respondents. For some respondents, the definition may have been their first exposure to the technology. What they are told can have a pronounced effect on how they answer subsequent questions.

The sensitivity of responses to wording is especially problematic when survey responses are used to infer or predict market behavior. If responses are sensitive to wording, how much can they reveal about choices consumers would make? While it is important to be cautious in interpreting survey responses, when taken together the surveys do tell a fairly consistent story.

Lack of awareness

One of the most notable regularities in survey responses is the lack of U.S. consumer awareness about agricultural biotechnology. Most studies find that roughly half of those surveyed have heard little or nothing about food produced using biotechnology, genetically modified (GM) foods or genetic engineering. Shanahan et al. (2001) reviewed 12 surveys conducted between 1993 and 2000, and in 10 at least 50% of the respondents had heard "not much" or "nothing at all" about biotechnology. A Gallup Poll conducted in 2001 found that 40% had heard "not much" or "nothing," down from 50% in a 1999 survey by the same firm (Saad 2001). A less clear pattern is revealed in three surveys conducted for the Pew Initiative on Food and Biotechnology (2001, 2003), an organization funded by the Pew Charitable Trusts to provide unbiased information and encourage public debate about agricultural biotechnology. In each survey, respondents were asked how much they had "seen, read, or heard recently regarding genetically modified food that is sold in grocery stores." The percentage of respondents who had heard "not too much" or "nothing at all" was 54% in January 2001, 45% in June 2001 and 65% in September 2003. These results cast doubt on the hypothesis that there is any clear trend in awareness, and suggest that awareness may be somewhat temporary, perhaps driven by recent media coverage.

While studies vary, the overwhelming message is that many Americans are unaware of GM foods. This lack of awareness provides another reason to interpret survey data cautiously. The Center for Science in the Public Interest (CSPI) is a nutrition advocacy organization funded by subscriptions to its *Nutrition Action Healthletter* and by donations from charitable foundations. In a 2001 report, CSPI noted that telephone surveys ask people questions about something they probably do not think about often or may know little or nothing about. Surveys are usually fast-paced, and there is not a lot of time for deliberation. Taking awareness (and knowledge) of respondents into account can help put other responses in perspective. For instance, in the 2001 Pew study, 73% said they were either "very" or "somewhat" concerned about the recall of taco shells and other corn products containing StarLink corn, a GE variety that was approved for animal feed but not human consumption. However, responses to the previous question put this result in a different light; only 57% had heard "some" or "a great deal" about the taco shell recalls. So, at least 16% of the respondents expressed concern about the recall but had not heard much (if anything) about it.

Extent of knowledge

Many surveys ask respondents to rate the extent of their knowledge or familiarity with biotechnology or genetic engineering. Two studies conducted in 1998 and 2000 found that only about 20% of respondents said they knew or understood "some" or "a lot" about GM foods (Shanahan et al. 2001). Between 1997 and 2002, several consumer surveys were conducted

Courtesy of USDA-ARS

Because genetically engineered cottonseed, canola, corn and soy are common in many processed foods, the percentage of foods in the supermarket with at least one of these ingredients is estimated as high as 75%. But in surveys, many consumers are unaware that they have been eating foods with genetically engineered ingredients.

Individual consumer surveys are subject to interpretation, but together they tell a fairly consistent story about attitudes and knowledge of agricultural biotechnology. *Above,* surveyors question consumers.

for the International Food Information Council (IFIC), an industry-funded organization that provides science-based information on nutrition and health to individuals and groups that communicate with consumers. The IFIC surveys (2003) found a higher proportion of the respondents having read or heard "some" or "a lot" about biotechnology, ranging between 33% and 47%, with no clear pattern over time.

More general knowledge (or lack of it) about how food is produced is sometimes revealed in the answers to questions that have little to do with biotechnology. The 2001 CSPI survey focused on food labeling. Respondents were asked about labels for a number of product characteristics, in addition to whether a food or its ingredients had been genetically engineered. In this survey, 40% thought that the words "made from crossbred corn" should appear on the food label if it applies. Further, only 40% said that they would purchase processed foods that were labeled as having been made from crossbred corn. Since nearly all corn varieties currently being used are crossbred, stated resistance to consuming this type of corn reveals a lack of basic knowledge about agriculture and how food is produced.

Other questions ask whether respondents have ever eaten a biotech product, or whether biotech products are available in grocery stores now. The IFIC studies conducted between 1997 and 2003 each asked "as far as you

At Pennsylvania State University's Ag Progress Days, Bt sweet corn was offered to consumers alongside corn labeled as "IPM" (grown using integrated pest management), along with informational brochures.

know, are there any foods produced through biotechnology in the supermarket now?" Over the years, "Yes" responses ranged from 33% to 43%. Although this proportion may seem low, given that roughly two-thirds of the items available at food retailers contain GE ingredients, 33% is a fairly high proportion for this type of question relative to other studies (perhaps because of the use of "biotechnology," which refers to a broader range of practices relative to "genetic engineering"). In the 2001 Pew study, only 19% said they had eaten GM foods, 62% said they had not and 19% did not know. When asked how many foods in a typical American grocery store they thought were genetically modified, only 14% of the 2001 Pew respondents thought that over half of the foods contained such ingredients.

Attitudes toward ag biotech

Questions attempting to assess consumer attitudes toward agricultural biotechnology have been included in many surveys in a number of forms. In some surveys, consumers are asked whether they think the risks outweigh the benefits (or vice versa), whether they support the use of biotechnology to produce food, or whether they think the use of biotechnology in food production will increase the quality of their lives. However, because consumer awareness and knowledge are so low, many respondents are being asked for their opinion about something they have not previously heard of or know little about.

Most surveys address this problem by providing a brief description of biotechnology or genetic engineering. The information provided is often excluded from reports describing results even though it can have an important influence on the responses. One notable example described by Shanahan et al. (2001) is a survey conducted by the Harris Poll in 1993. In a question designed to measure attitudes about the relative risks and benefits of genetic engineering, the dinosaurs in the movie *Jurassic Park* were given as an example of genetic engineering. The reference to *Jurassic Park* evokes a very negative image, so it is not surprising that 57% of respondents said they thought the risks of genetic engineering outweighed the benefits (the most negative response to this type of question in the surveys reviewed by Shanahan et al. 2001).

A similar but much less biased question was included in a series of surveys conducted by the National Science Foundation, an independent government agency that supports scientific and engineering research, as part of its Science and Engineering Indicators. Those surveys indicated that between 44% and 50% of respondents view the benefits of genetic engineering (generally, not specific applications to food) as outweighing the risks, while about 33% to 39% see the risks as outweighing the benefits (Shanahan et al. 2001). These surveys were conducted between 1985 and 1999, and the responses were fairly consistent over time. The IFIC surveys conducted between 1997 and 2003 show a slight decline in the proportion of respondents who thought that biotechnology would provide benefits within the next 5 years, from 78% in 1997 to 62% in 2003.

Given the variety of ways of asking questions about attitudes toward agricultural biotechnology, it is not surprising that results are mixed. The most striking consistency is the lack of consensus. For most attitude questions of this type, responses in favor or against are rarely more than 60% or much less than 30%. The 2001 Gallup Poll found that while a slight majority (52%) support the use of biotechnology in food production (38% opposed), a larger proportion strongly oppose it (14%) relative to those who strongly support it (9%). The 2001 Pew study had similar results, with more respondents (35%) strongly opposing the introduction of GM food (out of 58% opposing) than strongly favoring (8% out of 26% in favor).

The 2001 Pew study demonstrates some possible implications of asking the relatively uninformed for their assessment of the technology. Over half of the respondents said they had seen, read or heard "not too much" or "nothing at all" about genetic modification or biotechnology. Later in the survey, respondents were asked whether they thought GM foods were basically safe or unsafe, or whether they were not sure. The next question was the same, but this time it was prefaced with "Now, as you may know, more than half of products at the grocery store are produced using some form of biotechnology or genetic modification. Knowing this, do you think . . ." Initially, 29% said biotech products were safe, 25% said unsafe and 46% were not sure or did not have an opinion. However, when given the additional information about their availability in stores, over 30% changed their answer: 48% said biotech products were safe, 21% said unsafe and 31% were uncertain. There are a number of ways to interpret the switches. For instance, 19% of those who originally said they thought biotech products were unsafe and 37% of those who were originally unsure switched their answer to safe. This switch could be interpreted as trust in the food regulatory system or food retailers ("if they're selling it, it must be safe"), or as a kind of coping mechanism ("if I've been eating it, it must be safe"). These results suggest that information affects some respondents' attitudes, and that at least 30% are not committed to a position on the safety of biotech products.

Willingness to purchase

Willingness to purchase biotech products is often assessed by asking how likely survey respondents would be to purchase or eat a food produced using biotechnology or genetic engineering. The usual caveats apply about the influence of wording; not surprisingly, results are about as mixed as those concerning attitudes. The 2001 Pew study found that 38% of respondents were willing to eat biotech food, with 54% unwilling. In the IFIC surveys, about 70% said they would be willing to purchase biotech foods modified to resist insect damage so that fewer pesticides may be used, while the corresponding proportion is a bit lower (50% to 60%) for food modified to taste better or fresher. In the CSPI study, 40% to 43% said they would buy labeled biotech foods (the proportion depending on the type of food), about the same proportions as those who said they would buy food labeled as being produced from crossbred corn. Overall, stated willingness to purchase biotech products is fairly consistent with stated attitudes.

Preferences for labels

When consumers are asked if foods produced using biotechnology or genetic engineering should be labeled, a majority will say yes, usually around 80%. Eighty-six percent of the respondents to a 2000 Harris Poll survey said they thought biotech food should be labeled. In the 2001 Pew study, 75% said it was "very" or "somewhat" important that they know whether a product contains biotech ingredients.

In the CSPI study, 70% said that GE food should be labeled. However, in another question, consumers were given a list of characteristics for a box of Wheaties and asked to pick which one piece of information they would like to see added to its label. Only 17% chose "contains genetically engineered wheat," while 31% chose "contains pesticides in minute amounts" and 31% said they did not know or did not think any new information should be added. While the majority of consumers consistently say they would prefer biotech products to be labeled, this is a top priority for a relatively small group. Further, only 12% in the CSPI study said they would be

Consumers purchase Bt sweet corn

Bt corn is one of several widely adopted genetically engineered (GE) crops. It contains a gene from a soil bacterium *(Bacillus thuringiensis)* that causes the corn to produce a protein toxic to European corn borer and other insect pests, essentially building worm control into the corn. This form of pest control reduces pesticide costs and may improve yields; it is especially beneficial for sweet corn, which has higher insecticide loads than most other fresh-market vegetables. Producer benefits from choosing to plant a Bt sweet corn are clear, but uncertainty about consumer willingness to purchase GE corn reduces those benefits.

A study designed to measure consumer preferences for Bt sweet corn was conducted in central Pennsylvania in summer 2001. The goal was to assess consumer willingness to purchase Bt sweet corn and determine how consumers responded to price variations. Two types of corn were grown at the Penn State farm: one contained the Bt gene, and the other was a related variety that had not been genetically engineered. Corn was clearly labeled as either "Bt Sweet Corn" or "IPM Sweet Corn" and sold side-by-side at five stores in central Pennsylvania and at Penn State's Ag Progress Days. The IPM (produced using integrated-pest-management methods) and Bt sweet corn were described briefly in a brochure available to consumers in each store. The relative prices of Bt and non-Bt corn were varied from location to location and week to week. Retailers were encouraged to set the price of the IPM corn according to market conditions, but were instructed to sell the Bt cultivar at either the same price as the IPM corn, 15% less or 15% more. Sellers recorded how much corn of each type was sold each week.

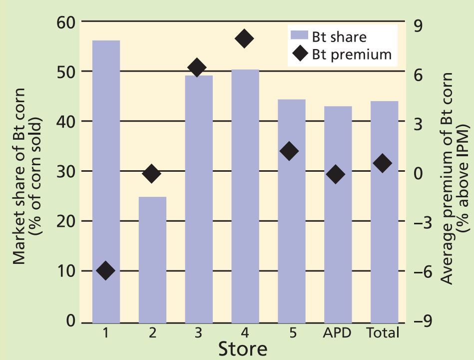

Fig. 1. Market shares (bars, labeled on left axis) and corresponding average price premiums (diamonds, labeled on right axis) for Bt sweet corn by store, plus at Penn State's Ag Progress Days (APD). Corn labeled "Bt Sweet Corn" was sold side-by-side with corn labeled "IPM Sweet Corn"; a brochure explained the difference between the transgenic (Bt) and integrated-pest-management (IPM) products.

The results from this geographically specific study cannot be interpreted as nationally representative, but they suggest that there is a viable market for Bt sweet corn. The overall market share of Bt sweet corn was 44%, shown in figure 1 along with the store-specific market shares. Price seems to have played a fairly minor role in consumer choices, as indicated by the fairly large market shares of Bt sweet-corn in stores 3 and 4, where price premiums were higher, on average, than in other stores. — *J.S. James*

This study was conducted by J.S. James, Shelby Fleischer, Twilla Parker and Michael Orzolek, Pennsylvania State University, University Park, Penn.

Results from a consumer-preference study in central Pennsylvania suggest that there may be a viable market for Bt sweet corn, *above*.

willing to pay for labeling of GE foods if it increased the cost of their family's food by $50 a year or more, but 44% were not willing to pay anything for the label information.

Other food safety issues

Some survey findings indicate consumer concern about biotech food relative to concerns about other food safety issues. On average, consumers seem to be more concerned about pesticide residues than biotechnology. For example, the 2001 Pew study asked how much respondents worried about several different food safety issues. About one-third said that biotechnology or biotech products were "one of the things that worries" them "most" or "a great deal" about food safety. However, this proportion was dwarfed by those who said chemicals and fertilizer use (46%), Salmonella (66%) and freshness (71%) worried them "most" or "a great deal" (multiple responses were allowed). Similarly, the CSPI study found that 56% of respondents thought food with imported ingredients should be labeled, and 43% thought labels should indicate whether crops were grown "using practices that cause farm soil erosion" (relative to 62% who thought GE ingredients should be indicated). These results indicate that looking at biotechnology in isolation is likely to overemphasize consumer concerns — for many, it is just one of several food safety issues they think about.

Experimental approaches

While surveys indicate some variables that affect consumer decisions, an important aspect is usually omitted: the influence of prices and income. As the CSPI study showed, there is a big difference between asking people if they think biotech products should be labeled and asking them how much more they would be willing to pay for those labels. In addition, surveys are usually hypothetical in nature — respondents do not have to commit to actions that are consistent with their stated attitudes or preferences. In contrast, results

Courtesy of UC Biotech Web site

Consumers can avoid biotech ingredients by purchasing certified organic produce and foods, which cannot be grown using biotech crops. It is difficult to determine how important the absence of biotech ingredients is to consumers relative to other components of organic certification.

from experimental auctions, which incorporate purchases, have been shown to more closely approximate how consumers would behave in a market environment. In one type of auction, participants are brought to a common location, given some money and asked to bid on a product. After bids are collected, the "winning" bidders are determined, and they use the money received earlier to purchase the product being auctioned.

To date, only a few experimental auctions have been conducted that measure consumer valuation of biotech and nonbiotech food products. Tegene et al. (2003) conducted a series of 12 experimental auctions in 2001 in Des Moines, Iowa, and St. Paul, Minnesota. Participants were asked to bid on two sets of products, each including vegetable oil, tortilla chips and Russet potatoes. In one set, the products were labeled as made using genetic modification; in the other set, this label was omitted. On average, consumers bid 14% less for the biotech-labeled product. The participants in each auction were given one of six different sets of information that included either pro-biotech, anti-biotech or third-party objective information, or some combination. Not surprisingly, the difference in bids between the labeled and nonlabeled products was influenced by the type of information provided, with the largest difference occurring when participants received only negative information and vice versa.

Results from these auctions suggest some consumer resistance to biotech foods, but the influence of the information provided suggests that consumer resistance is somewhat malleable. Experimental auctions reflect one-time decisions, and may not represent repeat purchasing behavior. However, there is still great opportunity to learn about consumer preferences for biotech products using this method.

Another method is the market experiment, in which biotech and nonbiotech products are clearly labeled in a retail environment and consumer purchases are measured. These studies require retailer cooperation and a product suitable for study, which make them difficult to conduct. Two have been conducted using fresh-market sweet corn, by the University of Guelph (Powell et al. 2003) and Pennsylvania State University (see box, page 103). In these studies, biotech corn accounted for roughly 60% and 40% of the corn sold, respectively, indicating some degree of consumer acceptance.

Making sense of consumer views

The studies discussed do not show overwhelming opposition to biotech products, and yet consumer acceptance is still cited as a barrier to adoption or development of biotechnology. While there are no readily apparent explanations for this contradiction, survey results provide some insight; and despite methodological shortcomings and variations, important

Corbis/Matt Stone

***Far left*, Friends of the Earth placed advertisements in support of Oregon's Measure 27, which would have required labeling of genetically engineered foods but did not pass in 2002. *Left*, activists have staged protests against biotech foods, such as this march in Boston in 2000.**

conclusions can be drawn. While some consumers are indifferent to the technology, the rest are split roughly half in favor and against biotech products, with a small share strongly opposed. When asked, most consumers say biotech products should be labeled. However, the most important and fairly consistent finding is that the majority of consumers are uninformed about biotechnology and, more generally, about how food is produced. Given these consumer characteristics, is biotechnology an aspect of the food system that *should* be consumer-driven?

If actions were taken to more closely align regulations with the stated preferences of consumers, would their subsequent actions be consistent with stated preferences? The debate about the use of recombinant bovine somatotropin (rbST), a growth hormone, in milk production provides a striking example to the contrary. While consumer surveys indicated sizable opposition to the use of rbST, there were no statistically significant changes in the demand for milk when the FDA approved its use (Aldrich and Blisard 1998). Consumers may say one thing but do another. Further, it is possible that consumer issues will fade once researchers stop asking consumers for their opinions about biotech products. If Measure 27 on the 2002 Oregon ballot had passed (it did not) it would have provided mandatory labels on biotech foods, as well as an interesting opportunity to compare stated preferences with market behavior.

The small group that strongly opposes agricultural biotechnology is quite vocal. Anti-biotech activist groups such as Greenpeace and the GE Food Alert are adept at communicating with the public, and willing to use inflammatory language and theatrics, as seen in their Web sites (www.greenpeaceusa.org and www.gefoodalert.org) and public demonstrations. They may oppose agricultural biotechnology as a whole, but they often target individual companies (such as with mock company Web sites depicting products and brands as dangerous). Specific companies targeted may shift their focus from satisfying customers to avoiding negative publicity. Publicity stunts and negative information campaigns would have little effect on those who know about and understand the technology. The lack of consumer knowledge gives negative publicity campaigns their power.

While education is unlikely to settle the debate about the relative costs and benefits of agricultural biotechnology, it would at least enable consumers to understand the choices they make when they do their food shopping. Education poses a challenge because any educational materials must compete with a multitude of other messages totally unrelated to food or biotechnology. Further, messages about agricultural biotechnology are abundant, some are difficult for the layperson to understand and information presented by different sources is often contradictory. Government agencies and universities can play an important role in providing and disseminating objective and accessible information to consumers about biotechnology and food production.

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Regulatory challenges reduce opportunities for horticultural biotechnology

Keith Redenbaugh
Alan McHughen

Development of transgenic horticultural crops has slowed significantly in recent years for several reasons, including the European Union's moratorium on biotech approvals, lack of tolerance levels for adventitious (accidental) presence in food and seed, significantly increased regulatory costs and decreased acceptance by food wholesalers and retailers. While progress in the United States has slowed and approvals in the European Union stopped, some countries such as China continue to develop biotech products for their internal and external markets that will affect the U.S. and California industry. Within a few years, China will emerge as the leader in biotech horticultural crops.

Calgene's Flavr Savr tomato was successfully sold under the MacGregor's brand in the United States. Consumers were willing to purchase it, but the product was not financially profitable and was ultimately withdrawn from the market.

Horticultural crops were the first biotech crops commercialized in the United States, beginning with Calgene's ground-breaking Flavr Savr tomato in 1994, followed in 1995 by Asgrow's virus-resistant squash and DNA Plant Technology's Endless Summer tomato. The Flavr Savr tomato, with its superior flavor and shelf life, was well received by consumers, garnered repeat purchases and demonstrated that consumers were receptive to fresh produce labeled as genetically engineered (Bruening and Lyons 2000). In 1996, Zeneca launched a biotech processing-tomato product that from 1999 to 2000 was the best-selling tomato paste (puree) in the United Kingdom. The paste reduced processing costs and resulted in a 20% lower price. However, despite their consumer benefits and initial market acceptance, none of these tomato products were financial successes and none are being sold today. In the first instance, production and distribution costs of the Flavr Savr proved prohibitive. In the second case, Zeneca decided not to continue growing the tomatoes in California and shipping the paste to the United Kingdom. When Zeneca ran into the European moratorium, they were unable to get approval for growing the tomatoes in Europe. Once the supply of the tomato paste was exhausted, the product disappeared from the grocery store shelves.

These early products of horticultural biotechnology are often overlooked because of the huge successes of biotech field crops such as feed corn, soybeans and cotton. Since their introduction in 1996, biotech field crops have quickly gained wide acceptance by farmers and were grown on more than 167 million acres worldwide in 2003, primarily in the United States, Canada, Argentina, Brazil and China (James 2003) (fig. 1). India recently approved biotech cotton and Brazil approved biotech soybeans, for a total of 18 countries that have approved commercial field production of biotech crops. All of these crops are designed for pest and weed control, with either insect or herbicide resistance. As a result, sales of conventional agricultural pesticides declined 7.4% in 2000, while biotech-based varieties jumped 12.9% (Schmitt 2002). The worldwide value of all seed business (biotech plus conventional seed) rose from $15.3 billion in 1996 to $16.7 billion in 2001, but the value of conventional seed fell during the same period from $14.9 billion to $13.4 billion, indicating a healthy value of $3.3 billion in 2001 for biotech seed worldwide. Although the European Union (E.U.) moratorium on new registrations has affected introduction of the newest biotech field crops, the utilization of current products is increasing.

The success of biotech field crops is in sharp contrast to restricted commercial opportunities for biotech fruits and vegetables. There are few examples of transgenic horticultural crops that are currently being grown and marketed successfully: virus-resistant squash is planted on a small acreage in the southeast United States, and virus-resistant papaya has been grown in Hawaii since 1998 (Ferreira et al. 2002; see sidebar, page 92). Whereas Zeneca was able to obtain food approval for its tomato in the United Kingdom in 1995 (as did Calgene for the Flavr Savr tomato), no food approvals have been allowed in the European Union since an unofficial moratorium was imposed in 1998, in effect stopping the import or cultivation of any new biotech crops. Japan has also restricted imports of biotech foods, requiring suppliers to obtain food and environmental approvals prior to importation. Commodity organizations, shippers-packers and grocery chains in the United States have also been reluctant to introduce new biotech varieties and foods because of logistical difficulties in segregating food for export markets to Europe and Japan. For example, even though it resulted in a significant reduction in insecticide use, Monsanto's insect- and virus-resistant New Leaf potato is no longer available because a major processor (McCain Foods) and fast-food chain (McDonald's) prohibited their suppliers from using this variety (Cornell Cooperative Extension 2003).

Gianessi et al. (2002) calculated that there would have been 1 billion pounds of yield gain in 2001 and a reduction of 1.5 million pounds of pesticide active ingredients applied if growers had planted the New Leaf potato (see sidebar, page 94). Research activities with horticultural crops have also been cut back, with the number of field trials conducted declining since 1999 (fig. 2). Together, the E.U. moratorium, the failure of the European Union to establish tolerances for the adventitious (accidental) presence of biotech crops in food and seed, labeling issues and the reluctance of the marketing chain to accept new biotech foods have virtually halted commercialization of new biotech fruits and vegetables.

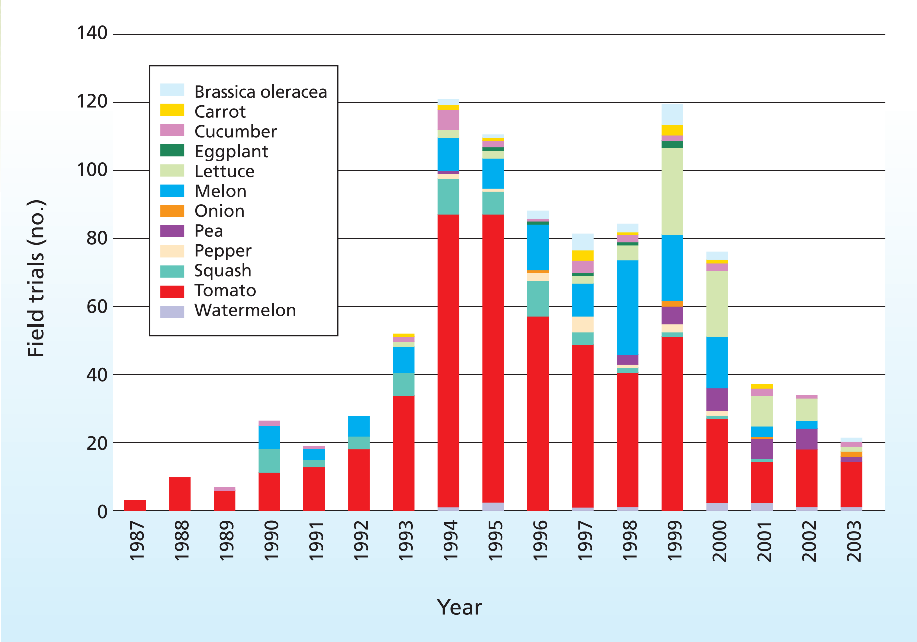

Fig. 2. U.S. field trials of biotech fruits and vegetables, 1987 to 2003. (*Brassica oleracea* includes broccoli, cauliflower, kale, cabbage and Brussels sprouts.) Source: http://www.nbiap.vt.edu/cfdocs/fieldtests1.cfm.

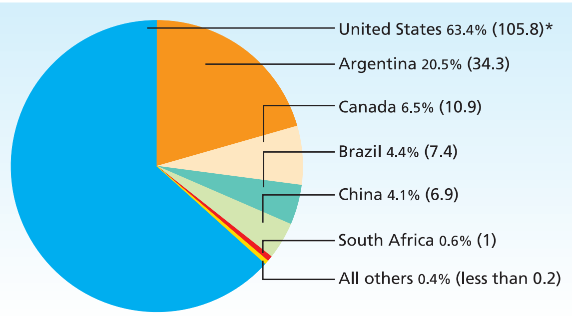

Fig. 1. Percentage of commercialized transgenic crops planted by countries, out of total global acreage (167 million) in 2003. (*Numbers in parenthesis are million acres.) "All others" includes countries that planted 200,000 acres or less: Australia, Mexico, Spain, Romania, Bulgaria, Germany, Uruguay, Indonesia, India, Colombia, Honduras, Philippines and France. Source: James 2003.

Crops approved as safe

Despite initial consumer acceptance, biotech horticultural products are virtually absent from today's market. Are U.S. consumers concerned about the safety of these products? They do not appear to be, since they trust the U.S. government's oversight. The regulatory requirements to demonstrate food, feed and environmental safety of biotech crops are well established in the United States. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regulates the field testing and commercial release of genetically engineered (GE) plants; the U.S. Environmental Protection Agency (EPA) ensures the safety and safe use of pesticidal and herbicidal substances in the environment; and the U.S. Food and Drug Administration (FDA) governs the safety and labeling of the nation's food and feed supply (APHIS 2002).

Extensive safety data are generated for each specific transformation event (the insertion of a specific segment of recombinant DNA into a specific variety). In general, it takes dozens or hundreds of transformation events, each of which must subsequently be regenerated into a transgenic plant, to identify one or two that will be used for commercialization. This compares to the hundreds or thousands of plants that may be evaluated in a traditional breeding program to identify a single commercial line. However, unlike with traditional breeding, each commercial transformation event must have its own dossier of safety assessments and meet key data requirements, including toxicity, nutritional data, allergenicity and environmental impacts (see box, page 108).

Companies have conducted these studies for all biotech products commercialized to date, and U.S. and international regulatory agencies have granted approvals (see box, page 109). No case has been documented to date of harm to humans or the environment from the biotech crops currently being marketed, although "genetic drift" from transgenic to conventional crops has occurred as it has for millennia between conventional crops. Now some Mexican growers have expressed concerns under the North American Free Trade Agreement (NAFTA) about preserving the biodiversity of their maize due to gene flow from transgenic corn (NACEC 2004).

Certainly, information of this type is needed to identify potential hazards and ensure the food and environmental safety of crops developed using biotechnology. Despite the track record of currently approved biotech crops, many opponents continue to demand that additional safety studies be conducted due to concerns such as genetic drift, out-crossing with wild species and food safety. For example, the U.K. Royal Society (2002), an organization of distinguished scientists, made the following conclusions:

- "There is at present no evidence that GM foods cause allergic reactions."
- "There is no evidence to suggest that those GM foods that have been approved for use are harmful."
- "Risks to human health associated with the use of specific viral DNA sequences in GM plants are negligible."
- "It is unlikely that the ingestion of well-characterized transgenes in normal food and their possible transfer to mammalian cells would have any significant deleterious biological effects."

Nonetheless, in the same report, the Royal Society recommended that more studies be conducted using the latest analytical techniques to test each and every compound produced by the biotech crops, including compounds released as volatiles. The Royal Society then recommended that post-marketing

Courtesy of Martina McGloughlin

Zeneca's biotech tomato puree (paste) was successfully sold in the United Kingdom from 1996 to 2000.

surveillance be conducted, "should GM foods be reintroduced into the market in the U.K." Although it could not identify any specific safety hazards in current biotech products, the Royal Society did not recommend that such foods be allowed back into the United Kingdom. Regardless of the extent of safety testing and absence of evidence of harm, the bar may continue to be raised as new testing technologies are developed, making it increasingly expensive to meet regulatory requirements.

Regulatory and other barriers

In addition to safety assessments, there are a number of significant barriers to developing new biotech horticultural crops, including the added costs of variety development, regulatory approval, post-commercialization stewardship and the reluctance of the horticultural marketing industry to accept products grown from biotech varieties. Many of the hurdles faced by companies developing biotech varieties do not exist for traditionally bred varieties, including the following issues.

Seed movement and field testing. Experimental biotech varieties can be moved interstate and tested in the field only under permit from the APHIS, to prevent mixing with nonbiotech seed. During the experimental phase, it takes at least 10 days to obtain a permit for seed movement and 30 days to obtain one for field release.

Adventitious mixing. Specific protocols must be developed, implemented and enforced to prevent adventitious

Key data requirements for U.S. safety assessments of new transgenic crops

Product description: data on the host or parent plant, introduced or novel genetic material, and intended effect of the inserted gene.

Molecular characterization: data on the location and manner in which the target gene is inserted into a single site in the host plant's DNA.

Toxicity studies: as necessary, tests demonstrating the safety of the transgenic protein.

Nutritional data: analyses of the fruit or commodity collected over several growing environments and growing seasons.

Substantial equivalency: data and information showing that the biotech variety differs from comparable nonbiotech varieties only with respect to the intended effect.

Allergenicity: analyses showing that a transgenic protein is unlikely to cause allergic reactions in humans.

Natural toxicants: analyses showing that there is no increase in the levels of natural toxicants.

Environmental impact: studies demonstrating that the biotech variety is unlikely to have an adverse effect on the environment, including:
- Outcrossing and gene flow, to evaluate whether the introduced trait is likely to move from the crop to related wild species.
- Germination and flowering, to determine whether the introduced trait is likely to alter seed germination, flowering time or other properties that affect the plant's ability to reproduce in the wild.

Patrick Tregenza/USDA-ARS

There are often dozens of varieties for a particular horticultural crop. *Above*, seeds of the world's most unusual lettuces are safeguarded in an ARS gene bank in Salinas. Genetically engineered lettuce has not been commercialized.

U.S. regulatory approvals of biotech crops

http://vm.cfsan.fda.gov/%7Elrd/biocon.html
http://usbiotechreg.nbii.gov
http://www.isb.vt.edu

mixing with other varieties. Such mixing can occur as a result of pollen movement from a biotech field to a conventional field or during seed harvest and cleaning. Adventitious mixing occurs when very small amounts of biotech seed mix with other nonbiotech seed. Regulatory agencies in some countries establish "tolerances," the maximum allowable amount of adventitious material (similar to tolerances for pesticide residues). For biotech varieties at the experimental stage (unapproved events), the tolerances are usually zero in food and seed. For biotech varieties approved for commercial growing and consumption, the thresholds for adventitious presence vary from country to country, ranging from less than 1% to 5% for food ingredients, and 0.3% to 1% for seed. By comparison, conventional seed-purity thresholds are usually between 1% and 10%, depending on the crop and varieties.

Handling procedures. Separate breeding and seed production programs are needed for biotech crops, with increased isolation and strict handling procedures to prevent cross-pollination or adventitious mixing. Increased seed purity standards — over the standards for conventional seed — are also required throughout growing, harvesting, cleaning, milling, storage, coating, packaging and shipping.

Tracking, training. In order to achieve tolerances an order of magnitude stricter for biotech varieties than is required for conventional varieties, biotech-specific internal tracking and testing procedures must be implemented. Additional training on handling of biotech crops is required throughout the development and marketing chain — from molecular biologists and breeders to seed producers and distributors. Each new employee who might be involved with biotech varieties at any level must be specially trained. Depending upon the type of product, grower training and post-commercialization stewardship programs may be required.

Increased development costs

These additional requirements have increased the cost of developing biotech varieties (in excess of costs to develop traditionally bred varieties) to at least $1 million per allele (if limited strictly to the United States) and more likely to $5 million or more per allele, depending on the number of countries in which approvals are required. An allele is a single transformation event, which contains the genetic trait of interest and expresses the desired phenotype in the crop.

These additional costs and issues are the same for both field and horticultural crops. Due to the large acreage of field crops, the costs can be justified by the market size of the biotech varieties. The same is not true for horticultural crops because of the small acreage of each crop. One strategy has been to limit marketing of a biotech horticultural crop to just the United States. However, due to the international trade in horticultural commodities, there are few examples of products under development in which both the seed and the product could be contained solely in the United States. More likely, a biotech variety will need approvals in a number of countries to which the product might be exported. For example, biotech processing-tomatoes grown in California will end up being exported as tomato paste or other products to many countries around the world, each of which must give food approval prior to commercialization. And, if the processed product contains seeds that might be viable, environmental studies and approvals are also be required in the importing country, even if the importation is intended only for food consumption. Importing countries may also impose additional and unique requirements, such as labeling or the ability to trace the product back to the producing farm, as in pending E.U. regulations.

The end-result of a successful biotech development program is a new allele that produces the intended effect, has passed the thorough safety testing and has received approvals and registrations from appropriate government agencies. In the 1990s, developers of biotech varieties assumed that once a biotech product was shown to be safe, it would be produced and marketed just like any other commodity. A biotech allele would be equivalent to a traditional allele, and there would be no need for product segregation, labeling or special handling. While this is largely the case in the United States, this assumption is no longer valid because of labeling requirements in the European Union and other countries.

Another assumption was that product approvals could be achieved generically for a specific gene and crop. That is, once a particular gene product was shown to be safe, it could be introduced into additional varieties without retesting. Instead, approvals are based on specific transformation events. Consequently, if different varieties are transformed with a given gene to produce a

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IR-4 Project targets specialty crops

Robert E. Holm
Daniel Kunkel

Pesticide applications for "minor" or "specialty" crops — typically those grown on less than 300,000 acres nationwide — often do not get the full support of product registrants because the potential economic benefits are perceived as much more limited than for applications targeting crops grown on large acreages, such as soybeans and field corn. The IR-4 Project is a unique partnership of researchers, producers, the crop-protection industry and federal agencies designed to increase pest-management options for specialty crops, which include vegetables, fruits, nuts, herbs, nursery crops and flowers. (Most of the crops grown in California fit into this category.)

With funding from the U.S. Department of Agriculture, state agencies, commodity groups and other industry sources, IR-4 researchers and cooperators generate field and laboratory residue data, which are submitted to the U.S. Environmental Protection Agency (EPA) to secure regulatory clearances for using safer pest-control techniques on specialty crops. Projects are prioritized based on requests from growers, commodity groups, and USDA and land-grant university researchers. Since 1963, IR-4 has contributed to more than 7,300 regulatory clearances for specialty crops.

The IR-4 Project is a unique partnership of researchers, producers, the crop protection industry and federal agencies designed to increase pest-management options for specialty crops.

In 1996, IR-4 responded to the federal Food Quality Protection Act (FQPA) by shifting its strategy from product defense (support for older pesticides needing reregistration) to working with reduced-risk/safer chemistries and biopesticides. The program also expanded its Good Laboratory Practices (GLPs) efforts, started a Methyl Bromide Alternatives Program and initiated a pilot program to support new transgenic horticultural crops. Because they are also grown on smaller acreages, transgenic horticultural crops face many of the same regulatory hurdles as uses on conventional specialty crops.

Sherrilynn Novack

Matt Hengel, regional laboratory coordinator of the IR-4 Western Region, tests hops residue at the UC Davis Department of Environmental Toxicology.

Focus on herbicide tolerance

The IR-4 team initially identified herbicide tolerance and insect resistance as potential opportunities for assisting transgenic specialty crops through the regulatory review process. It then narrowed down the focus to herbicide tolerance, recognizing that the FQPA could possibly limit the use of several key herbicides for vegetables due to regulatory concerns about toxicology and groundwater contamination. The other justification for focusing on herbicide tolerance was that the newer herbicides in the development pipeline for major crops had limited tolerance on specialty crops, prompting companies to restrict their uses on vegetables due to product liability concerns.

Sweet corn. IR-4's first transgenic project was the result of research conducted by Gordon Harvey at the University of Wisconsin, who was looking for alternatives to the use of atrazine — a potential groundwater contaminant — in Wisconsin sweet-corn production. Harvey conducted studies on glufosinate-tolerant (Liberty Link) sweet corn and demonstrated excellent weed control. The commercial varieties linked the Bt gene with the glufosinate-tolerant gene to provide additional protection against corn borer and corn earworm, two major sweet-corn pests.

IR-4 then facilitated the residue assessment programs required by EPA in 1997, 1998 and 1999. As a result, EPA granted Section 18 "emergency use" permits for the herbicide-tolerant sweet corn in Wisconsin, Minnesota and Michigan in 1999 and 2000. However, due to concerns about consumer acceptance expressed by sweet-corn processors, no significant commercial acreages of these varieties were planted in 2001 and 2002. Nonetheless, IR-4 submitted a complete registration package to EPA for glufosinate-tolerant sweet corn in 2003.

Lettuce. IR-4's other herbicide transgenic project was glyphosate-tolerant (Roundup Ready) lettuce. IR-4 staff met with Seminis Vegetable Seeds (licensee of transformation technology) and Monsanto (glyphosate registrant and gene technology licensor) in 1998 to discuss potential technology applications. The project was placed on the IR-4 30-month "fast track," with submission to the EPA scheduled for 2001. The program was a cooperative partnership between Seminis Vegetable Seeds (seeds and technology support), Monsanto (residue analysis and technical support) and IR-4 (field residue program, project management and petition preparation and submission).

However, in 2000 several grower groups expressed reservations about the program primarily due to concerns about public acceptance, leading the partners to slow the program down. During this period, field results from several university researchers demonstrated excellent weed control in glyphosate-tolerant lettuce, resulting in reduction of hand-hoeing costs. It is still not certain when or if IR-4 will submit a registration package to EPA.


Scott Bauer/USDA-ARS

The interagency IR-4 program evaluates the safety of agricultural chemicals intended for use on specialty crops. In Salinas, Agricultural Research Service agronomist Sharon Benzen displays broccoli grown in test plots, which will be used to determine pesticide residue levels.

Future directions

IR-4 cannot take on additional specialty-crop biotechnology projects without new funding from the USDA (Agricultural Research Service and Cooperative State Research, Education, and Extension Service) and support from IR-4 management and stakeholders. Current funding is just adequate to cover the existing core programs of reduced-risk chemistries, biopesticides, ornamentals and methyl bromide alternatives. Additional funding from Congress or other sources (either public or private) would be necessary. IR-4's core competencies are in field residue studies and chemical laboratory analyses conducted under GLPs. Safety and environmental testing on specialty crops, especially allergenicity testing of newly expressed proteins in transgenic crops, is well beyond IR-4's existing capabilities.

Under current and proposed regulatory guidelines, the best approach for such testing might be to seek approval first in major acreage row crops such as corn, cotton, soybeans and rice, and allow those approvals apply to specialty-crop uses, as was the case for Bt sweet corn following the approval of Bt field corn. Of course, this approach is limited to traits that are applicable in both agronomic and horticultural crops, and will likely exclude many traits directed toward output quality.

IR-4 management and stakeholder support issue is even more difficult, as they are not in unanimous support of developing agricultural biotechnology, principally due to consumer concerns in Europe and to a lesser extent the United States. In the future, the IR-4 framework could be useful to address the pest-control needs of horticultural and other specialty crops via plant biotechnology, once a consensus is reached that they are cost-effective and safe for the environment and consumers.

R.E. Holm is Executive Director and D. Kunkel is Assistant Director, IR-4 Program, North Brunswick, N.J.

range of biotech varieties, each is an independent transformation event subject to all of the regulatory requirements. Because this is prohibitively expensive, developers must transform just one variety, register that event, and then use traditional breeding methods to incorporate the transgene into other varieties. This greatly delays and increases the cost of developing multiple biotech varieties in a given crop. This is particularly restrictive for horticultural crops, in which many varieties are required to meet different seasonal production requirements and diverse consumer preferences, and any single variety has a relatively small market share. For example, dozens of different types and varieties of lettuce (such as iceberg, romaine, leafy) are grown throughout the year as production shifts between summer and winter locations in California, Arizona and Florida.

Some agronomic seed companies budget $50 million for the full commercialization of a new biotech crop, in addition to the standard costs for developing and marketing a traditional variety. Given the small acreage of horticultural crops and their much lower overall value, it is difficult to justify the investment in transgenic horticultural crops. For example, the total U.S. market for iceberg lettuce seed is about $27 million. A typical single variety is worth about $150,000 to $250,000 during its 5-year market lifetime, which suggests that garnering a large market share of lettuce varieties with significant added value would be necessary in order to pay for the additional costs imposed on biotech varieties.

Commercialization opportunities

Despite this gloomy picture, regulatory strategies may be possible that would protect public and environmental safety while decreasing the cost of introducing biotech specialty crops (Strauss 2003). Plant breeding companies employing biotechnology can manage and reduce regulatory costs by carefully and deliberately

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China aggressively pursuing horticulture and plant biotechnology

Jikun Huang
Scott Rozelle

AS the world debates the costs and benefits of plant biotechnology, swinging between optimism generated by a long list of breakthroughs and pessimism caused by a consumer backlash in some places, a new source of plant biotechnology discoveries is emerging in a most unlikely place: China. And the discoveries being made are more than cosmetic transformations. China's research community has made a major investment into understanding the structure and function of the rice genome, the use of agrobacterium to transform the rice plant, and new methods of transforming other crops, including a wide array of horticultural plants.

China has one of the largest and most successful agricultural research systems in the developing world (Stone 1988). Historically, much of China's research was focused on grain, and the government invested in research and development (R&D) as part of its pursuit of food self-sufficiency. Horticulture played only a small role in China's development strategy.

Economic growth, the rise of markets and the opening up of China's economy have resulted in a sharp shift in government policy and producer decision-making. As markets emerged in the 1990s, farmers reduced their area sown to traditional grain and fiber crops and began to cultivate vast tracts of produce. Fruit and vegetable area has nearly doubled in China, expanding by more than 20 million acres during the 1990s, adding the equivalent of a "new California" every 3 years for the past 12 years.

The Chinese research system has responded to the new demands. In the mid-1990s, top research administrators began allocating more funds to nontraditional crops. Researchers, including those in a nascent private-sector seed company, were given more freedom to work on broader array of crops and provided with incentives to shift to horticultural crops.

Research in modern plant biotechnology began in the mid-1980s. Chinese scientists now apply advanced biotechnology tools to plant science, regularly working on the synthesis, isolation and cloning of new genes, and the genetic transformations of plants. Our survey of China's plant biotechnology laboratories identified more than 50 plant species and more than 120 functional genes that scientists are using in genetic engineering, making China a global leader. China's scientists have generated an array of technological breakthroughs in transgenic plants and animals (Huang et al. 2002), and are currently working on a large number of horticultural crops such as tomatoes, melons and peppers (table 1).

Chinese scientists now apply advanced biotechnology tools to plant science, regularly working on the synthesis, isolation and cloning of new genes, and the genetic transformations of plants.

The technologies that have been approved for commercial release also demonstrate China's ability to move ahead with its biotechnology program. Among the varieties approved and licensed for commercialization before 2000 were shelf-life-altered tomatoes, color-altered petunias and pest-resistant peppers. Although approvals for genetically modified (GM) food crops have slowed recently, China was allocating about 9% of its research budget to plant biotechnology in 1999. In the late 1990s, China accounted for more than half of the developing world's expenditures on plant biotechnology. Recently, officials announced a plan to drastically raise research budgets.

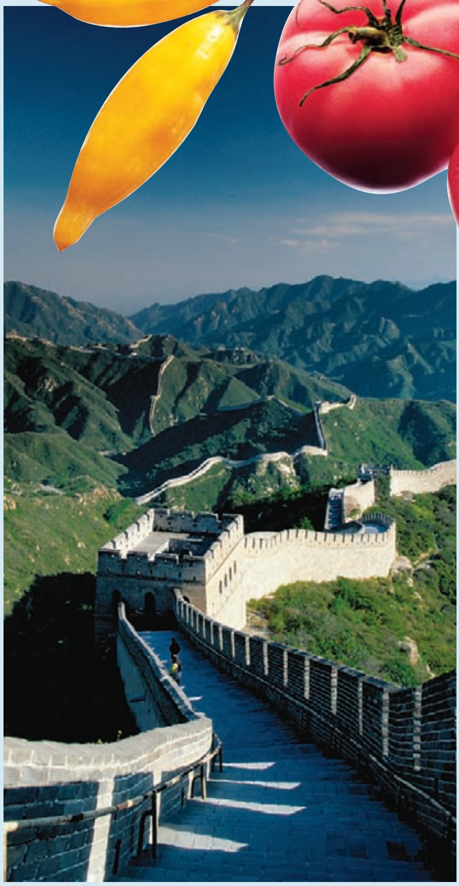
Many issues face China's research administrators. China's government recently put into place a regulation and biosafety system, but it is new, underfunded and has not proven its ability to enforce regulation. Chinese leaders are struggling with issues of consumer safety and acceptance, both within their own country and in countries that import its farm commodities. Almost nothing is known about how

TABLE 1. Field trials, environmental releases and commercialization of genetically modified horticultural plants in China through 2000

Crop	Introduced trait	Field trial	Environmental release	Commercialized
Cabbage	Turnip mosaic virus resistance	Yes	No	No
Tomato	Cauliflower mosaic virus (CMV) resistance	Yes	Yes	Yes
	Tobacco mosaic virus (TMV) and CMV resistance	Yes	No	No
	Shelf-life altered	Yes	Yes	Yes
	Cold tolerance	Yes	Yes	No
Melon	CMV resistance	Yes	No	No
Sweet pepper	CMV resistance	Yes	Yes	Yes
Chili	CMV and TMV resistance	Yes	Yes	No
Papaya	Papaya ringspot virus resistance	Yes	Yes	No
Petunia	Flower-color altered	Yes	Yes	Yes
Pogostemon*	Bacteria wilt resistance	Yes	No	No

Source: Author survey.

*An Asian shrub, used to make patchouli oil for fragrances and medicinal purposes.



China has dramatically expanded its production of fruits and vegetables, while allocating significant research funds to agriculture biotechnology. *Above*, Chinese scientists have developed genetically engineered crops, including peppers, tomatoes, papaya and cabbage (conventional crops shown).

Chinese consumers would react if they knew that their food was produced with GM varieties, although recent research suggests a relatively high degree of acceptance.

China's government also must decide if it will continue to bear almost the entire burden for funding biotechnology research. There is almost no private-sector funding. In the late 1990s, total spending by foreign firms on agricultural research in China was less than $16 million (Pray et al. 1997). China has options for increasing private research but is constrained by poor intellectual property rights (IPR), underdeveloped seed markets and prohibitive regulations on private firms.

Finally, the size of China's research investment, the improved education of its scientists that are involved in plant biotechnology research and its past success at developing biotechnology tools and GM plants suggest that its plant biotechnology industry may one day become an exporter of research methods and commodities. In both industrialized and developing countries, opportunities are expanding for contract research, exporting GM varieties, and selling genes, markers and other biotechnology tools. China has advantages such as large groups of well-trained scientists, low-cost research, limited regulation and large collections of germplasm.

At the same time, it has the disadvantage of almost no commercial biotech industry, a fragmented seed industry, public researchers inexperienced in working with corporations and a weak IPR regime. The Chinese agricultural-biotechnology sector will have to compete with the private and public sectors in other countries — the private life-science giants, smaller private biotech firms in industrialized countries, and universities in the United States and other industrialized countries. Because of its lack of capital and experience in global competition, China may have trouble competing in the most lucrative markets. However, the multinational life-science companies may be willing to leave relatively minor crops, including many horticultural crops, to China.

The emergence of China as an agricultural trading nation, and its rising strength in plant biotechnology research, offers fundamental challenges to California. China has a large advantage in producing labor-intensive horticultural crops, given its low wage structure and virtually unregulated agricultural economy. Indeed, China has already begun to make inroads into fruit and vegetable markets in East Asia that were once dominated by California growers. In contrast, California's marketing infrastructure and UC-based agricultural R&D system give it an edge in producing and delivering high-quality products and competing for foreign markets. To the extent that science will improve the quality and marketability of China's fruit and vegetable producers, plant biotechnology will improve China's competitiveness.

Inside China, where consumer acceptance is less of an issue, a more productive farming sector could mean less room for California's products. However, if China relies primarily on plant biotechnology to improve product quality, it might give California an advantage in world markets. As a developing country with a poor reputation for emphasizing food safety, China may not easily garner access to world markets for commercial releases of GM fruits and vegetables. Countries such as Europe and Japan are already skeptical about GM foods and likely would be especially concerned about importing them from a nation with a relatively short and untested consumer and biosafety record.

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determining the necessary testing requirements. Costs can be reduced by focusing development on biotech genes that have already been commercialized in agronomic crops, since expensive toxicity studies done on a new protein produced in a biotech agronomic crop can be used for the same protein produced in a biotech horticultural crop.

The USDA IR-4 program conducts and pays for the collection of efficacy and safety data on pest-control chemicals for "minor" or "specialty" crops, which include most horticultural crops (see sidebar, page 110). A new, expanded "biotech IR-4" program focused on full crop registration, including EPA, USDA and FDA requirements, could benefit horticultural crops being developed in universities, government laboratories and small companies. This is particularly critical for the next generation of transgenic products, which will be more consumer-oriented and specific to horticultural crops. Because horticultural products in the pipeline are likely to have altered nutritional or quality traits, specific safety tests will be required that cannot rely on data generated for agronomic crops. Without a program like IR-4, testing requirements could preclude such products from ever being developed and reaching the market.

As demonstrated by Calgene and Zeneca with their early tomato products, consumers are receptive to labeled products that have clear quality or price benefits. However, focusing entirely on consumer-oriented traits would forgo valuable benefits for crop production, such as virus resistance, which could have enormous advantages for producers that would not be readily recognized by consumers. As further experience is gained with biotech methods, regulatory requirements should be relaxed for categories of products posing little health or environmental risk. In addition, generic crop and gene approvals (such as glyphosate-resistance approval for all alleles in all leafy vegetables), rather than the current "event-specific" approach (separate approvals for each allele in each vegetable), would do much to encourage further development of such products.

USDA-ARS

Greenpeace/Daniel Beltra

***Left*, genetically engineered seed and crops are subject to stricter handling, transporting and tracking procedures to prevent cross-pollination and adventitious (accidental) mixing with conventional crops. The presence of Starlink corn in food products showed that there were weaknesses in the ability to segregate grains on their way to market. *Right*, in August 2003, Greenpeace activists blocked a trainload of biotech corn as it attempted to cross the Rio Grande into Mexico, claiming that it threatened native land races of maize.**

Around the world, farmers desire and in some cases, demand the benefits that can come from the improved varieties. In India, for example, extensive precommercialization field trials of insect-resistant cotton found average yield increases of 80% along with a 68% reduction in insecticide use (Qaim and Zilberman 2003). Farmers saw the value of the varieties and grew 25,000 acres of insect-resistant cotton in 2001, prior to government approval (in 2002). Similarly, a significant percentage of soybeans in Brazil was grown from herbicide-resistant seeds smuggled into the country from Argentina and propagated by farmers, as Brazilian courts held up their release despite governmental approval. While planting of insect-resistant corn has not been approved in Mexico, Mexican workers returning from the United States have brought back seed corn for planting, and biotech food grain sold in Mexico has also been planted. At the 2002 Institute of Food Technologists' annual meeting, E.C.D. Todd of Michigan State University reported that Thai farmers are smuggling and planting biotech seeds from China. While the distribution of biotech varieties outside of legal channels cannot be condoned, these examples illustrate that farmers are aware of the advantages these varieties can deliver. As research continues at many companies, universities and government laboratories, biotech horticultural products having similar attractions for growers and consumers (see page 89) may overcome the current financial and logistical hurdles facing their commercial development.

Future prospects; biotech in China

Despite vocal opposition, agricultural biotechnology continues to advance. China has made significant strides in commercializing GE horticultural crops over the past 10 years and may well become the world's leader during the next 10 years (see sidebar, page 112). China was the first country to commercialize biotech plants, beginning with field production of thousands of acres of virus-resistant tobacco in 1988, followed by virus-resistant tomatoes (500 acres) and sweet pepper (6 acres) in 1994 (Chen and Zhu 1994; Rudelsheim 1994; Zhou et al. 1994; Stipp 2002). In the mid-1990s, China was criticized by an American delegation for having only a provincial and not a national product-approval system. For several years afterward, it was difficult to determine whether further commercial plantings of biotech crops occurred in China (Redenbaugh et al. 1996).

Interestingly, China established 1997 as the "official" commercialization date for biotech cotton, tomato, sweet pepper and petunia, which is when the crops were authorized by the agricultural-biotechnology safety office of the Chinese Ministry of Agriculture (Z. Chen, personal communication, LMOs & the Environment Conference, Durham, NC, 2001). Chi-

Many of the biotech crops on the market today are genetically engineered for insect resistance. At Monsanto's laboratory in St. Louis, proteins are screened, *left and right,* for insecticidal activity. In the micro-wells, *center,* the insect eggs or larvae of the target species are placed in protein material that is incubated for several days and then examined for survival or growth of the insect.

na currently claims to be second only to the United States in agricultural biotech research, development and cultivation, and China is taking full advantage of uncertainty caused by the European Union's stance on biotech approvals. Beijing University vice president Chen (1999) stated, "I expect that in 10 years between 30% and 80% of the rice, wheat, maize, soya, cotton and oilseed crops in China will be transgenic crops. We can take advantage of this 4-year halt [E.U. moratorium] to turn China into a world power in genetically modified organisms."

China is in an excellent position to develop and create internal markets for biotech horticultural crops and clearly has the opportunity to surpass the United States in biotech crop development. Recently, China erected barriers to the importation of biotech grains, creating confusion for U.S. and world exporters, while backing away from some of its earliest commercial biotech products (Macilwane 2003). It is not known whether this is due to internal concern over biotech products or fear of jeopardizing its own export markets to Europe, or is a trade barrier to allow for additional internal development of biotech products. Greater clarity will occur should this issue come before the World Trade Organization (WTO).

Regulatory issues and costs are reducing commercial opportunities for new biotech crops in the United States. Of course, China will need to meet the requirements of any country receiving their exports, but currently it is unclear whether any of China's biotech products are being exported. Korea and Japan are not likely to press this as a trade issue. Other internal political issues are currently complicating commercialization efforts within China, but these are likely to be only short-term barriers (Economist 2002).

While the United States falters over biotech fruits and vegetables, China is positioning itself to be the world leader in coming years. For the American horticultural industry, the results could be devastating if the United States loses its current competitive edge and more agricultural production moves overseas.

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Public-private partnerships needed in horticultural research and development

Gordon Rausser
Holly Ameden

University-industry partnerships are proliferating in the United States, as public funding for high-level research continues to decline yet knowledge plays an increasingly important role in industrial processes. The horticulture industry benefits from such arrangements by influencing research directions and gaining access to innovations and complementary research in agri-cultural biotechnology. Given the nature of this industry, the obstacles to developing effective partnerships are substantial. Private horticulture institutions should form consortia of both small- and medium-sized firms, and they should understand the need for faculty and academic freedom. More enterprising members of a consortium can capitalize on the research contacts and pursue firm-specific, applied-research partnerships. Potential drawbacks are the exclusion of smaller firms and inequitable benefits-sharing within the consortia.

Horticultural research is conducted primarily in the public sector, with research at private institutions playing a relatively minor role. As a result, research gaps naturally emerge between the basic research generated by public institutions and the research needs of industry. One approach for reducing this gap is to form public-private research partnerships that harness the complementary research and academic expertise of universities with the commercialization and marketing expertise found in industry. Such partnerships are proliferating, especially between universities and large life-sciences companies. Unfortunately, there are few concrete examples of such partnerships in agricultural biotechnology for the horticulture industry. The challenge is to adapt models of these partnerships to the research needs and structure of the horticulture industry, which produces crops such as fruits and vegetables, nuts, and nursery and ornamental crops.

The traditional research paradigm posits a one-way flow from basic science conducted in public institutions to applied research and commercialization undertaken largely by private industry. This characterization does not accurately portray current trends in research and development (R&D). Increasingly, public universities and private firms engage in joint research and establish interactive relationships. Several factors have contributed to this trend, including recent legislation (the Bayh-Dole Act of 1980), the restructuring of many of the larger life-sciences firms (such as Monsanto and Syngenta) and an alignment of private and public incentives to pursue long-term R&D efforts (Rausser 1999).

The potential benefits from university-industry partnerships in the field of agricultural biotechnology are obvious. Scientific and practical knowledge can complement each other, leading to more rapid and far-reaching innovation. Universities need funding for their researchers, as well as intellectual property held by private companies and access to modern, commercially

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Novartis

Partnerships can link university research expertise with the commercialization and marketing savvy of industry: such partnerships are proliferating in the United States. For example, in 1998 the Department of Plant and Microbial Biology at UC Berkeley, *left*, entered into a 5-year, $25 million research agreement with a multinational life-sciences company, Novartis, *right* (Basel, Switzerland), and its successor company, Syngenta.

developed enabling technologies (such as gene expression profiles and genome maps) to ensure a first-rate graduate education for students. For its part, industry is interested in accessing new research and innovation, developing new products and hiring highly trained graduate students.

However, obstacles to the formation of successful agreements are significant. Both parties in a research partnership face serious risks. These risks are rooted in the conflict between a university's academic objectives and the private firm's corporate incentives. One critical risk is the potential co-opting of the academic research agenda by private interests. University researchers risk the loss of academic freedom and integrity while industry risks the loss of investment capital, privacy and proprietary information. Differences between the university's educational objectives and corporate goals, as well as differences in the cultures, institutional incentives and time frames, can lead to a clash of cultures and values. Intellectual property (IP) rights issues are also a frequent source of contention. Given these risks, both parties need to enter into carefully structured research agreements.

Structuring agreements

Most work examining research partnerships focuses either broadly, on such issues as the source of research funding, basic provisions of these agreements and associated problems and consequences (Blumenthal et al. 1996; GUIRR 1999; NAB 2001), or narrowly, on specific aspects of a particular type of agreement (NIH 1994). Although this literature is useful, it does not effectively address how to structure these public-private research partnerships. In response to this need, we have constructed templates based on the three stages of any university-industry research partnerships, which provide a framework for characterizing their "front-end" and "back-end" options (Rausser and Ameden 2003).

University-industry research partnerships come in many forms. They may be targeted, with private firms designating specific research agendas, or they may be nontargeted. Research projects may have short or longer time horizons. Universities may enter agreements with a single private company or with groups of firms sharing a common interest (an industry consortium). Collaborations may cover a single research project or be "mega-agreements" covering a large range of interactions (examples include UC Berkeley–Novartis and Washington University, St. Louis-Pharmacia).

Because of the inherent uncertainty in the research process, research partnerships can be structured in terms of *ex ante* decisions (those made prior to initiating a research partnership) on the options embedded in the three stages of any agreement. These embedded options are specific decision points, such as determining which partner will control the research agenda. Universities can define policies on this option *ex ante*, before potential partners are approached.

Stage I: Setting the bargaining space. To start, potential research partners consider possible collaborations and associated tradeoffs. The vital aspect of this stage is determining exactly how partners will be identified and selected. Although deliberately seeking out partners rather than waiting to be approached with a proposal requires more effort upfront, it can substantially broaden the set of choices. For example, the public partner could elicit competitive bids from multiple private partners rather than just accepting or rejecting a single proposal.

Stage II: Negotiating the agreement. Next, the agreement is negotiated and may or may not involve a formal contract. Front-end options determine the nature and scope of the research activities that the partnership will undertake, while back-end options determine how any benefits generated by the partnership will be distributed and how knowledge assets such as patents and commercial products are disseminated. Decisions in the front-end include specifying the research agenda, asset contributions, governance structures and scale of operations. Back-end options include designating patent-filing responsibility, property and licensing rights, royalty rates and how research results will be disseminated.

Stage III: Reviewing and renewing the partnership. Finally, the outcome of the partnership is assessed, with an eye toward whether to renew the agreement. Currently, there is no standard approach for formal review of large- or small-scale agreements. To assess whether a research partnership was successful or not, interested parties must rely on the informal reviews and vague impressions of both partners along with more tangible outcomes, such as the number of patents generated by the research. A key policy challenge is the development of concrete indicators or measures of productivity for public-private research partnerships.

Templates for partnerships

Based on these stages of forming agreements, we have designated four groups of templates.

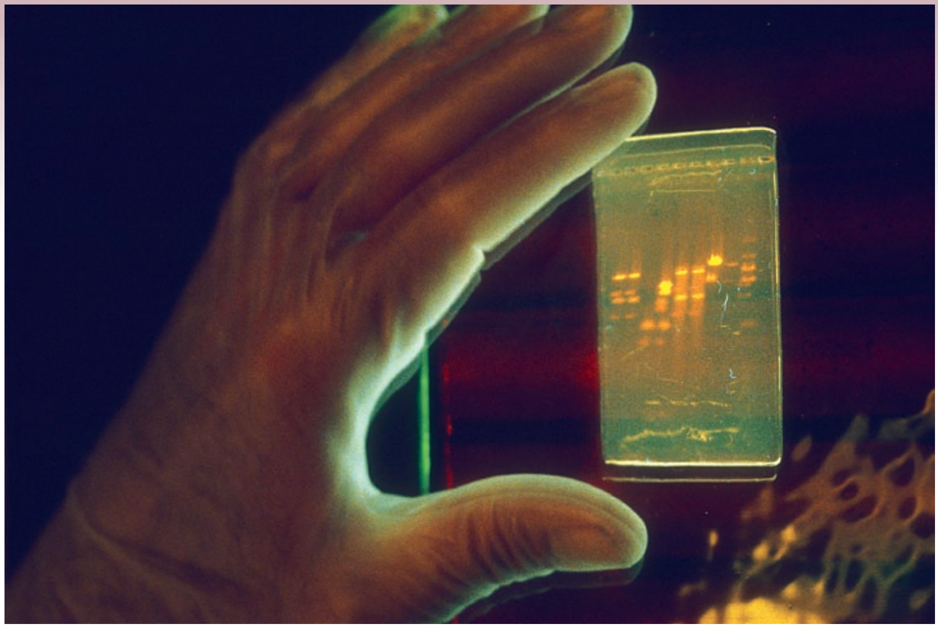
Strategic partnerships involve comprehensive, multiyear commitments between a university, or an academic department in a university, and a large company, with both partners dedicating significant assets. Formal procedures for determining research agendas and control of back-end assets are specified. Given their size, these agreements tend to come under significant scrutiny and often external review.

One such agreement was the 5-year, $25 million research agreement between Novartis (and its successor company, Syngenta) and UC Berkeley's Department of Plant and Microbial Biology. The relationship, which generated approximately 20 innovations, was the subject of an internal campus review by the office of the Vice Chancellor for Research. The review found the research had not been skewed toward applied biotech research as feared and that graduate students were the primary beneficiaries.

Research unit/center partnerships usually also involve the dedication of significant resources. Instead of involv-

Differences between the university's educational objectives and corporate goals can lead to a clash of cultures and values.

ing existing academic departments, however, these research units are set up separately, allowing more distance between the partnership and the academic community at the university. Such partnerships may be linked to a single company, commodity group or companies that provide some or all of the financial resources for the research center. For example, the Seed Biotechnology Center at UC Davis is a partnership between the College of Agricultural and Environmental Sciences and the California seed industry. The College provides research space and faculty time, while the industry funds additional research and programmatic personnel. Specific research projects are funded through diverse grants and contracts with both public agencies and private sources.


Jack Kelly Clark

Smaller firms have the capacity to rapidly apply new technology, but when it comes to techniques involving recombinant DNA they often do not have the assets to develop commercially viable products. Partnerships can help by sharing the costs of research, development and testing that are needed to bring a genetically engineered product to market. *Above,* gel is used to separate DNA molecules according to their length.

Sponsored projects are small to large commitments with a specific research agenda designated at the outset. As with strategic partnerships, either partner may approach the other, but instead of defining a governing structure for selecting research directions, specific research projects of particular duration and budget are proposed. Depending on the nature of the bargaining space (e.g., private partner proposes project versus the university approaches private partner with research needs), the university's options on the front-end can be more restricted. Sponsored projects may act as testing grounds for relationships and serve as precursors for more far-reaching strategic partnerships. Through more than 50 commissions and other organizations, industry groups provided more than $22 million to support public research programs at UC Davis last year, a large fraction of that in the plant sciences.

Informal arrangements are generally the initial mode of contact between university and industry partners. Through networking with contacts, industry scientists identify valuable university counterparts and vice versa, and set up simple arrangements involving minimal transaction costs. These agreements can either be transparent, public collaborations or may involve more indirect arrangements such as corporate gifts that are not tied to any specific collaboration or in-kind donations of services, equipment or materials. This category would include pesticides or tractors donated for a field trial and technical expertise for setting up a research program.

Horticultural industry and research

The horticultural research industry is composed primarily of small to medium enterprises (Dixon 1998) with small markets for individual products. Because of their relatively smaller size, these firms are able to rapidly apply new knowledge and technology. However, when it comes to genetically engineered crops, the smaller firms generally do not have the assets to develop new products.

Research funds in horticulture come mainly from the public sector (Sansavini 1998; Dixon 1998). The reluctance of major biotechnology R&D companies to dedicate funds to horticultural research is, in part, because technological advances in horticulture are not viewed as "low-hanging fruit." The commercial value is not nearly as attractive as for annual agronomic crops grown on large acreages. In addition, consumer acceptance of genetically modified foods is considered a major obstacle to the adoption and commercialization of agricultural biotechnology. Current biotech research focuses on reducing the environmental impacts of horticultural production, food safety, product quality and new-product development (Robitaille 1998).

Public-private research partnerships could greatly benefit the horticulture industry, and domestic and international research partnerships in horticulture are considered especially important for developing economies (Robitaille 1998). Dixon (1998) notes that successful entrepreneurs in horticulture maintain a continuous dialogue with scientists; partnerships are one approach for guaranteeing this dialogue. Dixon also notes that linkages between research and industry (public and private relationships) have improved "where levy funding systems have been established to support scientific endeavors." In other words, more formal financial arrangements between partners are likely to yield the best exchange.

Strategies for horticulture R&D

The most relevant partnership model for the horticulture industry is that of less formal, single or multiple-project partnerships (sponsored project and informal arrangements). In pursuing these partnerships, the implications of all three stages of the partnership should be considered *ex ante*.

In Stage I (setting the bargaining space), private horticulture institutions seek to align research incentives and form consortia of small and medium firms with parallel research interests to concentrate intellectual and financial resources. These consortia are organized by crop or pest type (or other research interests) to facilitate networking, identify key researchers at public institutions and propose specific research projects. (A proportional-contribution / equal-sharing scheme between consortia members is likely to be the most effective self-governing approach given the public nature of research leads and outcomes.)

The university should accept or reject these proposals based on the research synergy and embedded options. Although all universities share a common set of core principles that guide their decisions, different institutions emphasize different objectives; the private partner should consider the university's research climate when considering research partners.

In Stage II (negotiating the contract), the private partner considers the type of research to pursue in the partnership. Given the nature of research objectives at universities, the horticulture industry partner should propose research projects that are more basic, have longer time frames and are not adequately addressed by current private research efforts. These partnerships are more likely to be successfully negotiated if the industry partner understands, *ex ante*, the need for faculty and academic freedom. On the backend, university guidelines and policy usually constrain its researchers to specific conditions for patenting research, and licensing and disseminating results (publication delays). Although there is some variation, these constraints are fairly common at universities.

Stage III (reviewing the partnership) is best accomplished if specific goals or benchmarks are incorporated into the initial agreement. This gives both sides criteria to judge whether the partnership is achieving its goals and justifies renewal.

Consortia benefits and risks

Both partners should establish links so that industry can more effectively utilize public research and universities can secure access to research funding and cutting-edge enabling technologies. These collaborations can serve as stepping-stones to more formal, long-term agreements. Alternatively, once initial consortia-university research partnerships are established, more enterprising members of the consortia can capitalize on the research contacts and pursue firm-specific, applied-research partnerships.

The primary obstacle to forming research partnerships is high transaction costs. The process of identifying appropriate researchers as potential partners can involve significant search costs. And once potential partners have been selected, the time and effort involved in negotiating a research agreement, especially given the differing objectives of public versus private institutions, can be substantial. The consortium approach is a strategy for sharing these costs. If the consortia are not well structured, however, reduced external transaction costs may be replaced by higher internal costs of organizing and running the consortia. Inequitable benefits-sharing within a consortium may also be a source of conflict. And although this approach is intended to serve the needs of medium- to smaller-sized firms, the smallest enterprises may still be excluded (especially in subsequent partnerships).


Jack Kelly Clark

The time and effort involved in negotiating public-private research partnerships is substantial, but such arrangements can be fruitful for both parties. *Above,* a UC scientist uses tissue culture to propagate grapes in the laboratory.

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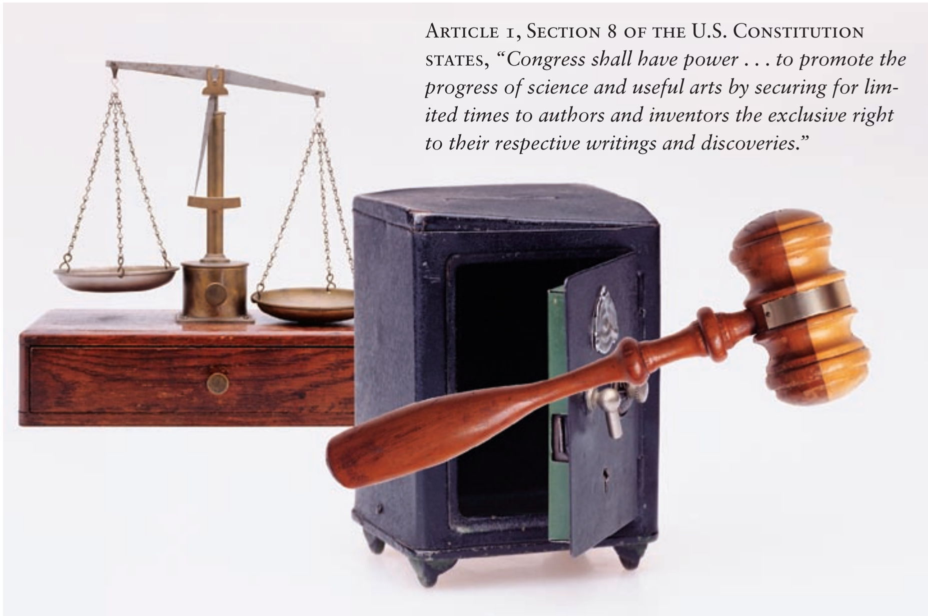
RESEARCH ARTICLE

Access to intellectual property is a major obstacle to developing transgenic horticultural crops

Gregory D. Graff
Brian D. Wright
Alan B. Bennett
David Zilberman



Article 1, Section 8 of the U.S. Constitution states, "*Congress shall have power . . . to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.*"

Gathering the legal rights to all the intellectual property necessary for marketing a genetically engineered product can be daunting, especially for smaller companies and public institutions. And the transaction costs to secure "freedom to operate" can be considerable.

Inefficiencies in accessing intellectual property (IP) appear to be hindering otherwise valuable research and development (R&D) in horticultural crop varieties. While leading private-sector agricultural biotechnology firms with strong IP positions and commercial freedom to operate (FTO) see insufficient incentives in the small, fractured markets of horticultural products, researchers with public-sector support for horticultural projects but weak IP positions may find that the best way of gaining FTO and moving forward is to band together and provide mutual access to one another's technologies. The Public Intellectual Property Resource for Agriculture (PIPRA), headquartered at UC Davis, is a new coalition of U.S. universities and foundations committed to this strategy.

Stories and rumors have circulated for years about biotechnology projects in horticulture being shelved because of intellectual property (IP) conflicts. In a typical situation, a plant scientist at a university agricultural experiment station or a smaller seed firm has developed a remarkable new variety using the cutting-edge scientific tools of plant biotechnology. Then, as they or the nursery or the growers' association with whom they work take the next steps to develop and release the new variety to commercial growers, their efforts are quickly and quietly shut down by a letter from an attorney. The letter alleges that the new variety contains a piece of technology that infringes upon a client's IP claims. Furthermore, the patent owner appears not even to be interested in negotiating a license. And to this day, the legendary variety sits in storage somewhere in a greenhouse or a freezer, unused and sadly neglected.

Of course, it is difficult to establish the definitive reasons why a project does not come to fruition, especially when there are numerous factors simultaneously affecting the outcome. Prior patents may be just a convenient excuse — and the patent owners a scapegoat — for tough decisions made to terminate unpromising or economically unattractive projects. Still, while patents do provide convincing incentives for private firms to invest in agricultural research and development (R&D), taking the necessary steps to respect the rights of patent ownership does add an additional layer of costs for developing new crop varieties. Economists call these additional costs "transaction costs"; they include legal fees for searching and filing patents and expenses for negotiating and drafting licenses. Royalties paid for using another's technology are not IP transaction costs. Rather, they are "rent" paid to use the technology and to compensate for the R&D expenditures spent to create it.

Commercial developers of agricultural biotechnologies often take measures to avoid incurring these IP transaction costs. They may shift their R&D strategies or even acquire other companies to avoid dependence on outside technologies, thereby limiting expenses and preventing the complications and uncertainties inherent in "renting" them (Graff, Rausser et al. 2003). These measures, however, can be costly too. Either way, costs faced under an IP system can, in theory, cancel out the private incentives created by IP to pursue innovation. More troubling, IP can even prevent publicly funded innovation from having its intended social impact. Horticultural genetics may be one such area of stalled innovation. Yet are there any good indicators of this stalling beyond just stories and rumors? And if so, can we establish links with IP?

Biotech R&D trends

Recent U.S. Department of Agriculture (USDA) registrations for field trials of transgenic crops show that R&D in horticultural crops is lagging when compared with the major row crops. Even leading transgenic horticultural crops such as melon, lettuce, strawberry, grape, apple and sunflower are hardly represented in field trials (fig. 1A; see page 106). Horticultural crops are completely dwarfed by corn, the single most commonly tested transgenic crop, which by itself is the subject of almost half of all transgenic field trials.

Of course, U.S. production of any single horticultural crop is far less valuable than U.S. production of corn. Less field-testing is to be expected for less valuable crops. But, even when applying a rough calculation to account for the differences in size and value of individual crops — dividing by the annual value of each crop's U.S. production (fig. 1B) — horticultural crops tend to show a greater farm-gate value per field trial. In other words, horticultural crops are subject to fewer genetic field trials, and presumably receive less biotech R&D, for every dollar of crop production.

Furthermore, the proportion of transgenic field trials conducted by public-sector research organizations, such as state universities or the USDA, versus the proportion conducted by commercial firms, varies widely by crop type (fig. 1C). Public-sector involvement in the field-testing of the 10 leading transgenic crops — mostly major row crops — averages just 15%. Yet, in the next 20 mostly horticultural transgenic crops, public-sector involvement averages much higher, around 40%.

These numbers should be interpreted cautiously, as the samples representing many of the horticultural crops are small and the ratios are taken over just a few field trials. For example, 16 field trials have been done on trans-genic papaya (all by public research organizations) and only 11 on

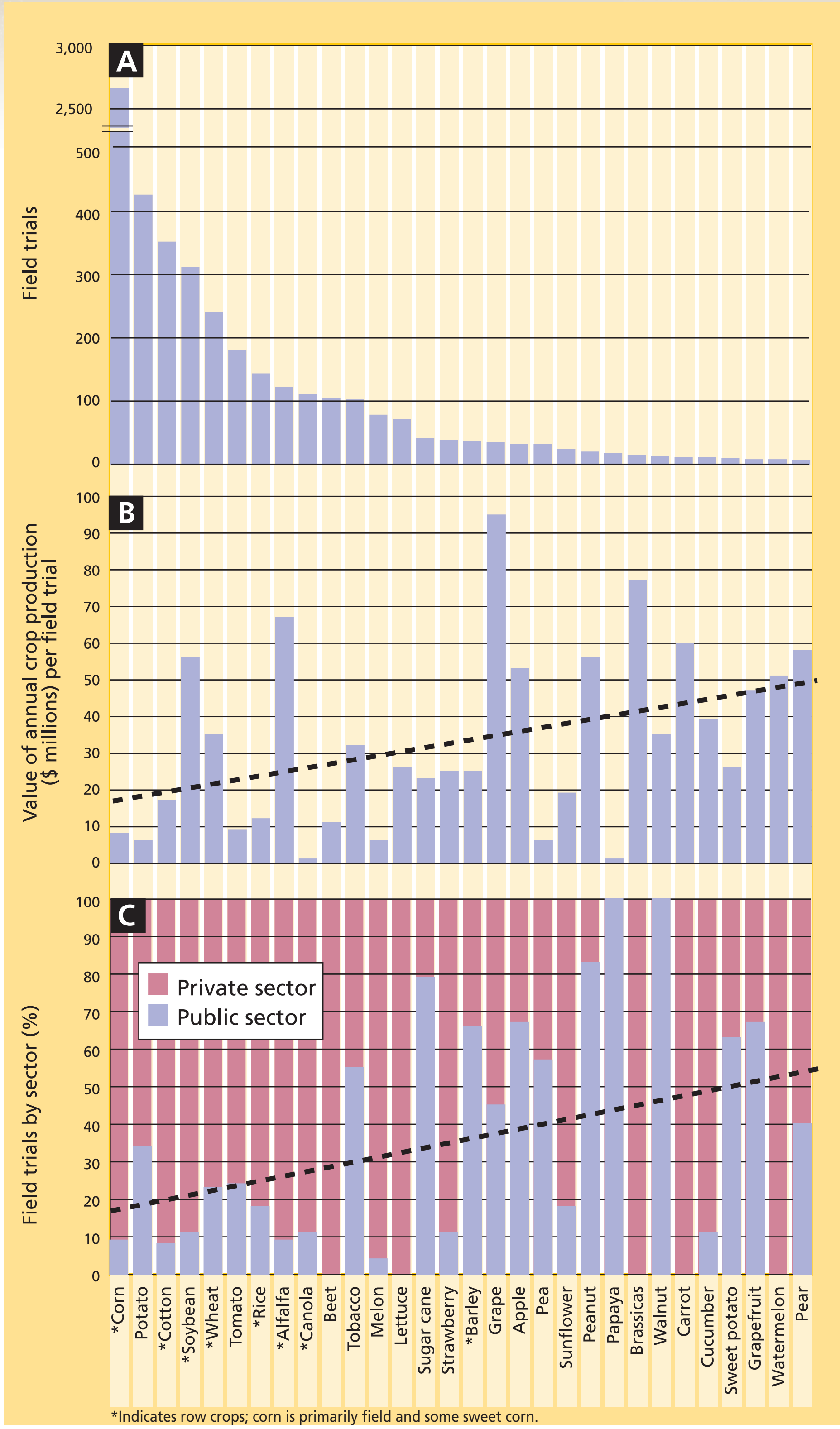


Fig. 1. (A) Top 30 transgenic crops, ranked by total number of field trials registered at USDA-APHIS from June 1997 to May 2002; (B) value of U.S. crop production in 1997 divided by the number of U.S. field trials of the top 30 transgenic crops; (C) percentage of U.S. field trials of top 30 transgenic crops that were conducted by public-sector agricultural R&D organizations. In figures 1B and 1C, the dotted lines draw simple linear comparisons across crops, ranked according to total transgenic field trials, in order to illustrate questions about broad categorical differences in R&D investment for different crops; as such, they do not represent statistically tested trends or relationships.

Dario Cantu

Courtesy of USDA-ARS

With grant support from the California Strawberry Commission (CSC), UC scientists genetically engineered the strawberry variety 'Selva' with a pear fruit gene for resistance to fungal pathogens. However, the engineered lines have not been tested because of the CSC's subsequent reluctance to support that effort. *Left,* young genetically engineered strawberries in the greenhouse. *Right,* conventional strawberries.

transgenic walnut (10 by UC and one by a USDA lab in California).

Despite this variability, there appears to be less investment in biotech for horticultural crops than for major row crops, both in absolute terms and relative to overall crop values, while a greater proportion of that smaller R&D investment in horticultural crops comes from the public sector. Involvement by commercial firms in horticultural crops seems to be missing. While this data is too sketchy to conclude outright that commercial firms are underinvesting in horticultural biotechnology, it allows us to ask whether they might be, and if so, why.

After a few early excursions into horticultural crops — most notably by Monsanto, Asgrow and Calgene (both now Monsanto subsidiaries) as well as by Syngenta's predecessors at Zeneca — major agricultural biotechnology firms have virtually shut down their product development in horticultural crops. Long-shelf-life tomatoes, virus-resistant squash and insect-resistant potatoes have not taken off as did Bt corn and herbicide-tolerant soybeans. Some of the specialized vegetables seed firms, such as PetoSeed (which became Seminis), and some of the smaller agricultural biotechnology firms that specialized in vegetable crops, such as DNA Plant Technologies (later bought out by Seminis), continued their biotechnology efforts a bit longer. Yet those efforts appear to have all but dried up in recent years.

Instead, fruit and vegetable seed companies with active research and production activities, such as Seminis, Danson, Golden Valley, Harris Moran and others, continue to pursue their product development goals through conventional breeding techniques. One exception is the Scotts Company, which is currently seeking regulatory approval for a biotech product for golf courses, a glyphosate-resistant bentgrass. Indeed, most of the biotech work in horticultural varieties is conducted in university laboratories doing basic plant science. Occasionally, those projects spin out a commercially interesting trait or technology, but university technology-transfer offices have a hard time finding commercial partners among the seed firms, nurseries or growers' associations.

Factors discouraging investment

As with any investment, there is a degree of risk involved in putting resources into the development of a new transgenic horticultural variety. Future returns are uncertain, and expected returns are weighed against costs incurred to enter the marketplace. Such considerations also apply, more generally, to public-sector investments in research. Although the measures of success may be more in terms of scientific advancements than earned profits, the practical importance of a new discovery is still important. (Consider, for example, the scientific as well as commercial impact of virus-resistant papaya [see page 92]).

Market demand. The size and strength of demand for a new transgenic variety will determine the size of returns on the investment. Market uncertainties for agricultural products are nothing new, due to such factors as disruptive competition in supply, cyclical price fluctuations and changes in consumer demand. However, some food consumers, such as in Europe, are skeptical of foods produced using biotechnology. While a majority of U.S. consumers seem relatively unfazed by the genetic contents of processed bulk commodities such as soybeans and feed corn, consumers could react more strongly to obvious modifications of products in the produce aisle. Yet specific market uncertainties surrounding the use of transgenics could be addressed by the selection of technologies and traits that deliver real tangible benefits to consumers in ways that are perceived as unambiguously safe.

Regulatory approvals. The process of regulatory approvals for GM crops is essential to assure the safety of the technology. The R&D costs associated with gaining approval are considered up-front or "sunk" investments, and they must be spent to gain access to the market. These costs can be greater if the transgenic crop contains novel proteins or pest-control components, as additional assessments are required.

In major row crops, investments to obtain regulatory approval can be recouped from the small technology

photos: Trevor Suslow

Several different fruits and vegetables have been genetically engineered to resist viral diseases, for which there are often few sources of natural protection. A single gene from the virus itself is inserted into the plant genome, thereby preventing the virus from making copies of itself and causing disease symptoms, fruit damage and crop losses. *Left,* yellow zucchini affected by viral diseases. *Right,* in a field test, genetically engineered zucchini (right) was much hardier than the conventional crop (left).

fees charged on each bag of transgenic seed, which are multiplied out over millions of acres planted; however, with horticultural crops the distribution of regulatory costs is often concentrated onto much smaller markets. In many horticultural crops, several different varieties are commercially important. If introgression of the new trait via back-crossing is not an option, such as may be the case for clonally propagated varieties that do not breed true, each variety must be separately transformed in the lab, and each must be separately tested and approved. Regulatory costs would add up, but they could not be spread out over nearly as large a market as could row crops. Still, returns per acre from horticultural varieties tend to be much higher, and the costs of specialized pesticides replaced by transgenic traits may also be higher. In addition, regulatory costs can be expected to decline as more risk assessments are completed, government agencies become more adept at judging the merits of different biotechnologies, and the policies and procedures become streamlined and finely tuned. In addition, the extension of an approach similar to the IR-4 program, which provides regulatory assistance for pesticides targeted to the needs of specialty crops (see page 110), could reduce the regulatory burden on transgenic specialty crops.

Access to intellectual property. Transaction costs for gaining freedom to operate (FTO) in the relevant IP-protected technologies can be considerable. As with regulatory costs, the total IP transaction costs are independent of market size, and a larger number of transgenic varieties means more costly negotiations and more deals to cut. One industry estimate put the costs of negotiating a single crop genetics deal as high as $100,000. When multiple patented genetic technologies are stacked in a cultivar, as is increasingly the case, the problem is compounded.

Uncertainty over the total amount of IP transaction costs scares off investment in R&D projects, unless the expected returns are particularly attractive. This will continue as long as there is uncertainty in the IP landscape for plant biotechnologies and genetic materials. With the number of patents in this area growing at an exponential rate, IP access could be a deterrent to biotech R&D in horticultural varieties for years to come.

IP hurdles for horticultural crops

IP access is a general problem for all of crop biotechnology. The reasons lie in the cumulative nature of the genetics and biotechnologies embodied in transgenic varieties. Plants are complex systems, and a healthy, productive crop plant has numerous genetic and metabolic pathways functioning together. Those genetics are inherited from breeding stock or can be added using biotechnology. A genetically engineered seed or plant cultivar may contain three different kinds of technological components that can be protected as IP, including (1) the germplasm of the plant variety, (2) the specific genes that confer a new trait and (3) the fundamental tools of biotechnology such as genetic markers, promoters, and transformation methods. The IP situation is complicated by a number of additional factors that add to the transaction costs.

Complex intellectual-property law. Different technological components of a transgenic crop variety are covered in the United States under different forms of IP law. If a variety is clonally propagated, the germplasm — the plant variety itself — can be claimed as IP at the U.S. Patent and Trademark Office (USPTO) under a Plant Patent, established in 1930 by the Plant Patent Act to protect against cuttings being taken, repropagated and directly resold under another name. Seed-propagated varieties can be claimed as a form of IP under the USDA system of Plant Variety Protection (PVP) certification, established by the Plant Variety Protection Act in 1970. And, since 1980 — following a landmark decision by the Supreme Court in *Diamond v. Chakrabarty* over the patenting of a genetically engineered microorganism — all kinds of "invented organisms," including novel plant germplasm, have come to be claimed as IP under standard U.S. utility patents. (In practice, plant varieties being claimed by inventors are almost exclusively corn and soybeans, not horticultural varieties.)

The U.S. Patent and Trademark Office manages intellectual property under the Plant Patent Act of 1930, the Plant Variety Acts of 1970 and 1994, and general utility patents that can cover the products of and processes used to develop genetically engineered seeds and crops. *Left to right,* U.S. patent office locations past (Washington, D.C.), present (Arlington, Va.) and future (Alexandria, Va.).

Subsequent technological and legal developments following *Diamond v. Chakrabarty* now allow utility patents to protect invented genes, proteins and other gene products, as well as biotechnology tools such as transformation of genetic contents, selection using genetic markers, and regulation of expression using genetic promoters. Finally, a significant part of the value of an agricultural variety often lies not in its technological or biological characteristics *per se* but rather in its recognition and reputation among consumers in the marketplace. That "brand" name can be protected as IP by registering it as a trademark with the USPTO.

The challenges posed by multiple layers of IP law are, if anything, greater for horticultural varieties than for row crops: plant patents, PVPs or utility patents may cover the germplasm; utility patents typically cover the gene and biotechnology tools used; and trademarks are more often used to protect variety names. In leading row crops such as corn and soybeans, germplasm as well as the genes and biotechnologies are protected more consistently under only utility patents. While trademarks like Roundup Ready or Liberty Link refer to input traits and may be of some value in marketing to farmers, the identities of such agronomic traits command little notice or value from final food consumers.

Exporting to global markets. For many important horticultural crops, exports constitute a large share of output, so FTO under IP must include freedom in foreign markets. Since the various IP rights important for plants are administered nationally, an exporter must check FTO separately in each foreign market. In general, the tools of biotechnology are more likely to be patented in just the major markets — such as the United States, Europe and Japan — and less likely to be patented in countries with smaller markets. Uses of biotechnologies specifically for minor crops are less likely to be widely patented in multiple countries than are uses in important field crops. However, as a result of the International Union for the Protection of New Varieties of Plants (UPOV) agreement first established in 1961, PVP systems are widely available overseas for the protection of clonally propagated varieties, and such varieties do tend to be widely registered in multiple countries. Still, not all types of biotechnologies, genes or plant germplasm can be protected in all countries. For example, utility patenting of plants is allowed in only a few countries (including the United States).

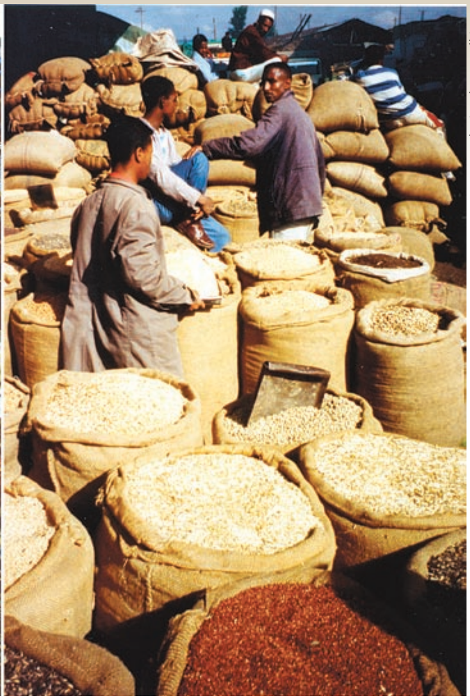
Beyond these trends, however, there are no hard-and-fast rules as to which technology will be protected in which country, as each inventor decides where to seek protection (Binenbaum et al. 2003). As a result, those seeking FTO are confronted by an often bewildering international patchwork of IP rights, where the negotiations needed for a particular transgenic variety can differ significantly each time it crosses a national border.

Intellectual-property holders. Unless a new transgenic variety is developed by an integrated effort at a large company backed by a broad IP portfolio, a number of different owners — including companies, individuals, universities and even governments — will have valid IP claims over the technologies and genetic contents that end up being included in it. That means there are numerous owners to track down, negotiations to conduct, billable legal time to hire, and multiple royalty payments to administer. The costs and headaches involved in working out "who owns what" and "who owes what to whom" can balloon into what economists call the "tragedy of the anti-commons" and render the development process unfeasible. The "tragedy" is arguably worse in horticultural crops than in row crops. Given the smaller markets involved, there is less incentive in industry to consolidate IP portfolios around horticultural crops. Also, not one of the public-sector organizations or their typically smaller commercial partners in horticultural crop development has a complete IP portfolio in plant biotechnology.

Uncertain ownership of rights. When technologies are patented, it is often not clear who currently owns particular aspects of each technology. This uncertainty is cleared up in the courts through patent interference cases, where attorneys and scientists undertake intensive "surveying" of the "property lines" between the patents and technologies in question. Sometimes these cases drag on for years, keeping key technologies in legal limbo and the R&D community guessing as to who is the rightful owner. Yet, for most registered patents there is no such scrutiny. As a result, the boundaries for a considerable expanse of technological territory are not clearly demarcated, creating considerable uncertainty as to when a new application could be considered to be infringing or "trespassing." In horticultural crops, the lack of clarity about the scope and validity of patent claims is especially important. Because the markets are smaller, fewer products have been developed and fewer contests have been fought to establish legal precedents. Furthermore, just the anticipation of possible legal costs can shut a project down before it ever gets off the ground.

New biotech crops must meet the intellectual-property and regulatory requirements of importing countries, and there are no firm rules as to which technologies will be protected or regulated in which countries. This situation can create serious difficulties for exporters. *Right,* food market in Benin; *far right,* Ethiopia.

1999 IFPRI/Philippe Berry



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Transfer of rights. IP covering a crop variety may be sold, licensed or transferred to another organization at any time. The transfer of rights can occur either in part (nonexclusively) or in whole (exclusively). The transfer can happen in just one territory where it is protected (such as the United States) or in multiple territories. The transfer of rights for a biotechnology tool or gene could be specified for use in just one crop (such as corn), in several crops (such as all cereal grains), or in any and all crops. Finally, to make matters worse, the fact that the IP rights have been transferred may be considered commercially sensitive information and not be made public.

Other issues. Any organization managing the release of a new crop variety faces uncertainty about which IP rights actually cover what technologies, who holds those rights in which countries, and to what degree a specific new transgenic variety infringes on those rights. Resolution of such uncertainty is not less costly for crops with small market value. Even after reliable information is obtained, uncertainty remains about negotiating the permissions. IP owners are not required to negotiate licenses, and they may feel there is not enough potential revenue in minor crops to make their licensing efforts worthwhile. They may also be concerned about technology stewardship, given the nervousness among consumers about food biotechnology and its status as a hot media topic. They may worry that the mishandling of their technology by a small and relatively inexperienced horticultural player could lead to stronger regulations, potentially eroding that technology's value in its major crops, or jeopardize public perceptions about biotechnology overall.

Public-sector IP management

In response to IP congestion and continuing uncertainties, several leading U.S. public-sector agricultural research organizations have come together to create the Public Intellectual Property Resource for Agriculture (PIPRA), an organization providing collaborative IP management solutions to public-sector and smaller private-sector players in horticulture (Atkinson et al. 2003; see sidebar, page 127). While individual universities and even the USDA have small and uncoordinated IP portfolios in plant genetics, together they hold a fairly comprehensive set of technologies that could be useful for developing transgenic varieties (Graff, Cullen et al. 2003). PIPRA seeks to coordinate the disparate portfolios of its member organizations to support specialty crop applications. With the offices of technology transfer of its member organizations, PIPRA is pursuing several cooperative strategies.

Licensing terms. First, PIPRA seeks to develop and adopt more precisely focused terms of licensing, with specific distinctions for the "fields of use" to which a technology is licensed. A company that licenses a technology invented at a university can still get the full benefit of using the technology in those major row crops in their line of business, even if the license clearly defines and grants exclusive use of the technology in just those crops. Such a license effectively "reserves" the rights to use the technology in any other crops. Horticultural firms could then make separate agreements with the university to use the technology in only their defined specialty crops. An advantage of this strategy is that it can also apply to other minor uses, such as "alternative" crops (such as cassava or millet) or humanitarian applications in staple crops for developing countries (such as vitamin A–fortified Golden Rice). By discriminating between big markets and multiple smaller markets — including those with limited commercial value but important social benefits — public-sector scientists could see their inventions earn royalties in the big markets of major row crops while still helping to improve smaller crops or increase food security in world's poorest regions.

PIPRA database. A database will, for the first time, list in one place current information about all of the patents of PIPRA's members and their availability for licensing alongside information about technologies published in the scientific literature (and thus publicly available), in sufficient detail to identify which technologies can be accessed for which uses. The database will offer

The costs and headaches involved in working out "who owns what" and "who owes what to whom" can balloon into what economists call the "tragedy of the anti-commons" and render the development process unfeasible.

a clear, complete and certain "universal listing" of technologies available from PIPRA's member organizations and the public domain.

Commercial patent databases and professional legal staff are available to researchers in large private companies to search through the "prior art" (the records of what is already patented) to make FTO analyses of a new product's IP position. Such resources are seldom available to academic and government researchers. The PIPRA database will decrease uncertainty about what cannot be used by showing what can be used.

Patent-pooling. PIPRA is investigating the creation of patent-pooling mechanisms, which would collect IP submitted from its member organizations, package the technologies together and offer unified licenses for the "bundled" IP in a field of use, such as a specific crop, or in a particular state or country. This process mimics, in a virtual way, how large commercial firms have assembled their IP portfolios to provide FTO in major field crops. Its feasibility will depend — at least at the outset — on the extent to which public-sector organizations are able and willing to provide access to patents covering key enabling biotechnology tools already licensed to the corporate sector.

Even if used to access technologies on just a patent-by-patent basis, coordinated information and streamlined access to academic and government-owned IP could help decrease transaction costs and improve efficiency in technology-transfer markets. There is ample room for improvement here, as some have complained that negotiating licenses from universities and government agencies is often less efficient than negotiating licenses from firms. PIPRA can improve public-sector technology transfer for agriculture by providing information, tools, and precedents for efficient licensing.

Greater opportunities lie in the steps being taken to coordinate access, package IP bundles, and target uses

Canola Council of Canada

Sacramento Bee/Chris Crewell

***Right*, the orange canola seeds have been genetically engineered to produce high levels of beta-carotene. Monsanto has licensed the technology and is working with the Tata Energy Research Institute in India and Michigan State University's Agricultural Biotechnology Support Program to develop high beta-carotene mustard for possible use in India. *Above*, a conventional canola plant.**

in lower-value markets such as horticultural crops and traits important for food security in developing countries. These are, generally speaking, areas in which commercial firms are not interested or capable of serving. Such collaboration is not surprising, given the history and ethos of cooperation among agricultural experiment stations within the land-grant system. Public-sector institutions also have greater legal flexibility to enter into collective IP management arrangements, given historical antitrust concerns about abuses of patent-coordination efforts in industry.

Even more important will be the establishment of ongoing precedents and mechanisms for the treatment of future IP. Academic and government researchers will go on making important discoveries and inventing new technologies for agriculture. Those future inventions will, from their inception, be handled in ways — such as being listed in the universal database, licensed for targeted "fields of use" and included in IP-pools — that will make them accessible in a carefully proscribed manner, not just to top commercial bidders, but to anyone else in the broader agricultural community who can make good use of the technology, including horticultural researchers and growers.

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Nonprofit institutions form intellectual-property resource for agriculture

Deborah Delmer

Current practices in patenting and intellectual property (IP) protection have created barriers to the use of biotechnology and advanced agricultural technologies for the creation and commercialization of new crop varieties. The complex and cumulative nature of biological innovation requires access to multiple technologies that are often exclusively owned or licensed. For example, commercializing a single variety of transgenic tomato could involve obtaining the rights to use a variety of technologies and genes from numerous life-sciences companies, government agencies and universities.

Obtaining "freedom to operate" (FTO: the ability to clear all IP barriers and bring a product to market) for transgenic crop varieties is difficult. There is considerable uncertainty as to who holds what rights to particular technologies, and negotiating access to those rights is time-consuming and costly. This is a problem for the major international agricultural companies that focus primarily on high-volume crops such as corn, soybeans and cotton; for research institutions that work on specialty crops grown on much smaller acreages, such as tomatoes, strawberries, apples and cabbage; and for public institutions that work on staple crops for humanitarian use in developing countries.

The international agricultural companies have taken steps to solve their FTO problems through mergers and cross-licensing agreements that bring together essential IP components within one company. However, public-sector institutions — such as universities, government agencies, international agricultural research centers and others working on specialty and staple crops — are still struggling to find ways to gain FTO. In addition, donor agencies such as the Rockefeller and McKnight foundations, which have a long history of investing in agricultural research that benefits subsistence farmers in developing countries, have also found that IP constraints are reducing the flow of technology.

Public resource for ag

Universities and other nonprofit institutions have generated many key patents related to agricultural biotechnology and they will most likely remain an important source of innovation. However, no single institution has the complete package of technologies required for commercialization of a biotech variety. Although some institutions are developing ways to deal with these problems, there are still many examples of public-sector inventions that have been licensed exclusively to private-sector partners. In late 2002, representatives of more than a dozen U.S. public-sector agricultural research institutions (including UC) joined with the U.S. Department of Agriculture and the Rockefeller and McKnight Foundations to discuss access to patented agricultural technologies for the development and distribution of improved specialty crops and those targeted for the developing world.

The participating institutions are pursuing an initiative called the Public Intellectual Property Resource for Agriculture (PIPRA), which will explore the following collaborative IP management strategies:

- Developing licensing strategies that retain specific rights for humanitarian and specialty crops while allowing and encouraging licensing of such technologies to the private sector.
- Developing and maintaining a database of public-sector IP assets that includes information on IP licensing status and technologies that are in the public domain.
- Creating technology "packages" that would provide both FTO and the material resources (such as vectors, promoters, trait genes) required for specialty or humanitarian applications.

At present, PIPRA focuses only on IP generated by them, whereas another new entity called the African Agricultural Technology Foundation is dealing with access to private-sector technologies for targeted crop applications in sub-Saharan Africa (www.aftechfound.org). Other issues that limit the commercialization of genetically engineered crop varieties — such as public acceptance and high costs for regulatory approval — must be addressed by other initiatives.

No single institution has the complete package of technologies required for commercialization of a biotech variety.

Next steps

PIPRA is moving forward with a process that will forge collective action in technology management among a significant number of nonprofit institutions active in agricultural biotechnology research. This initiative is intended to be widely inclusive; at present about 25 major institutions are involved and more are being sought. UC Davis professor Alan Bennett was recently selected as PIPRA's executive director, and its offices will be based on campus. PIPRA intends to move forward in a cooperative manner and craft solutions to problems that arise. To this end, activities are under way that will answer important questions about the types of collaboration needed, including developing case studies, assembling a database, involving additional public-sector institutions, and engaging private-sector and other key stakeholders. The group is stimulating broad discussion to help uncover the implications of new IP management strategies, and to identify critical issues that must be addressed to make this initiative successful.

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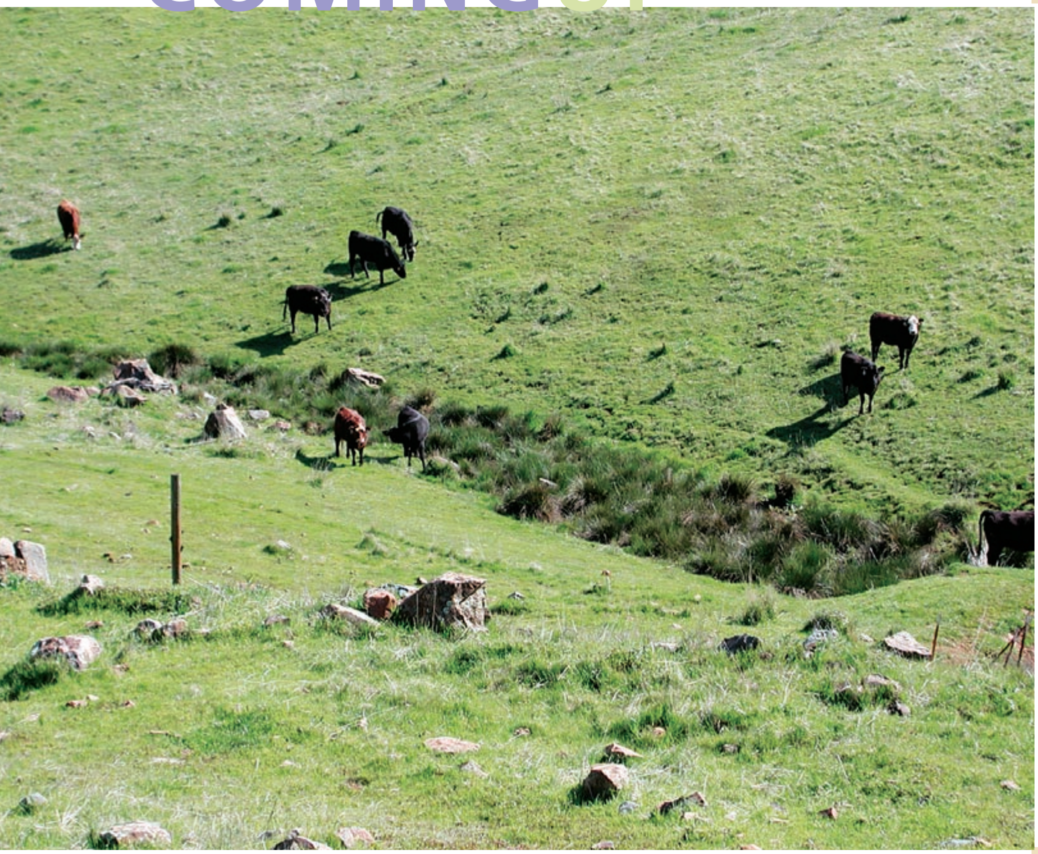
COMINGUP



Water quality in streams and wetlands

Wetlands and creeks are highly productive ecosystems, valued for the abundant wildlife habitat, biodiversity, water quality and human uses that they provide. The next issue of *California Agriculture* presents peer-reviewed studies on various aspects of preserving and maintaining the state's critical aquatic resources. In two studies, UC scientists evaluate how spring-fed wetland ecosystems and stream channels respond to cattle grazing in California oak woodlands. To help dairy operators protect groundwater, UC scientists compare irrigation practices for the reuse of dairy manure water in order to prevent unnecessary application of nutrients to fields. Another study examines the impact of aerial applications of the herbicide clopyralid (used to control yellow starthistle) on adjacent streams and vernal pools, as well as its toxicity to an aquatic toad. Finally, scientists evaluate the accuracy of the transparency tube, an inexpensive, simple method for measuring water clarity and suspended solids in streams and waterways.

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