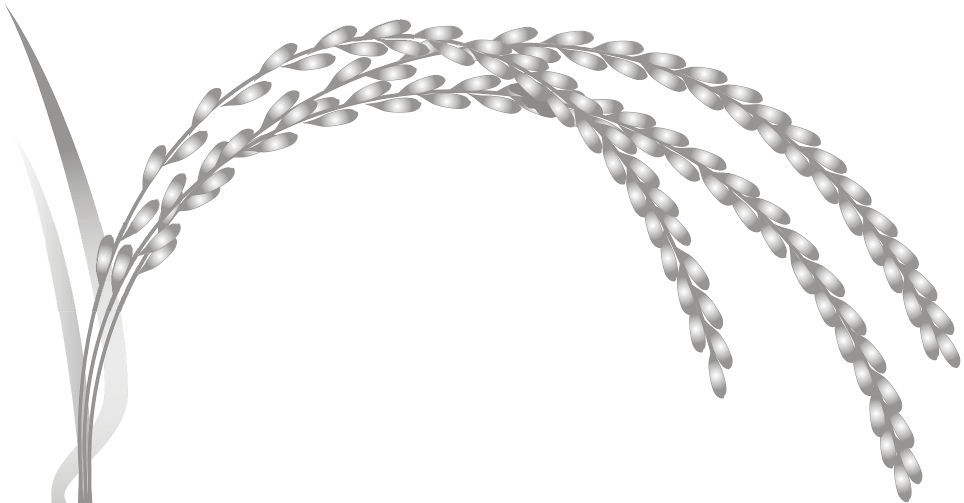

Executive Summary

Executive Summary

The objective of this report is to provide a concise review of the scientific literature on the benefits and risks of food biotechnology for the State of California Food Biotechnology Task Force and its Advisory Committee and is in response to California Senate Bill 2065 of 2000. The primary focus of this report is on crop biotechnology (the applications of biotechnology to agriculture) and any positive or negative impacts on human and animal feeding and the environment. Approximately 70% of the human food products in the marketplace contain some fraction of crops developed by the new biotechnology. However, approximately 75% of the U.S. corn and soybean crops, which are often planted to spliced-DNA lines, are consumed by farm animals.

Many definitions have been applied to the term "biotechnology." A useful, broad definition – the application of biological systems and organisms to technical and industrial processes – encompasses a variety of old and new processes and products. The new biotechnology, a set of more precise enabling techniques for genetic analysis and modification at the molecular level, includes but is not limited to the precise cutting and joining of DNA to introduce new genetic constructions into organisms; synonyms include spliced-DNA technology, gene splicing or recombinant DNA (rDNA) technology.

The new biotechnology techniques offer a more versatile and precise method of introducing one or more genes (functional segments of DNA) into a plant from unrelated organisms than with traditional plant breeding or other forms of genetic modification such as radiation, embryo culture, and chemical mutation. In this report, we will use the terms "new biotechnology", "spliced-DNA", "rDNA", and "transgenic" to avoid the confusion generated by "genetically modified organisms" (GMO), and genetic engineering. The Food and Drug Administration has discouraged the use of "GMO" because studies have indicated that consumer anxiety and misunderstanding increases whenever the word "genetic" is used.

Agricultural biotechnology of the last two decades has shown promising benefits for increasing food and fiber production for a burgeoning world population, reducing pesticide pollution, improving food quality, and providing new pharmaceuticals and bio-fuels for the future. Agricultural biotechnology is a genetic modification tool used to customize plants with special qualities that can allow farmers to grow crops that are more nutritious, more resistant to pests and diseases, and more productive. There are many types of genetic modification that do not involve spliced-DNA technology.

In the future, new crop plants may be the source of valued medicines, biochemicals, chemical feedstocks, and specialty "niche" crops.

Current and Near-market Benefits of New Biotechnology Products on the Market

Primary Benefits	Secondary Benefits
• Plant resistance against insects • Herbicide tolerance • Plant resistance against pathogens • Reduced pesticide use • Higher crop yields • More nutritious composition of foods • Improved taste and quality	• Improved pest and weed management • Improved soil conservation and reduced acreage requirements • Reduced water and soil contamination by pesticides • Reduced input agriculture • Preservation of natural resources • Expanded crop gene pool

The introduction of any new technology brings not only benefits but also risks, both real and imagined. Spliced-DNA crop technology has raised potential questions regarding food safety risks, environmental risks, and other social and ethical issues for the consumer. Two facts about spliced-DNA crops have fueled the debate about their regulation and acceptance. First, the source of the introduced DNA may be taxonomically distant from the plant species, e.g., from a bacterium. Second, current technology does not control the location in the genome at which the new, DNA-spliced transgene is introduced. However, discussions and debates about the possible consequences of large scale production of spliced-DNA crops and the consumption of spliced-DNA foods often have been based on unsupported suppositions as well as facts with the worst case scenarios based primarily on suppositions. The ethical principles and goals that should be considered in this debate are: ensure that all stakeholders are heard; maintain a safe, nutritious, and plentiful food supply; preserve ecosystems; and balance agricultural production and wise stewardship of the earth.

Potential Benefits and Risks

Potential Benefits Expected in the Near Future	Potential Risks
• Reduced fertilizer use • Reduced levels of natural toxins in plants • Reduced crop/food spoilage • Simpler and faster methods to monitor for pathogens, toxins, and contaminants in foods • Improved animal feeds	• New food allergies • Antibiotic resistance transfer • Pollen contamination/gene flow • Decreased genetic diversity • Development of insect resistance • Development of weed resistance • Development of virus resistance/new viruses • Increased naturally occurring toxins • Crossing species boundaries • Effects on non-target organisms • Long-term effects • Social effects of new technology
Potential Benefits Expected Further Down the Road	
• Plant-produced pharmaceuticals & vaccines • Reduction of allergenic proteins; enhanced protein quality • Turning plants into biosensor for hazardous materials • Tolerance to drought and floods • Tolerance to salt and metals • Tolerance to heat and cold • Save plants threatened by extinction	

Many critics of spliced-DNA technology believe that the economic benefits of spliced-DNA crops have not been distributed equitably. Although scientific data are sparse and just being developed for pest resistance and herbicide resistance varieties, the early indications suggest that U.S. farmers are currently receiving the greatest economic benefits of pest-resistant *Bacillus Thuringiensis* (*Bt)* cotton and herbicide-tolerant soybeans (42% to 72%). U.S. consumers appear to receive the least benefits from these crops, 7% and 4% of the total, respectively. Monsanto Company, one of the pioneering firms in the applications development of spliced-DNA crops, and other seed companies received most of the remaining economic benefits.

Probably the most striking effect of these crops is the reduction in pesticide applications (15 million fewer applications for cotton and 19 million for soybeans per year). In the case of *Bt* cotton, growers were able to reduce insecticide applications by 2.7 million pounds in 1999. The value of currently available traits conferred by spliced-DNA genes, depends in a given growing season, on the degree of pest or weed infestation. The new spliced-DNA "agronomic" traits lend reliability to crop production by being available from the planted seed, with little additional effort and reduced requirements for surveillance and reduced attention to application methods and timing. Reliability in production and reduced pesticide usage are of value to the consumer even if the benefits are not obvious in food prices. Future spliced-DNA genes conferring quality traits rather than agronomic traits likely will provide improved food quality and other benefits more obvious to the consumer.

The 19th century efforts in crop genetic improvement, in the form of sexual crosses, including crosses between species, and selection for improved traits, preceded the establishment of genetics as a science. More aggressive manipulations of plant genes in the 20th century took the form of mutations induced by radiation or chemicals and development of plant organ and tissue culture techniques, all preceding the first laboratory experiments in spliced-DNA, transgenic plants in 1983. The field test of new biotechnology plants took place in 1987 and the first commercial field test was in 1992. The first commercial production was in 1996 after the safety studies were completed in 1995. Currently, there are 53 transgenic crop varieties that have been deregulated for commercial production in the United States. Research and testing is being conducted on dozens of plant species, and commercial scale production of gene-spliced crops including soybean, corn, canola, cotton, potato, squash, and papaya is underway. The global acreage of these crops has increased from 4.3 million acres in 1996 to almost 110 million acres in 2000 in 13 countries on all six continents. Field-testing of new transgenic crops continues in both developed and developing regions of the world.

Though the production of transgenic crops is growing in developing countries, transgenic plants should not be regarded as magic bullets that will eliminate poverty and hunger, because these global problems have significant political and social components that influence the availability of food even where food can be grown in sufficient amounts. However, all approaches to crop improvement must be considered in order to improve the efficiency of agriculture and thereby minimize human suffering and reduce the ecological impacts of a global population expected to increase by 50% during the first half of the 21st century.

Compared to the major field crop agriculture of the U.S. Midwest and South, California's highly diverse agriculture has had only limited experience with transgenic crops, mainly cotton. California is the nation's primary producer of health-benefiting foods in the form of fresh fruits and vegetables. In contrast to the agronomic spliced-DNA-conferring traits that are prominent in today's field crops, California's crop agriculture could benefit from improved quality traits such as enhanced vitamin, flavanoid or mineral content, and better flavor and texture. However, agronomic traits such as herbicide tolerance, salt tolerance, and drought resistance also could be of value in a variety of California crops. Many new crops (approximately 30 varieties) have been developed by the new biotechnology in California's research laboratories and are being field tested; however, the costs of registration and concerns regarding food processor and consumer acceptance have delayed their entry into the market place.

The health of farm animals may also be improved through biotechnology by developing crops that are more easily digested by animals, and by reducing the phosphorous, nitrogen, and odor of animal waste. Transgenic crops and their products have been grown and marketed extensively since 1996 without any reported ill effects on human and animal health.

In this report, we present an overview of the current thinking on the new biotechnology. Although referencing national and international studies, we are particularly concerned with the impact and importance of the new biotechnology to Californians. A synopsis of the following nine chapters prepared by scientists in their fields of specialty is provided to summarize the balance of the report. The scientists who have contributed to this report are all currently involved with assessing the opportunities and concerns of the new biotechnology at the state, national, and international level.

Chapter 1, Biotechnology Overview, Product Applications Consumer Response by Christine Bruhn, Director, Center for Consumer Research, University of California, Davis.

This chapter presents a general overview of biotechnology, food biotechnology, a discussion of benefits and risks, product applications, and consumer attitudes.

In a consumer survey conducted in 2001, only about 36% of the U.S. consumers were aware that genetically engineered products were in the marketplace even though as much as 70% of the processed foods they were eating could contain some ingredients that originated from transgenic crops. On the other hand, as many as 70% of the consumers indicated that they would purchase produce modified by biotechnology to reduce pesticide use, 66% would purchase produce modified to contain more vitamins and nutrients, and 58% would purchase products modified for better taste. In conclusion, 64% of the consumers surveyed value the benefits of genetic engineering and have confidence in scientific innovation that will bring benefits in the next five years.

Chapter 1: Biotechnology Overview

Food Applications-Potential Benefits	Areas of Concern-Potential Risks
• Increased crop yield • Improved nutrition • Reduced allergenicity • Medical benefits • Healthier farm animals • Environmental benefits • Aids in food processing	• Agribusiness consolidation and competition • Allergenicity • Antibiotic resistance transfer • Contamination of organic crops • Decreased genetic diversity • Environmental balance • Herbicide resistance • L-Tryptophan • Naturally occurring toxicants • Pest resistance • Virus resistance

Chapter 2, Safety of Foods Derived from Genetically Modified Crops by George Bruening, Professor of Plant Pathology and Director, Center for Engineering Plants for Resistance Against Pathogens, University of California, Davis.

This chapter covers the food safety perspective from the viewpoint of postulated general risks, comparison of outcomes from conventional and spliced-DNA gene transfer, food labeling and the "precautionary principle." Those who are concerned with possible effects of spliced-DNA crops appear to accept two hypotheses on implicit benefits or implicit risks.

The scientific issue is whether transgenic crop products are quantitatively different from crops resulting from non-spliced-DNA technologies. Each hypothesis is discussed regarding the location and degree of expression of a transgene, the antibiotic gene, and proteins and allergens. Nutritional benefits discussed include the changing of the oil content mixture in soybeans to produce high-performance cooking oils and reduced saturated fats to improve cholesterol nutrition of humans. "Golden Rice®" varieties have been developed to increase the beta-carotene content, a precursor of Vitamin A, and iron for eliminating a severe nutritional deficiency in children in rice-consuming cultures. Although increased allergenicity in crops is still a major concern and risk to food safety and labeling issues, it is pointed out that the techniques of genetic engineering have and can be used to reduce allergens in foods as they have done experimentally in rice, wheat and other foods. European regulators have invoked a "precautionary principle" as part of their official regulatory framework for transgenic crops and crop products but not for conventionally developed crops and crop products. Essentially, this principle requires the technique to be absolutely safe. Since this is a standard unattainable by human endeavor, political judgment may be substituted for scientific analysis.

Chapter 2: Food Safety

Benefit Hypotheses	Risk Hypotheses
• Research to date together with the history of safe usage of the transgenic proteins in agriculture and/or their similarity to already occurring constituents provide a substantial assurance of safety of our foods.	• A gene, gene fragment or other DNA sequence from a taxonomically distance source, introduced into an uncontrolled location in the plant genome, results in a greater risk than a DNA sequence from a closely related source introduced by a conventional genetic cross or DNA sequences modified by other conventional techniques. • Adverse effects may appear only years or decades after widespread deployment of spliced-DNA sequences in crop plants, because current testing of spliced-DNA crops will likely fail to detect problems not currently recognized or problems that may appear later due to postulated variability, instability or delayed effects associated with spliced-DNA crops.

Chapter 3, Transgenic Crop Plants and the Environment: Benefits and Risks by Norman C. Ellstrand, Professor of Genetics and Subray Hegde, Research Geneticist, University of California, Riverside.

This chapter points out that technological innovations bring their own set of benefits and risks to the environment. No technology is 100% safe. This is true for transgenic crop plants that contain novel traits incorporated by the tools of biotechnology. The available information suggests that transgenic crops may hold both promise and peril for the environment depending upon a variety of factors including the type of transgenic crops grown under cultivation, the nature of the transgenic traits involved, and the geographic location of crops in relation to wild relatives.

The most important criterion in the risk-benefit analysis of the impacts of transgenic crop plants on the environment is that the risks or benefits should be compared to conventional agricultural practices. Detection of slow and cumulative negative impacts of transgenic crops on the environment is harder to measure relative to immediate benefits. Since these transgenic crops have been grown commercially for such a short period of time, it is difficult to know the full extent of these risks. So far, there is no evidence that transgenic crops harm the environment any more than traditional agriculture; however, without systematic monitoring, the lack of evidence of damage is not necessarily a lack of damage.

Chapter 3: Transgenic Crop Plants

Potential Environmental Benefits	Potential Environmental Risks
• Indirect environmental/economic benefits for higher crop yields • Reduced chemical toxicity in the environment due to pest-resistant cultivars • Efficient use of renewable resources such as land, water, and soil nutrients • Accurate monitoring of environmental pollution using pollution-sensitive transgenic plants	• Movement of transgene itself with subsequent expression in a different organism or species • Direct or indirect risks with whole transgenic plants • Non-target risks associated with the transgene product outside the plant • Risks associated with increased use of herbicides • Risks associated with the resistance evolution in pest populations

Chapter 4, Spliced-DNA Crops in California by George Bruening, Professor of Plant Pathology and Director, Center for Engineering Plants for Resistance Against Pathogens, University of California, Davis.

A revolution in crop agriculture since 1996 has resulted in substantial penetration of spliced-DNA cultivars into U.S. plantings of cotton, soybean, and corn. California has generally been a leader in agricultural innovation but only spliced-DNA cotton has seen signification production in California.

The high costs of research and of satisfying regulatory requirements meant that the first implementations of spliced-DNA crops were with crops having very large-scale plantings. In 2001, transgenic cotton accounted for 36% of California's cotton acreage. The author points out that the intense genetic manipulation to which cotton has been subjected, represents what has occurred in major crops in general and serves as an illustrative example of the benefits and risks. Transgenic cotton grown in California contains transgenic traits for herbicide resistance (bromoxynil and glyphosate), insect resistance (*Bt*) and stacked transgenes for both herbicide and insect resistance. The benefits of herbicide-tolerant cotton have been documented at a savings of $150 per acre. In addition to improving yield and quality of cotton, the use of these varieties allows for better conservation tillage and narrow row spacing for more plants per acre. Synthetic insecticide applications have been reduced to levels not seen since the 1940s. New pest-resistance cultivars might lead to efficient crop cultivation where pest pressure previously made production impossible. This could be especially important to crop production in rapidly urbanizing California and in developing countries.

There are concerns about the level of the regulatory processes and protocols used to instill public faith in the safety of spliced-DNA crops. A recent 2002 report from the National Academy of Sciences, Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, called for an enhanced regulatory process by soliciting greater public input and more scientific peer review. In the United States, there are three federal government agencies that have primary responsibility for regulating bioengineered foods: the Food and Drug Administration, the Department of Agriculture, and the Environmental Protection Agency. Many critics believe that the lack of coordination between the three agencies has lead to regulatory inconsistency, regulatory scrutiny not commensurate with risk, lack of risk balancing, excessive paper work, and excessive costs of testing and registration. Therefore, three sections of this report have been devoted to the regulatory policy and process for registration of transgenic plants.

Chapter 4: California Situation

- California produces over 350 different agricultural crops and has the largest food and agricultural economy in the nation with a gross cash income for 1999 of $26.7 billion.
- It is the nation's leader in agricultural exports shipping over $6 billion in both food and agricultural commodities around the world.
- Its agricultural industry generates more than $70 billion in related economic activity for the state.
- California has been a leader in the technology and development of new and improved crops through its agricultural research in both the public and private sectors.
- California is headquarters for the global biotechnology industry.

Potential Benefits

- The most extensive commercial transgenic crop produced in California is cotton, its second largest cash crop, and it remains important for both domestic use and for export.
- The potential for California to gain economic benefits comparable to those seen for the major field crops.

Potential Risks

- The costs of registration, a major financial hurdle for most small acreage specialty crops which are a substantial portion of California's 350 different crops.
- The future public acceptance of about 30 crop species that have been the subject of field testing permit requests for spliced-DNA crops in California still remains uncertain.
- Ability of California to remain competitive in the global agricultural economy of the 21st century.

Chapter 5, Federal Regulations and Policy on Transgenic Plants by John E. Vanderveen, Emeritus Scientist of the Center for Food Safety and Applied Nutrition, Food and Drug Administration.

As discussed in this chapter, the federal government has in place a broad and comprehensive approach for policy formation and regulation of developing and using recombinant DNA (rDNA) biotechnology derived foods as mandated by federal law. In the United States, there are three federal agencies that have had primary responsibility for regulating bioengineered foods and have maintained an active process for setting policy on bioengineered foods since the 1980s. They are the Food and

Drug Administration, the United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).

Traditional regulatory approaches for many classes of new products have focused on an evaluation that considers both the magnitude and likelihood of plausible health or environmental harms on one hand and the expected benefits on the other hand. For transgenic crops, the highly risk-averse approach to regulation has taken the "precautionary principle." The idea of this principle is that governments should implement regulatory measures to prevent or restrict actions that raise even conjectural threats of harm to human health or the environment as long as there is incomplete scientific evidence as to the potential significance of these dangers. An analysis of food safety in 2000 by the Institute of Food Technologists stated unequivocally that the theoretical considerations and empirical data do not support more stringent safety standards for biotechnology products than those that apply to conventional foods. Dozens of new plant varieties produced through conventional breeding and genetic modification techniques other than genetic engineering enter the marketplace and food supply every year without any scientific review or special labeling. Currently, the paperwork and field trial testing required by the USDA for gene-spliced organisms is 10-20 times more expensive than the virtually identical organisms that have been modified with conventional genetic techniques.

The challenge for regulators is to balance all the competing factors in a way that reduces overall harm to public health. It is important that regulators take into consideration the ambient level of restraint generally imposed by society on individuals' and companies' freedom to perform legitimate activities such as scientific research.

Chapter 5: National and International Regulatory Systems

- Regulations of bioengineered foods are divided into four main areas:
    - Safety of cultivation and environment
    - Plant incorporated protectants
    - Safety regulation of rDNA biotechnology derived foods
    - International harmonization and trade
- The Food and Drug Administration (FDA) has broad authority to regulate all foods that are derived from new biotechnology food crops.
- The USDA Animal and Plant Health Inspection Services (APHIS) is responsible for protecting the environment from pest and disease, field testing, and commercial sale of agricultural bioengineered plants.
- The EPA is responsible for registering plant incorporated protectants, setting environmental tolerances, and establishing exemptions in and on crops.
- The USDA Economic Research Service conducts research on the economic impact of the production of rDNA biotechnology-derived crops.
- Other federal agencies have roles relating to policy development, international harmonization, research, and information.
- The United Nations' Food and Agricultural Organization (FAO), World Health Organization (WHO), United Nations Environmental Program (UNEP) is the focus of most of the international agreements and standards. The major international activity concerning standards for foods derived from rDNA is centered in the committees of the joint FAO/WHO Codex Alimentarius Commission (CAC).
- The World Trade Organization (WTO) is the authoritative scientific body to be used in trade disputes.
- The Organization for Economic Cooperation & Development (OECD) assists in fostering marketing systems and building strong economics in developing countries.

Chapter 6, State Regulations by Dave Luscher, Senior Agricultural Biologist and John Steggall, Senior Environmental Research Scientist, Pesticide Management, California Department of Food and Agriculture.

The authors of this chapter describe how California, like most states, has deferred to the federal government for regulation of biotechnology products. The California Department of Food and Agriculture (CDFA) reviews and provides comments to the United States Department of Agriculture (USDA) on forward applications for federal permits to bring new spliced-DNA organisms or crops into the state for research purposes. Currently, CDFA does not have the in-house technical expertise to do an in-depth critique of the genetic engineering methods and of the special environmental hazards.

Chapter 6: State Regulatory Control

- In 1985, a state task force was formed to review state and federal regulations regarding new biotechnology. The task force recommended that no special state regulations were justified for genetically engineered products.
- In 1994, a task force subcommittee recommended against specific labeling for biotechnology derived foods. Thus, food derived from genetically engineered sources is regulated in California under the same rules that govern conventional food industries. Some state agencies do request and review technical information regarding genetic modifications for research and experimental use permits.

Chapter 7, Science versus Presumption in Assessing Risk by Henry Miller, Research Fellow, Hoover Institution, Stanford University and Gregory Conko, Policy Analyst and Director of Food Safety Policy, Competitive Enterprise Institute, Washington, D.C.

The authors of this chapter suggest that the current federal regulatory policies on the testing and commercialization of plants and foods developed with the techniques of the new biotechnology make neither scientific nor common sense.

"Biotechnology" is a continuum of techniques for genetic improvement of plants and other organisms. There is long-standing scientific consensus that: the newer molecular techniques for genetic improvement are an extension, or refinement, of earlier, far less precise ones; adding genes to plants or microorganisms does not necessarily make them less safe either to the environment or to eat. The risks associated with gene-spliced organisms are the same in kind as those associated with conventionally modified organisms and unmodified ones; regulation should be based upon the risk-related characteristics of individual products, regardless of the techniques used in their development. There is no scientific rationale for additional regulatory requirements for the products of gene-splicing.

Dozens of new plant varieties produced through hybridization and other traditional methods of genetic improvement enter the marketplace and food supply each year – without any scientific review or special labeling. Many such products are from "wide cross" hybridizations in which large numbers of genes – including even entire chromosomes or whole genomes – are moved from one species or one genus to another and incorporated randomly into the host genome, yielding a plant variety that does not and cannot exist in nature. These new varieties of plants, obtained by pre-gene-splicing techniques – which are "genetically engineered" or "genetically modified" by any reasonable definition – have long been consumed widely and routinely in the United States, Europe and elsewhere; they include wheat, corn, rice, oat, tomato, potato, rice, pumpkin, and black currant. In order to reduce risks most effectively, the degree of regulatory scrutiny applied to individual products should be commensurate with the degree and type of risk being addressed.

Chapter 7: Governmental Regulation of Spliced-DNA Foods	
Potential Benefits	**Potential Risks**
• Balanced sound policy • Safety for farmers • Safety for food producers • Safety and assurance for consumers • Safety in the environment • Registration of new biotechnology products; foods, drugs, vaccines, and diagnostic tests	• Imposes unscientific, excessive regulatory requirements • Uses highly risk-averse approach to regulation • Uses "acceptable levels" that may not be biologically realistic • Subjects DNA-modified organisms to lengthily, mandatory pre-market review • Fosters inconsistent approach to the introduction of new plant varieties • Inflates the costs of research and development • Diverts and wastes public- and private-sector resources • Shrinks the numbers and kinds of products under development • Inhibits the development of environment-friendly products • Deprives consumers of choices in the marketplace

Chapter 8, Biotechnology and Intellectual Property by Brian Wright, Professor of Agricultural Economics, University of California, Berkeley.

In this chapter, the author deals with intellectual property right (IPR) issues. In recent years, patents have become an important means of protecting innovations by crop breeders and producers of related technologies. Patents have furnished strong investment incentives. But, the author argues that the number of patents relevant to particular lines of research is increasing rapidly, and overlapping, uncertain, and conflicting claims threaten the freedom of researchers to operate. In the private sector, one response has been mergers and takeovers to eliminate the need for costly and difficult negotiation of licensing transactions. But, the public-sector breeder is still crucial for most California crops, and means must be formed to give them adequate freedom to operate in producing new cultivars for California's farmers. In general, changes in biotechnology and intellectual property protection are mutually reinforcing.

The scope and power of IPRs in biotechnology has grown, its international reach has expanded, and the innovative response has been impressive. The Plant Variety Protection Act of 1970 administered by the USDA gives some protection to new distinct varieties against unauthorized sale for replanting and places restrictions on replanting saved seed by producers. Enforcement, however, has been difficult except in the case of hybrid seeds that will not breed true when replanted. Historically, the dominant player in producing new crop varieties has been the public sector. Starting in the 1980s, biotech companies formulated a strategy of selling crop protection traits. In response to high transaction costs and other difficulties with licensing patents, the first wave of integration of agricultural chemical, biotech companies, and seed companies created major life science companies such as Monsanto and

Novartis. Now the industry is moving toward mergers that could integrate the input and output side of agriculture driven largely by attempts to get around further contracting problems associated with IPRs for new biotechnologies, and to obtain the benefits of greater market power.

Implications of these mergers for California producers depend upon the focus of the private-sector investment in agricultural research, now match or exceed the public investment in research. To date, the bulk of private investment has focused on a small number of high-value crops, mainly corn, soybeans, and cotton that represent large markets. California's main crops have not been the prime targets of genetic engineering efforts by large agricultural biotechnology companies. Thus, if the development of new biotech crops for California's agriculture is left to the private sector, many applications of biotechnology to California crops are likely to be delayed or blocked altogether. Collaboration between producer groups and public-sector universities and public institutes is one promising way of bringing biotechnology to California's specialty crops. Policymakers should try to ensure that nonprofit researchers have access to the necessary enabling technology on reasonable terms.

Chapter 8: Intellectual Property Rights

Potential Benefits	Potential Risks
• Provides strong incentives to agricultural research • Provides legal protection for biological innovations • Encourages private-sector investment in agriculture • Makes private crop research attractive for the first time in non-hybrid crops • Biotech research gives value to intellectual property rights (IPRs) in agriculture • Research organizations, both public and nonprofit, are able to capture more of the value generated by biotech research than just giving it away for free	• Favors well-financed private research conglomerates • Limits or blocks some collaborative private and public research efforts • Limits freedom to operate in agricultural research • Promotes proliferation of conflicting proprietary rights • Limits research access by national and international research centers • Difficult to enforce infringement, protection, and legal challenges • Need for development of alternative forms of technology transfer

Chapter 9, A Guide to Current National and International Scientific Reports by Tamara Schiopu, MBA Candidate in Environmental Management and Seymour Van Gundy, Emeritus Dean and Professor of Nematology, University of California, Riverside.

In this chapter, the authors provide an introduction and a brief summary of the many national and international scientific reviews conducted since 1999.

The controversy and debate on food biotechnology and the development of transgenic crops is global in nature and extends from the scientific community to the farmer and the public consumer with the eventual resolution of policy and regulation in the hands of governmental agencies and politicians. The Internet has become the primary means of information exchange and provides an instant communication on the benefits and risks of transgenic crops by all the scientific organizations, governmental agencies, public consumer organizations, and individuals that want to make their reports, views, and opinions known to the world. For example, a search on any commercial search engine will provide more than 79,900 citations. Unfortunately, there is no Internet screen to identify those that report information based on scientific data.

Obviously, an extensive review of all the information available on transgenic crops is beyond the scope, timeframe, and resources of this review. Only summaries and recommendations of the most important recent scientific reports are presented for comparison and extension of some subject areas not covered in the body of the report. The full reports are readily available to the consumers as downloads on the Internet. Additional web-links are available in the appendix. The subject of food biotechnology has been reviewed by many national and international scientific panels in the last two years and there is now extensive literature available in this report for those who want to develop a meaningful understanding and dialog that is based on sound science.

Chapter 9: Scientific Reports

Many scientific organizations who have endorsed the safety and benefits of new biotechnology and transgenic crops include the U.S. National Academy of Sciences, Genetics Society of America, American Medical Association, and American Dietetic Association and internationally the World Health Organization, Food and Agricultural Organization of the United Nations, The Royal Society of United Kingdom, and Third World Academy of Sciences.