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Implications of Gene Flow in the Scale-up and Commercial Use of Biotechnology-derived Crops: Economic and Policy Considerations

Corn, canola, and soybean are three of the major biotechnology-derived crops grown worldwide. (Photos courtesy of the USDA Online Photography Center and the USDA Agricultural Research Service Image Gallery.)

Abstract

This paper reviews the concept of gene flow—the successful transfer of genetic information between different individuals, populations, and generations (to progeny) and across spatial dimensions. The paper also discusses the relatively limited situations in which gene flow is likely to cause economic problems in the production of commercial biotech crops. Gene flow is presented in the context of an associated phenomenon, adventitious presence, in which unwanted substances unavoidably make their way into the production, channeling, and marketing system of grain and crop products.

Because reproductive biology differs markedly among crop species, so does the potential for outcrossing and subsequent gene flow. Economically or environmentally significant gene flow into weedy relatives of these crops often is limited because of restricted geographical overlap of the crop and weed regions or because the weedy relatives are not exceptionally competitive or invasive.

Numerous useful traits are being imparted into biotech and nonbiotech crops. Most of these traits are likely to have little impact on the dynamics of gene flow, especially outside of agricultural fields. Precommercialization procedures that take into account the specific trait being introduced will help to insure that impacts of gene flow remain low. Where trait characteristics warrant, a variety of production practices can be used to mitigate gene flow, and novel genetic/molecular containment technologies are being developed to accomplish similar goals.

The economic consequences of gene flow from biotech crops may differ in crops produced for seed (to be planted) vs. crops produced for commodity uses (to be consumed or woven into textiles), or in traditional vs. niche marketplaces. Approaches to minimize potential negative impacts are discussed.

Potential risks and benefits of

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maintaining or altering the existing safety and regulatory mechanisms are addressed in the context of public policy considerations. These considerations include the potential benefits of establishing thresholds for unapproved biotech substances in any commodity and for approved biotech substances in a commodity labeled as nonbiotech. Existing regulations are costly and can discourage development of beneficial products. Regulatory approaches that consider benefits and costs more holistically may facilitate improved development of these technologies.

To date, there have been no major health or environmental setbacks due to gene flow from biotech crops; in fact, these crops have led to significant, documentable improvements and, in some instances, decreased environmental risks. Education addressing the realistic advantages and challenges of continued development and commercialization of biotech crops, as well as nonbiotech crops, will be a key to public understanding and discourse related to future policy toward biotech crops.

Introduction and Background

In the past quarter century, molecular biologists have developed biological, chemical, and physical methods to isolate and multiply genes from one species and introduce them into another. Collectively, these methods are known as transformation. Essentially all species are related because their cells can read a common genetic code. Genes introduced into organisms via transformation are called transgenes, and recipients of transgenes are called transgenic organisms. Other roughly synonymous terms include recombinant, genetically modified, or genetically engineered organisms. In this paper, the terms "biotech" and "nonbiotech" are used in place of "biotechnology-derived" and "nonbiotechnology-derived" to designate the transgenic organisms being discussed.

The United States is the largest producer of biotech crops; worldwide, the area planted to biotech crops has expanded rapidly, increasing more than fifty-fold since its first commercialization in 1996 (James 2006). In 2006, biotech crops expanded to 102 million *hectares*[1] (ha), a 13% increase compared with 2005 use, and were produced in 22 countries on six continents. This recent expansion was greater in developing countries (21%) than in developed countries (9%). Developing countries (principally China, India, Argentina, Brazil, and South Africa) now plant more than 40% of the global biotech crop area (James 2006). To learn more about benefits commonly associated with agricultural biotechnology, readers are directed to the U.S. Department of Agriculture (USDA) Agricultural Technology website (USDA 2007).

The overall purposes of this document are to (1) identify the nature of gene flow in relation to biotech crops and the limited conditions within which *gene flow* potentially can lead to economic problems and (2) put gene flow in context with the broader practical problem of *adventitious presence* (AP) in the production, channelling, and marketing system for agricultural commodities. The specific objectives are to

- describe the types of biological traits being imparted into biotech crops and their gene flow ramifications;
- review the potential for and occurrence of gene flow from major commercial biotech crops related to AP;
- summarize the existing health and environmental risk assessment and regulatory mechanisms presently

[1] Italicized terms (except genus and species names) are defined in the Glossary.

in place for biotech crops before their approval for commercialization;

- discuss the potential economic effects of gene flow-derived biotech materials in the marketplace; and
- explore potential ramifications on policy and research, including biotech substance thresholds necessary to facilitate efficient, dynamic, and safe trade of agricultural commodities.

Gene Flow: Definition and Occurrence in Nature

In nature, genetic information is transferred between different individuals, populations, and generations (to progeny) and across spatial dimensions. This phenomenon, known as gene flow, serves as a mechanism to maintain the biological diversity that helps to ensure long-term survival of populations and species in variable environments. In animals, this transfer often results from interbreeding between populations of closely related individuals. In plants, such exchange of genetic information typically occurs via pollen dispersal. These are natural and ordinary phenomena that occur in conventional (nonbiotech) as well as biotech crops, but interest in understanding and managing gene flow has increased with the development of biotech crops. Humans have selected, adapted, and improved crops from diverse species for numerous purposes.

Gene flow is not an inherently adverse phenomenon. Gene flow is nearly ubiquitous in the biological world and has played a key role in the development of plant species as they exist today (Raven 1980). In fact, gene flow among sexually compatible plants is thought to be so widespread that the concepts of species based on the absence of gene flow are rendered useless in application to higher plants (Raven 1980). According to modern genomics, half of the corn genome is thought to consist of *exogenous* DNA from other lineages. Thus, genes flow in nature, and always have. In the context of this paper, gene flow refers to pollen-mediated gene flow that occurs between sexually compatible plant species.

Plant species differ in their propensity for gene flow via pollen. Many species have features that promote pollen dispersal, such as flowers that attract pollinators or pollen grains able to travel long distances by wind. Other species, though, restrict gene flow by self-pollinating before their flowers open. Movement of pollen away from its site of production can result in true gene flow only if (1) the pollen first effects fertilization to form seeds, and (2) seeds germinate, produce plants that express the gene (i.e., are not silenced), and are able to reproduce.

The ultimate outcome of gene flow from transgenic crops depends on the frequency of individuals containing the transgenes of interest, the future recruitment of their seeds from the soil bank, and the relative reproductive success of these plants. When plants with these genes are at a low frequency, they may disappear from the population if their recruitment from the soil bank is low, and if they have no selective advantage (e.g., a herbicide-resistant plant is not sprayed with that particular herbicide) or reproductive advantage over other plants. This disappearance from the population during random fluctuations in gene frequency is called genetic drift. If recruitment from the soil seed bank is high and there is a selective or reproductive advantage for this population, the genes are more likely to be retained and spread and may be incorporated into the gene pool of the recipient population. This process is called introgression. Introgression also is possible if plant populations with introduced genes persist at low frequency for several generations (a bottleneck) followed by conditions more favorable to their reproduction and competition.

In the context of this discussion, the transport of genetic traits via seed movement and/or dissemination due to mechanical means (e.g., *shattering*), wind, water, or distribution by birds or animals is considered a separate mechanism, not gene flow. In general, however, seed traits that encourage dispersal—shattering from the mother plant, structures that help seeds stay airborne or catch the fur of animals, or hard coatings to survive digestion by animals—are absent from most domesticated crops. Seeds of certain agricultural weeds mimic crop seeds to aid dispersal by humans. Seeds also can confer the ability to disperse genes by remaining dormant in soil for extended periods before germinating.

Natural seed dispersal from crops tends to be lower than in their wild ancestors because crops have been bred to retain seeds before harvest to maximize yield. Crops harvested for their grain, however, have the potential for long-distance seed movement during commerce, including the possibility of spillage of grain during transport. Some *Brassica* spp., particularly canola, can survive in ditches along highways. In general, spilled seed and grain have not established long-lasting, troublesome populations outside of agricultural fields (Beckie et al. 2006; Crawley et al. 1993; Kareiva 1993). In some instances, however, biotech *Brassica* seeds have led to the establishment of transgenic feral populations of *Brassica napus* beyond agricultural fields (Aono et al. 2007; Saji et al. 2005; Yoshimura, Beckie, and Matsuo 2006).

Transgenes in crops have the potential to move within and among populations like any other gene. As in nonbiotech crops, pollen from a biotech crop can and does fertilize other biotech or nonbiotech varieties of the same crop; biotech pollen can and does fertilize sexually compatible wild plants; and seed from a biotech crop can and does become mixed with seed of different varieties, or even a different crop species. Gene flow is likely to contribute proportionately more to the total AP in crop species that have high natural levels of cross-pollination or *outcrossing*.

Numerous genetic improvement programs that confer a variety of useful traits to crops have been established in the United States and other parts of the world. Well-established approaches of *classical breeding*, including *induced mutagenesis* or *wide crossing*, as well as direct gene transfer via transformation, have been used in crop improvement. All these approaches are applied to a highly diverse group of traits,

Table 1. Examples of characteristics imparted to plants using all available approaches, and some estimates of the probable consequences from pollen-mediated gene flow[1]

	Potential Grower/Agricultural Problems	Potential Nonagricultural/Human Safety Problems	
New characteristics being imparted to crop plants[1]	Probable potential for natural selection process to transform crop into unmanageable "weed" or "volunteer"[2]	Probable potential for natural selection process to exacerbate existing problem or create new agronomic problems resulting from gene flow to wild/compatible relative[2]	Probability for off-site gene flow that would create significant adverse human health/nutrition impact[2]
Herbicide tolerance	med[3]	low–med[3]	neg[3]
Insect tolerance	low–med	med	neg
Disease tolerance (fungal, bacterial, viral)	low–med	med	neg
Nematode tolerance	low–med	low–med	neg
Salt tolerance	low–med	low–med	neg
Drought tolerance	low–med	med	neg
Cold/freezing tolerance	low–med	low–med	neg
Improved iron stress tolerance	low	low	neg
Increased water use efficiency	low	low–med	neg
Altered wound response	neg	neg	neg
Improved nitrogen use efficiency	low	low–med	neg
Early season vigor	low	low–med	neg
Hybrid vigor (for cytoplasmic male-sterile breeding system)	low	low	neg
Increased growth rate	low	low–med	neg
Reduced plant height	low	low	neg
Lodging resistance	neg	neg	neg
Shattering resistance	neg	neg	neg
Altered reproductive fertility	low	low	neg
Altered flowering time	low	low	neg
Male sterility	neg	neg	neg
Yield/yield components	neg	neg	neg
Quality components	neg	neg	low–med
Altered maturity date	low	low	neg
Improved fruit ripening	neg	neg	neg
Improved shelf life	neg	neg	neg
Altered fruit shape/flavor	neg	neg	neg
Seed protein or oil content	neg	neg	low–med
Seed protein or oil quality	neg	neg	low–med
Increased sugar or starch content	neg	neg	low
Altered enzyme expression	neg	neg	neg
Nutritional enhancement	neg	neg	low–med
Plant-made pharmaceuticals (PMPs) (many traits)	neg	neg	med–high
Industrial compounds	neg	neg	med–high

[1]Approaches include biotechnology as well as traditional plant breeding approaches that use long-established methods to introduce and select for desirable traits in crops. All traits are eventually manipulated through classical breeding methods before commercialization. For more information, see USDA–APHIS (2007a). These traits include *input traits* that some people perceive as primarily benefiting producers by decreasing their production costs, and, more recently, *output traits*, which often are perceived as providing more direct benefits to consumers. Uses and economic impacts of numerous biotech products have been summarized in a report by the European Commission (2007). For additional information, see Barton et al. (1997); Bradford et al. (2005); Information Systems (2007).

[2]These estimates are intended to convey a comparison of the most probable or reasonably expected outcomes relating to gene flow, not to address highly improbable, worst-case scenarios. The probable outcomes of gene flow listed for the traits in this table could differ from one biotech crop to another because some crop/weed species combinations are much more likely than others to experience high amounts of outcrossing or gene flow, and some weed species are inherently more aggressive or problematic than others (Table 2, Table 3).

[3]Key for degree of problem expected (author estimates). Negligible, "neg"; low, "low"; medium, "med"; high, "high." The degree of the problem is likely to vary for a given characteristic or trait depending on the reproductive biology of the species, the trait itself, and the cropping system in which it is used.

including resistance to insects, herbicides, diseases, and viruses; male sterility; delayed ripening; improved nutrition; and freezing tolerance (Table 1).

Distinctions between Gene Flow and Adventitious Presence

Gene flow is a biological feature that antedated humans by millions of years, whereas AP is, to a great extent, an artefact of human handling of biological materials. Adventitious presence has long been known and dealt with in conventional crops and has more recently become an issue in biotech crops. Without taking additional steps that might be very costly, some low level of AP is considered unavoidable in broad-scale commodity agriculture.

Kershen and McHughen have encapsulated the concept of AP in the production of agricultural commodity crops from certified seed: "…the crop starts with the highest degree of [seed] purity deemed commercially achievable, which then becomes increasingly less pure as various substances infiltrate at every step—from farm to granary to processor to retailer to consumer.…In the context of transgenic crops, the term describes the inadvertent presence of transgenic seeds or other material in conventional and organic crops. With respect to approved transgenic commodity crops, the issue is not agronomic performance, food safety, environmental protection, or animal or human health....Rather, concerns about adventitious presence are economic concerns: market access, contract specifications, and consumer preferences.… Adventitious presence is thus both historical and ubiquitous. Commingling at low levels among conventional, organic, and transgenic commodity agriculture is a fact that is neither surprising nor unique" (CAST 2005).

Gene flow may be viewed as one of several mechanisms by which agricultural plants, seeds, or products become inadvertently commingled in trace amounts with other seeds or products where humans may not intend them to be, resulting in AP of these substances. The issue of intent is important because AP usually applies to the presence of substances that are of secondary concern. Active intent to exclude something because it is hazardous is different from passive preference to exclude for cosmetic or aesthetic reasons.

In the context of this discussion, the basis for gene flow encompasses (1) movement of genetic information between populations, (2) sexual combining through gamete transfer, and (3) incorporating detectable alleles into a receiving population from a migrant population. Gene flow may contribute to or initiate an AP concern, but there are other contributors to AP, including seed dispersal via mechanical means, inadvertent seed or grain mixing, quality control failures, misidentification of a lot (other sources of genetic information but not involving gamete transfer), and simple human mistakes. Crop-to-crop gene flow contributes to AP because harvested grain typically enters the marketing system. Crop-to-wild relative gene flow, however, does not normally contribute to AP.

Gene Flow Potential with Wild/Weedy Relatives of World Crops

Weediness is a gene flow concern to the extent that there is gamete transfer among populations. If *hybridization* of a biotech crop to a nonbiotech crop or wild or weedy species occurs, gene flow is an issue. If a biotech crop escapes to the wild because of seed transfer and becomes a weedy feral population, this is not true gene flow (as defined in this paper) because no genetic information is exchanged between populations, even though the economic or environmental consequences of such seed transfers could be important in some instances.

When attempting to understand the potential ramifications of gene flow from biotech crops, it is useful to view the question in the context of the primary crops involved in global food and feed production. Worldwide, approximately 200 plant species account for nearly all the significant economic and culinary activities for humans, and approximately 10% of these account for 70 to 95% of the human caloric consumption (Table 2). Thus, key considerations for using biotech crops are the history and impact of gene flow from nonbiotech food and feed crops to the same crop or to wild and weedy relatives, and the likelihood that gene flow to weedy relatives will result in aggressive weedy populations of weed-crop crosses.

A recent review indicated that sexually compatible weedy relatives exist for all but four of the world's 25 most important food crops (Warwick and Stewart 2005). Among the world's 180 most damaging weeds, however, which collectively cause 90% of all crop losses due to weeds, only five groups (related weeds of rice, sorghum, rapeseed, sugarcane, and oats) are sexually compatible with the most important crops (Table 2). It is clear that the potential number of gene flow combinations between the world's most damaging weeds and its most important crops is small (Warwick and Stewart 2005).

The potential for gene flow often does not or cannot translate into actual gene flow for a variety of reasons, including separation of species due to differing habitats or geographic distribution. In many instances, the geographical distributions of major production areas of crops and their compatible weedy relatives do not overlap appreciably. Genetic barriers to wide crossing and nonsynchronized flowering periods may further limit gene flow. These facts emphasize that the number of weed-crop crosses likely to lead to extremely troublesome or unmanageable problems is small.

It is noteworthy, however, that whereas a given weed may not rank high globally, there can be significant losses on a local or regional scale—e.g., heavy infestations of *Oryza sativa* and *Aegilops cylindrica*, major weedy relatives of rice and winter wheat, respectively, grown in the United States and throughout the world, can cause substantial economic losses and have sometimes forced farmers to temporarily rotate out of or abandon these crops.

Table 2. World's 25 most important food crops and their sexually compatible weed species[1]

Rank	Crop	Scientific Name	World Area Planted[2] (M Ha)	World Yield[2] (MT)	Related Weeds: Sexually Compatible with Crop[3]	Rank among World's Worst Weeds[4]	Geographical Distribution
1	Wheat	*Triticum aestivum* *T. turgidum durum*	208	557	*T. aestivum* *Aegilops cylindrica* *A. tauschii* *A. triumcialis* *A. ventricosa*	>180 >180 >180 >180 >180	Nepal Turkey and U.S. Mediterranean: Iran Mediterranean: Morocco and Turkey Mediterranean: Morocco
2	Rice	*Oryza sativa* *O. glaberrima*	151	585	*O. sativa* *O. glaberrima** *O. barthii* *O. longistaminata* *O. rufipogon* *O. punctata*	77–180 >180 77–180 >180 77–180 77–180	Worldwide: >50 countries W. Africa Subsaharan Africa: Nigeria Subsaharan Africa Continental and insular Asia to New Guinea and north Australia, Latin America, Bangladesh Nigeria and Swaziland
3	Maize	*Zea mays*	141	636	*Z. mays* ssp. Mexicana*	>180	Mexico
4	Soybean	*Glycine max*	84	190	*G. soya*	>180	Northeast Asia: Korea, Taiwan, Japan; northeast China; Russia (Siberia); Argentina
5	Barley	*Hordeum vulgare*	55	139	*H. spontaneum*	>180	East Mediterranean to Iran and west central Asia: Iran and Jordan
6	Sorghum	*Sorghum bicolor*	44	59	*S. bicolor* *S. almum* *S. halepense* *S. propinquum*	>180 >180 Top 18 >180	Africa and U.S. Argentina, Australia, South Africa, and U.S. Worldwide: 51 countries, native Southwest Asia and adjacent Africa Southeast Asia: Philippines
7	Millet	*Eleusine coracana* *Pennisetum glaucum*	35	29	*E. coracana* ssp. Africana* *P. sieberanum*	>180 >180	W. Africa W. Africa and north Namibia
8	Cottonseed	*Gossypium hirsutum* *G. barbadense*	32	57	*G. hirsutum**, feral *G. tomentosum*: compatible?	>180 >180	Mesoamerica and Caribbean U.S.
9	Beans, dry, green, and snap	*Phaseolus vulgaris*	28	26	*P. vulgaris*: weed-crop-wild complex	>180	Peru and Colombia
10	Groundnut (peanut)	*Arachis hypogaea*	26	37	*A. hypogaea*	>180	Taiwan
11	Rapeseed (canola)	*Brassica napus*, *B. rapa*	24	36	*B. napus* *B. juncea* *B. rapa* (*B campestris*) *Hirschfeldia incana* (*B. adpressa*) *Raphanus raphanistrum* *Sinapis arvensis* (*B. kaber*)	>180 >180 77–180 >180 77–180 77–180	Europe, Argentina, Australia, Canada, U.S., 7 countries Australia, Argentina, Canada, Fiji, Mexico, and U.S. Worldwide (temperate climate): >50 countries Europe, Australia, southern Africa, Argentina, and U.S. Worldwide (temperate climate): 65 countries Worldwide (temperate climate): 52 countries
12	Sunflower seed	*Helianthus annuus*	21	26	*H. annuus* *H. petiolaris*	>180 >180	Mexico, South America, U.S., 11 countries U.S.
13	Surgarcane	*Saccharum officinarum*	20	1350	*S. officinarum* *S. spontaneum*	>180 77–180	Taiwan Asia, Africa, Middle East, Mesoamerica, 33 countries

—continued

Table 2. World's 25 most important food crops and their sexually compatible weed species,[1] continued

Rank	Crop	Scientific Name	World Area Planted[2] (M Ha)	World Yield[2] (MT)	Related Weeds Sexually Compatible with Crop[3]	Rank among World's Worst Weeds[4]	Geographical Distribution
14	Potato	*Solanum tuberosum*	19	311	None		
15	Cassava	*Manihot esculenta*	17	188	*M. esculenta*	>180	
					Manihot spp.*: all		
					*M. reptans**		Southwest U.S. south to Argentina
16	Oats	*Avena sativa*	13	26	*A. fatua*	Top 18	Worldwide: 56 countries, native to Europe, North America, Middle East, and Central Asia
					A. sterilis	Top 18	Europe, North America, Middle East, and Central Asia, 18 countries
17	Oil palm fruit	*Elaeis guineensis*	11	139	None		
18	Coffee	*Coffea arabica*	11	7	None		
		C. canephora					
19	Coconut	*Cocos nucifera*	11	50	*C. nucifera*; feral populations	>180	
20	Chickpea	*Cicer arietinum*	10	7	None		
21	Sweet potato	*Ipomoea batatas*	10	137	*I. trifida*	>180	Central and South America: Honduras and Mexico
22	Cowpea	*Vigna unguiculata*	9	4	*V. unguiculata*	>180	Niger and Nigeria (roadside weed)
23	Olive	*Olea europaea*	9	17	*O. europea*	>180	Mediterranean basin
24	Rye	*Secale cereale*	8	16	*S. cereale*	>180	Argentina, Finland, Iran, Turkey, and U.S.
					*S. montanum**	>180	Mediterranean basin east through Turkey to Iraq, Iran
25	Grape	*Vitis vinifera*	7	62	*Vitis* spp.*	>180	
					V. aestivalis	>180	U.S.
					V. candicans	>180	U.S.
					V. hastata	>180	Malaysia
					V. rotundifolia	>180	U.S.
					V. rupestris	>180	U.S.
					V. tiliaefolia	>180	Honduras
					V. trifolia	>180	India
					V. vulpina	>180	U.S.

[1]Adapted from Warwick and Stewart (2005). Although the information presented here focuses specifically on crops used for human consumption, many of the same major crops also are used heavily as sources of animal feed. Some crops traditionally considered animal feed (e.g., alfalfa) also are consumed as food in some instances.

[2]Area of production (million ha) and world yield (million metric tons) for 2003 from the FAOSTAT Web site, http://faostat.fao.org/default.jsp.

[3]All species, except those followed by an asterisk (*), are listed as a weed in Holm et al. (1979), or listed as a weed in Global Compendium of Weeds at Web site http://www.hear.org/gcw/index.html.

[4]Holm Classification: "Top 18": ranked 1 to 18 of worst weeds by Holm et al. (1977); "19–76": ranked 19 to 76 by Holm et al. (1977); "77–180" : ranked 77 to 180 by Holm et al. (1997); ">180" indicates not listed among the 180 worst weeds or not listed as a weed.

Additional details on the potential consequences of gene flow between crops and wild relatives are discussed by Ellstrand (2003).

The nature of biotech traits—specific traits introduced using biotechnology methods—is central to the evaluation of the probable consequences of gene flow to weeds and wild relatives. Weed crosses with herbicide-tolerant biotech crops are likely to be favored in some agricultural fields where the herbicide is used. In areas where little or no such herbicide is used (e.g., native lands), the weed–biotech crop crosses will not be favored. Development of weed resistance via *selection pressure* from repeated herbicide applications in herbicide-resistant crops (in the absence of gene flow) often poses greater risks than that from gene flow to related weed species (Beckie, Hall, and Warwick 2001; Warwick et al. 2004).

Biotech crops conferring stress tolerance (e.g., to water deficits, diseases, insects, salt stress, or nutritional deficiencies) may need more scrutiny because their crosses with weedy relatives may impart selective advantages in both agricultural and nonagricultur-

al areas (Andow and Zwahlen 2006). Thus, some traits obtained from biotech crops could theoretically facilitate development into problematic weedy or wild species. But highly domesticated crops such as maize or wheat (whether as *volunteers* or as crosses with wild relatives) still will be relatively less invasive than less domesticated crops such as rapeseed, cultivated oats, sugarcane, and rice (Warwick and Stewart 2005).

Of greater concern is the threat from importation of weeds or other plants from foreign lands (Warwick and Stewart 2005). Seeds or grain of virtually all crop plants have been distributed globally for the past two centuries, and associated ecological problems in virtually all instances came from weeds present in the seed lots or from wild plants that were thought to have some useful or aesthetic purpose and were, therefore, purposely introduced. Instances in which fully domesticated agronomic or vegetable crops have become environmental nuisances are rare, even though those crops have been bred to exhibit disease and insect resistance and other traits similar to the traits currently being developed through genetic engineering. The likelihood that modification of one or a few traits in a domesticated crop with a history of environmental exposure would transform it into an aggressive weed also is very low, although some crops have contributed to the formation of feral weed populations (Gressel 2005). Even so, gene flow from the majority of biotech crops probably will have minimal or nondetectable adverse ecological impacts outside of agricultural fields.

Many novel, introduced weed species have been highly aggressive and successful. Approximately 10% of all introduced species typically develop into troublesome pests; those that do may be costly. In the United States, public and private landowners expend considerable resources to meet threats from numerous invasive weeds such as leafy spurge (*Euphorbia esula*), kudzu (*Pueraria lobata*), saltcedar (*Tamarix* spp.), johnsongrass (*Sorghum halpense*), and foxtail species (*Setaria* spp.) (CAST 2000).

Biology and Gene Flow Potential of the Major Biotech Crops

The reproductive biology of crops governs the frequency of outcrossing. Crop reproductive biology can range from nonsexual and almost exclusively self-pollinating to male-sterile and 100% outcrossing. Seed dispersal, another mechanism for moving genetic information, can be affected by the crop's biology, harvesting methods, and the seed or grain industry's operating procedures. Most crops have long-lived seeds that remain viable for many years if maintained under cool, dry conditions, but which generally have limited dormancy and do not persist more than a few years in soils under normal conditions.

Corn, soybean, canola, and cotton represent 99% of all biotech crops commercialized worldwide (James 2006). Some important differences exist in the potential magnitude and pathways of gene flow among crop species (Table 3). Seed dispersal occurs at a minimal level in all these crops. Pollen dispersal is limited in soybean, wheat, and rice. Canola is the most recently domesticated crop of the six shown in Table 3. Unharvested or spilled canola seeds have a better chance than seeds of the other five crops of surviving in the soil and giving rise to weedy volunteer plants or populations. Even so, for more than a decade, no such accidental canola populations survived or became established (Crawley et al. 1993). Feral cereal rye also has the potential to survive in volunteer populations. See Textbox 1 for more information on the biology and gene flow potential of soybean, corn, and canola.

Other Biotech Crops

In addition to the major biotech crops (soybean, corn, canola, and cotton), the United States also grows biotech papaya, squash, and alfalfa commercially (Lemaux 2005). Biotech virus-resistant varieties are credited with rejuvenating the papaya industry in Hawaii and are now grown on more than half of the papaya cropland. Transgenics have been produced in many crops/species for research purposes, but few are proceeding through the regulatory process toward commercialization. These crops include grain crops, vegetables, fruits, ornamental plants, forage crops, turfgrasses, and trees. Additional species granted nonregulated status or in the process of deregulation or approval include carnation, creeping bent grass, tobacco, tomato, plum, potato, beet, and sugar beet (Information Systems 2007; USDA–APHIS 2007a).

Limited biotech rice evaluations are underway internationally: Iran has explored the commercial production of Bt biotech rice (James 2006); and China has developed and is field testing biotech rice that is thought to be widely grown but has not yet been approved formally for domestic consumption. Pollen from biotech herbicide-resistant creeping bent grass in Oregon was shown to move several kilometers before fertilizing plants of the same species and a weedy relative (Watrud et al. 2004).

An emerging new category of biotech crops—pharmaceuticals, nutraceuticals, and industrials—has been engineered to produce specific proteins for medical or industrial products. An extensive discussion of these crops is outside the scope of this paper, but the reader is directed to several studies for further information: Berville et al. (2005); ISAAA (2006); USDA–APHIS (2005, 2007b).

Organic Crops: Issues Relating to Biotech Crops

Organic foods are a small but growing sector of U.S. agriculture, and presently occupy less than 3% of the U.S. food market. In the European Union (EU), the proportion of crops planted as organic for which biotech traits currently are available is not likely to expand appreciably in the near future (Brookes and Barfoot 2004a). Within the United States, organic certification standards historically have been self-defined and self-imposed by the organic community, but the standards were codified in 2002 with the creation of the USDA National Organic Program (NOP 2002).

Table 3. Production and export of major biotech crops and biological factors that may influence postcommercialization dispersal and persistence of transgenes in the United States and Canada[1]

	Soybean	Corn	Canola	Cotton	Rice[2]	Wheat[2]
Harvested area in 2005, United States (millions of hectares)	28.9[a]	30.4[a]	0.45[b]	5.6[a]	1.4[a]	20.3[a]
Harvested area in 2005, Canada (millions of hectares)	1.17[c]	1.13[c]	5.51[c]	0.0	0.0	10.1[c]
Percentage biotech in 2005, United States	87[d]	52[d]	82[b]	79[d]	0[b]	0[b]
Percentage biotech in 2005, Canada	60[b]	60[b]	82[b]	n/a	n/a	0[b]
Percentage of yield exported in 2005, United States[3]	31[a]	19[a]	20[e]	75[a]	52[a]	48[a]
Percentage of yield exported in 2005, Canada[3]	36[f]	2[e]	48[c]	n/a	n/a	60[e]
Extent of outcrossing	very low	moderately high (very limited at long distance)	moderate (limited at long distance)	low	very low	very low
Presence of sexually compatible wild or weedy relatives in United States[4, 5, 6]	–	–	++	–	++	+
Extent of volunteers found in rotational crops within agricultural fields[6]	+	++	++	–	++	++
Extent of volunteer or naturalized populations outside agricultural fields[6]	–	–	++	–	–	–

[1] References consulted for numeric data in table.
[a] USDA–ERS 2007a; USDA–NASS 2006.
[b] James 2005.
[c] Statistics Canada 2007a.
[d] USDA–ERS 2007b.
[e] Index Mundi 2007.
[f] CSEA 2006.

[2] Biotech rice and wheat are not produced commercially in the United States. Imidazolinone herbicide-resistant varieties developed using traditional mutation breeding methods have been grown in the United States since 2002. As of 2005, these varieties occupied approximately 20% of the rice and <10% of the winter wheat production areas, respectively, and their adoption is expected to continue to increase.

[3] Percentage exported: where whole seed vs. ground seed, flour, oil was specified, the export figure for whole seed was used. This can make a significant difference in the data presented in the resulting table. For example, the USDA tables show 31% of soybean production is exported as soybeans and 9% as soy meal. Table 3 in this paper uses the 31% figure.

[4] Wild cotton occurs in Hawaii and Florida. Wild relatives of canola, rice, and wheat include *Brassica rapa*, weedy rice (*Oryza sativa*), and jointed goatgrass (*Aegilops cylindrica*), respectively.

[5] Related information can be found in Ellstrand (2003, 2006) and Warwick and Stewart (2005).

[6] Key to symbols: (–) indicates absence, (+) indicates presence, and (++) indicates common.

Organic certification standards are based on the process rather than the product itself. There are no requirements for testing and no thresholds or standards are established for biotech material in the final organic product (NOP 2002).

In conventional food production systems, it has long been a common practice to set tolerances for the presence of many items found in food that customers do not expect or want. The organic community has the ability within certification standards to implement practical tolerances for the unintended occurrence of biotech elements in organic-certified foods that result from gene flow. (In a similar way, the organic community has already established practical tolerances for the accidental presence of unapproved pesticides.) This practice should be encouraged to prevent market disruption due to the occurrence of low level AP from biotech crops.

Additional issues relating to biotech crops and organic foods in the United States and the EU are timely and important, but they are beyond the length limitations of this paper. For further information, the reader is directed to the following additional studies: Bradford (2006); Messean et al. (2006); OFRF (2003).

Containment Approaches for Mitigation of Gene Flow

Pharmaceutical, nutraceutical, and industrial biotech crops typically produce nonfood proteins or other substances that justify additional measures to prevent their entry into the food chain and to minimize their environmental and human exposure. Novel molecular approaches are being developed to prevent unwanted transgene transfer between biotech crops and their relatives (transgenic containment), or to lessen the impacts

Textbox 1. Biology and gene flow potential of soybean, corn, and canola

	Production	Pollen	Seeds and Grain	Volunteers
Soybean (*Glycine max*) *Dicotyledonous* species	• World's main source of plant protein and oil (Boerma and Specht 2004) • In United States: (1) Used for high-protein animal feed and oil, industrial chemicals, and health foods (2) $18.5 billion annually (3) 30 million ha (4) Nearly half exported as grain, meal, or oil (5) Commercial biotech soybean introduced in 1996 with glyphosate-resistant varieties (Parrott and Clemente 2004) (6) About 90% has biotech resistance to herbicides	• Primarily self-pollinating • No sexually compatible wild relatives in North America • Outcrossing rates between adjacent plants 2% or less • Outcrossing at >15 m effectively zero (Abud et al. 2003; Ahrent and Caviness 1994; Caviness 1966; Ray et al. 2003) • Bees may facilitate increased cross-pollination • Limited probability of gene flow between biotech and nonbiotech varieties	• Transgenes dispersed primarily by seed dispersal during cultivation, harvesting, and marketing • Growers of nonbiotech soybean must establish system to achieve desired standards of seed quality: (1) Clearly define product expectations (2) Set quality management practices for production (3) Find seed source without AP biotech seeds (4) Consider using dedicated farm equipment, separate storage facilities, specific cleaning procedures, or standardized monitoring process (5) Employ specialized testing to prove grain shipments meet expected quality standards	• Volunteers from unharvested grain can complicate weed control options (especially if the transgene carries herbicide-resistant traits) and serve as a potential gene flow bridge to nonbiotech crops (Owen 2005) • Volunteers from unharvested seeds occur in U.S., but are not likely to disperse pollen or persist for more than one growing season
Corn (*Zea mays* L., also maize) *Monocotyledonous* species	• U.S. is largest producer, nearly 41% of world production: 30.4 million ha, $23 billion in 2005 • Nearly 54% of U.S. production used for livestock feed, 27% for refined products, 19% exported (U.S. Grains Council 2007) • Domestication has resulted in high-yielding plants completely dependent on humans for propagation (Matsuoka et al. 2002) • Most commodity corn is of hybrid origin • Hybrid seed industry provides majority of world corn seed • Commercial biotech corn introduced in U.S. in 1996 with hybrids that expressed insecticidal protein from common soil bacterium *Bacillus thuringiensis* (Bt) • Growers attracted to Bt (Cry-1-based) corn because it protects yield, simplifies pest management, and can lead to better quality grain by decreasing levels of naturally occurring *mycotoxins* (Munkvold, Hellmich, and Showers 1997)	• Outcrossing crop with separate male (tassel) and female (ear) flowering structures • Tassels produce 14-50 million grains of pollen per plant (Miller 1985), usually over a 5- to 8-day period • Large pollen grains have limited ability to travel in air currents • Pollen seldom survives for more than one or two hours (Aylor 2004; Raynor, Ogden, and Hayes 1972) • Most Bt corn pollen settles close to source (Ma 2005) • Little cross-pollination occurs at distances >500 m (Halsey et al. 2005; Jarosz et al. 2003); trace amounts of outcrossed corn could occur >1 km (Aylor, Shultes, and Shields 2003) • No sexually compatible wild relatives in the U.S. or Canada • Modern varieties can hybridize with weedy and wild teosinte plants in Mexico, where biotech corn has not been approved for cultivation but is approved for import for food and feed	• Hybrid seed does not *breed true* or maintain yield advantage in following generations when seeds are saved, so farmers purchase new seed each year • No company can guarantee that a bag of seed has no biotech seed or vice versa • No corn seed company would guarantee its seed to be 100% single hybrid material • Determining and verifying acceptable thresholds for AP in corn seed is complex, especially for markets where nonbiotech corn seed and products are requested	• Volunteers from unharvested grain are common and can complicate weed control options (especially if the transgene carries herbicide-resistant traits) (Owen 2005), but do not usually persist for more than one growing season • Volunteers are capable of dispersing pollen to nearby nonbiotech corn fields • Management should be taken into account when necessary to confine gene flow from biotech varieties

Textbox 1 (continued). Biology and gene flow potential of soybean, corn, and canola

	Production	Pollen	Seeds and Grain	Volunteers
Corn (continued)	• Combined trait products give growers more options to manage pests and optimize yields • Only pest populations known to evolve resistance to Bt were grown under organic conditions (Frutos, Rang, and Royer 1999; Tabashnik 1994)	• Genome consists of about 50% transposable elements of exogenous origin		
Canola (*Brassica napus*) *Dicotyledonous* species	• Bred for oil quality, high protein meal for animal feed, and low levels of several harmful natural products • Seed is third most important source of vegetable oil worldwide, about 11% (USDA–FAS 2007) • U.S.: grown on 0.4 million ha (James 2005), 2005 value of $148 million, net importer • Canada: grown on 5.5 million ha (Statistics Canada 2007a), 2005 value of $1.85 billion (Statistics Canada 2007b), exports 48% of yield, often as bulk grain (Index Mundi 2007) • Seeds produced using combination of *open-pollinated* and hybrid variety systems • Growers rarely replant seed from hybrid varieties because of loss of vigor and crop uniformity • Three herbicide-resistant traits commercialized in 1996 • Use of biotech canola in U.S. and Canada has not blocked access to most major international markets	• Primarily self-pollinating, but outcrossing between neighboring plants occurs at frequencies of 12 to 55% (Légère 2005) • Dispersed predominantly by insects and occasionally by wind • Outcrossing between adjacent crops averages 1% at common border and diminishes with distance • Pollen-mediated outcrossing between herbicide-resistant biotech and nonresistant fields detected at moderate distances (several hundred meters) (Hall et al. 2000) and long distances (several km) (Rieger et al. 2002) from biotech pollen source • Most open-pollinated and hybrid seed lots tested contained AP transgenes at amounts between trace and 2% (Légère 2005) • When a canola crop or volunteer outcrosses, offspring may contain two or more herbicide-resistance genes (Hall et al. 2000)	• Following harvest, grain enters handling system and may be commingled before export or transport • Seeds are small and can be lost at harvest, due to shattering losses or inefficient harvest • Losses at harvest are substantial and can exceed initial planting rates • Grain movement and loss within handling system are difficult to predict and provide well-known avenues for longer-distance seed transport • Well-established management practices successfully used in Canada (Beckie 2006; Beckie et al. 2004)	• Seed lost during grain handling can germinate along roadways and in other disturbed areas • Seeds that occur on or near soil surface usually germinate the following year and are rapidly depleted • Buried seed can remain viable for several years • Volunteer canola currently is an important weed within crop fields and field margins in Canada. These volunteers often make a much more important contribution to AP than gene flow does, and they may require additional management practices for cleanup. • Herbicide-resistant volunteers that are not controlled in herbicide-resistant crops can decrease yields, so producers commonly combine herbicides and rotate herbicide-resistant crops to decrease their abundance (Beckie 2006)

or spread of such transgenes in populations of these relatives (transgenic mitigation) as an alternative or supplement to containment approaches.

Gressel and Al-Ahmad (2005) have recently reviewed a number of these molecular approaches, particularly in the context of preventing or minimizing transgene establishment in volunteer crops or wild/weedy relatives. A widely discussed containment approach is to target transgenes to the organellar genomes in the cytoplasm (e.g., chloroplasts). Although it can occur, the transmission of cytoplasmic organelle through pollen is extremely rare and would greatly decrease the probability of gene flow via pollen. One limitation would be that it cannot prevent formation of transgenic hybrids that would result from inflow of pollen from wild/weedy species to the biotech crop plants.

A novel approach that greatly reduces this potential pollen outflow problem is the coupling of transgenes for cytoplasm-inherited traits with male sterility so that wild/weedy and nonbiotech relatives receiving transgenic pollen cannot produce seed.

The potential for gene flow could be further decreased by combining additional containment mechanisms in the same biotech crop.

Other containment approaches, such as the so-called "genetic use restriction technologies" (GURT), focus on causing sterility in second generation seeds. This sterilization effect could be restricted to the variety level (i.e., the variety cannot be replanted by growers unless new seeds are purchased) or to the trait level (i.e., the sterilization action will not occur until a proprietary activator compound has been applied to the crop). The advantage of this approach is that transgenic volunteers or hybrids resulting from either pollen inflow or outflow cannot produce viable seeds.

Several transgenic mitigation approaches are promising, and efficacy has been demonstrated in tobacco and oilseed rape (Gressel and Al-Ahmad 2005). These systems aim to prevent a significant buildup of transgenes in wild/weedy or volunteer populations, but do not prevent initial gene transfer. The desired primary transgene is tightly linked to another gene carrying a specific trait so that both genes are always inherited in tandem. The second trait would have a deleterious effect on the reproductive fitness of hybrids and volunteer progeny and would tend to minimize their population frequencies in agroecosystems and natural areas occupied by wild or weedy relatives.

Other approaches include mechanisms that allow production of pharmaceutical proteins only after harvest, or require postharvest treatments to activate the proteins (ISAAA 2006). As with any technology, none of these methods is likely to be foolproof under all possible scenarios. But they do represent a suite of emerging alternative technologies that could provide significant biological barriers against pollen-mediated escape of transgenes. Where the level of hazard would justify their use, such approaches would be suitable for pharmaceutical, nutraceutical, and industrial traits as well as traditional biotech crop traits.

Summary of Regulation and Risk Assessment for Biotech Crops

Regulation of Biotech Crops

Before being approved for potential commercialization in the United States, all biotech crops under development are evaluated extensively. Regulation of biotechnology in the United States stems from the Coordinated Framework for the Regulation of Biotechnology Products (1986). Reports issued by the Organization for Economic Cooperation and Development (1986) and a working group coordinated by the Royal Society of London (Royal Society 2000) have indicated that risks of biotechnology-derived crops are not fundamentally different from risks of conventionally derived products, that regulation should be on a case-by-case basis and based on a product's characteristics and end use, and that existing laws provide adequate authority for regulation of these products. Thus, biotech crops can be sold in the United States only with permission, premarket consultation, oversight, or regulation from one or more of several relevant federal agencies: the U. S. Environmental Protection Agency (EPA), the USDA–Animal and Plant Health Inspection Service (APHIS), and the U.S. Food and Drug Administration (FDA).

In general, the EPA (under the Federal Insecticide, Fungicide and Rodenticide Act [FIFRA] and the Federal Food, Drug, and Cosmetic Act [FFDCA]) and the USDA–APHIS (under the Federal Plant Pest Act [FPPA] and the National Environmental Protection Act [NEPA]) oversee the environmental safety of commercial releases of biotech plants in the United States. The Endangered Species Act (ESA) also applies to biotech plants. The FDA serves in a consultative manner relative to food and feed safety issues, though regulations are pending that would make the consultation process mandatory.

In 2006, the FDA issued new guidance encouraging early food safety evaluation, in part to minimize the possibility of potentially allergenic or toxic biotech crop-derived proteins entering the food supply before the FDA consultation was completed. The FDA's reasoning, in part, states: "As the number and diversity of field tests for bioengineered plants increase,…the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced under field tests with commercial seeds or grain may also increase. This could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA's voluntary consultation process for foods derived from new plant varieties…. FDA is issuing this guidance document to address this possibility" (USFDA 2006).

Thus, through the combined activities of the USDA, the EPA, and the FDA, the potential risks to human health and the environment are assessed thoroughly before the general release and potential commercial use of a biotech crop (Textbox 2). For additional information about safety considerations and practices for agricultural biotechnology, readers are directed to the USDA Agriculture Biotechnology website (USDA 2007).

The biotech crop can be produced and sold only if no unacceptable risks are identified, although additional conditions may be imposed by the EPA or the USDA. After the biotech crop is deregulated (approved) for general release, governmental regulatory and oversight mechanisms allow products to be pulled from the market if new data relating to safety justify such action. (Pharmaceutical production in plants would always be under permit and would never be deregulated for general release.) The USDA currently has no mechanism for conditional deregulation, but it can remove products from the market based on new information, as can the FDA.

Presently, there is no official mechanism for systematic postcommercial monitoring of biotech crops for these purposes. Some people have suggested that such a monitoring system warrants

Textbox 2. An overview of the movement of biotech organisms through the U.S. regulatory system. (Adapted from AGBIOS 2006.)

Research and development (contained)	• National Institutes of Heath (NIH) Guidelines for work with biotech organisms. • Voluntarily adopted by many organizations, compulsory for recipients of NIH grants.
Field trials	• Proposed release must be approved by APHIS either under notification (for crops and traits with great familiarity through direct experience; confidence of very low risk) or permit (more restrictive; for less familiar crops and traits with potentially elevated risk - e.g., plants expressing pharmaceuticals or industrial proteins). • Trials may be inspected by APHIS or state department of agriculture officials. • Summary reports of the trial must be submitted and APHIS promptly informed if anything unusual occurs in the trial. • Gene flow and inadvertent environmental release must be minimized. (Trial must be confined.) • APHIS oversees storage and transport of seed to and from trial sites. • For plants expressing pesticidal proteins, an Experimental Use Permit (EUP) from the EPA is required if the trials exceed 10 acres (4 ha) in a calendar year. • Public notification and comment is required for an EUP, but not for pesticide field trials generally.
General environmental release	• Applicants submit data to APHIS to allow determination of likely environmental effects and the potential for the biotech organism to become a plant pest. • APHIS reviews data and solicits public comment. • APHIS determines whether to grant nonregulated status or impose other conditions. • Nonregulated status required for general release, although regulated articles can be grown commercially (but not for general release) under permits, with restrictions similar to field trials. • For plants expressing pesticidal proteins, the EPA must grant the protein and the material required for its production (promoters, marker genes, etc.) a registration under Section III of FIFRA.
Use as food	• As is done for all nonbiotech foods, the FDA works through voluntary consultation with the developer of the biotech crop to ensure that food safety questions are addressed during development. The extent of consultation applied to foods derived from biotech crops generally exceeds that undergone by any conventional food. • Based on a favorable review of summary data and a presentation to FDA scientists, the FDA issues a letter saying it has no further questions.
Postcommercialization	• The USDA, the EPA, and the FDA have limited legal authority to demand immediate removal from the market should new and valid data bring into question the safety of the product to human heath or the environment. [USDA/ APHIS/FSIS ability in these areas is quite limited. This was the focus of much congressional scrutiny in 2007 due to melamine contamination of pet food.] APHIS issuances of nonregulated status are contingent on an ongoing requirement that unusual or adverse events must be reported to APHIS even after a determination is issued. Such new information can serve as the basis for modification or revocation of the determination if APHIS warrants. Thus, an initial favorable determination for a product does not give it a carte blanche release from any further oversight.

consideration (de Castro 2004). In rare instances it is possible that the presence of transgenics will be detected in production-scale agriculture that went undetected during preapproval field trials because those trials are of relatively small scale and short duration. If these rare occurrences pose a true risk or hazard to the environment, then correction, modification, or discontinuation of the existing practice may be justified.

Risk Assessment for Biotech Crops

Risk assessment is an important early step in the development and approval of biotech crops. Risk is the possibility of harm occurring. Risk assessment is the process by which potential harm is defined, integrated with an estimate of the likelihood of occurrence. As such, for a risk to be realized, there must be both a hazard (something adverse or harmful) and a likelihood of occurrence (exposure to the hazard). Something hazardous does not pose a risk without significant exposure, nor does prolonged exposure to something constitute a risk if it poses low hazard. Risk assessments can be qualitative—expert judgment can describe the harm—or quantitative based on calculated ratios of toxicity and probabilities of exposure.

In the context of biotech crops and regulation, both quantitative and qualitative methods have been used successfully in evaluation before commercial release. Risk assessments of biotech crops rely on several principles: they are science-based (generally use accepted scientific methods and analyses), case-by-case, iterative or recursive (risk conclusions are examined in light of new information), comparative (the nonbiotech crop is the basis for characterizing risk), and inclusive of all available information.

Importantly, the phenomenon of gene flow is the exposure part of the risk equation. Gene flow, however, is nearly ubiquitous in plants, and the majority of it carries no conceivable potential for negative outcome, or hazard. It is, therefore, a fundamental mistake to refer to the "risk" of gene flow in

those instances rather than its "probability." The term "risk" should be used in conjunction with gene flow only in those instances in which a credible hazard can be identified and potential exposure might thereby produce some meaningful risk.

In practice, risk assessment is a process of collecting information over time, beginning with small-scale, contained experiments and progressing to a larger scale based on experience. Decisions about the scale of release of biotech plants depend on the knowledge of the biological activity of the introduced trait, its behavior in the crop, the degree of pre-existing familiarity with the trait (e.g., in other crop species) and the crop (e.g., with other biotech traits), and the proposed management practices. The molecular and *phenotypic characteristics* of the initial transformants are determined in the laboratory, greenhouse, and growth chambers. These data, along with the developer's assessments of familiarity with the introduced trait, are used in applications for permission to carry out field trials. Data from the field trials and the laboratory are used to assess the risks of general release of the crop. Regulators must have this information to determine if any significant changes have occurred relative to the traditional crop that could give rise to an adverse impact in the environment.

To date, all biotech crops approved for commercial use in the United States have been shown to pose minimal or negligible risk to the environment and human and animal health. It has been suggested, however, that more stringent, potentially more accurate methods of precommercialization and/or postcommercialization environmental evaluation may be justified. These methods would be used especially to evaluate traits such as tolerance to drought or high salt levels that could enhance survival/invasiveness of crops or their hybridized weedy relatives in natural or nonagricultural areas. More detailed discussions of these and related subjects are presented in other publications (Andow and Zwahlen 2006; de Castro 2004; Pilson and Prendeville 2004; Raybould 2005; Snow et al. 2005; Wolfenbarger and Phifer 2000).

Are Major Changes in the Regulatory System Justified Based on Gene Flow?

There is rapid innovation of novel products of plant biotechnology that offer improvements in human health and decrease the environmental footprint of agricultural practice. The case-by-case paradigm of risk assessment and regulatory decision-making followed for biotech crops must remain flexible to accommodate such innovation. The USDA has been conducting an environmental impact assessment as a precursor to new regulation for biotech crops. Central to this effort is the redefinition of the data and assessments required under a staged permitting process that recognizes the degree of uncertainty regarding risk of a given product. Any new rule-making should recognize and establish tolerances for the occurrence of biotech elements in foods and feeds.

Risk assessments conducted before the commercialization of biotech crops provide assurances of no unreasonable harm to human health or the environment; gene flow considerations are part of these regulatory assessments. After regulatory approvals, remaining uncertainties relate largely to the economic consequences of AP gene flow. Establishing meaningful and reasonable thresholds for biotech materials in nonbiotech commodities or seeds could go a long way toward stabilizing international markets and facilitating coexistence between biotech and nonbiotech crops.

Because uncertainty exists, it is useful to establish some probabilistic framework and compare expected benefits and costs. While considering the environmental and health costs of biotech crops, it is important to assess these costs relative to the costs that they exclude. For example, if the introduction of biotech crops decreases the need for pesticides that have negative health and environmental side effects, consider the cost of the gene flow compared with the cost of decreased contamination and damage associated with pesticide use. The extra yield associated with biotech crops also has to be balanced against the extra costs.

Introduction of any technology has an element of learning and involves some risk, but with time, it is possible to understand the magnitude of these risks better and to determine whether the technology is sustainable. With regard to gene flow, there have not been any major setbacks; in fact, there are significant, documented gains from increased productivity and decreased risks associated with pesticide use. The current regulatory process, however, may be damaging the prospect of growth and decreasing the well-being of populations in developing countries, where gains from biotechnology may have significant welfare-enhancing effects (Anderson 2006; Evenson 2006). Therefore, using a more holistic approach to regulating biotech crops, by comparing all benefits and costs, may lead to elimination of some of the regulatory restrictions on these crops.

Economic/Commercial Implications of Gene Flow and Adventitious Presence

The most likely adverse commercial consequence of gene flow involving biotech crops is the presence of low levels of unapproved biotech elements (e.g., grain or grain dust) in the commodity, even though gene flow is but one of many processes that may result in the presence of these biotech elements. The same adverse consequences generally do not occur when biotech elements have been approved and deregulated; in the United States, once biotech crops are deregulated, they can be distributed and sold, under Federal regulations, like any conventional crop.

The pollen from a biotech plant could fertilize a nonbiotech variety, and vice versa, and the resulting hybrid seed may possess the biotech trait. Detection of such hybrids may lead to loss of premiums or to price-lowering (Textbox 3). The volume of products affected by such discovery may be substantial, depending on the quality standards and sampling procedure of the affected product. Because standards of seed identity for nonbiotech variet-

Textbox 3. StarLink Corn Case Study

StarLink Corn Case Study

The StarLink incident illustrates the disruption and economic loss that can result from failure to segregate grains effectively. The Bt corn variety StarLink was approved by the U.S. government in 1997 for use in animal feed but not in human food (NRC 2004). Slow digestibility of a particular protein (Cry9c) had initially raised concerns about a possible link between this trait and human allergy, but biotech proteins in StarLink corn were subsequently shown not to be responsible for allergic reactions (CDC 2001; Lemaux 2005). Although in 2000, StarLink corn was planted on only 141,600 ha (0.4% of the total U.S. corn area), and the majority of the grain produced went for animal feed, genetic sequences from StarLink corn eventually were detected in consumer food products distributed throughout the United States and in exported corn (Goldberg 2001). In response to these detections, the government undertook a comprehensive testing program for this biotech material in corn-derived foods in the U.S. food supply.

Apparently, biotech sequences from StarLink corn detected in this incident resulted from a grain channeling system incapable of reliably segregating grain intended for feed from that intended for food uses (i.e., an AP-related issue, not gene flow per se) (Lemaux 2005). A pollen dispersal component (i.e., gene flow), however, cannot be ruled out entirely (Goldberg 2001).

StarLink eventually found its way into the U.S. seed corn supply, prompting the USDA to purchase seed corn that tested positive for StarLink. Although not proven conclusively, gene flow via pollen dispersal was considered the most likely initiating event that led to StarLink in seed corn (Goldberg 2001). After concerted effort and expenditure of more than $13 million (USDA 2001), StarLink corn has been effectively purged from the U.S. grain system.

Although the grain industry still incurs costs related to the sampling and testing for StarLink biotech substances, numbers of samples and detections have decreased dramatically (USDA–GIPSA 2006); the last single positive detection occurred in April 2005. Any corn that tests positive for these substances continues to be directed toward approved domestic uses only. This example demonstrates that it is possible to remove a biotech crop variety from the market if the need arises.

The uncertainty about grain quality led to a transient decrease in corn prices that resulted in a loss of value to non-StarLink corn growers of $500 million by some estimates (Carter and Smith 2004). Other analyses suggest, however, that the overall effects of StarLink on import demands for U.S. corn were minimal (Schmitz, Schmitz, and Moss 2004). Loss of the European Union market for U.S. corn has now largely been replaced by markets in other parts of the world and by alternatives such as biofuel markets. Recent export levels were near a seven-year high (USDA–FAS 2006).

ies are stricter, the cost of gene flow to related crops increases. The magnitude of this potential gene flow problem can be decreased by an increase in the buffer zone between biotech and nonbiotech varieties, but the resulting decline in land-use flexibility for the biotech varieties can decrease profitability, slow adoption, and negatively affect smaller operations.

Weediness or Invasiveness and Off-target Effects

Another economic implication for consideration has a regulatory emphasis: Will the crop itself or gene flow into its wild relatives create an economic pest? The scientific framework for asking and answering this question has been introduced in earlier sections (Table 1, Table 2, Textbox 2). In the majority of instances, there is a very low probability that an approved biotech crop introduction could create an environmental risk different from that of a nonbiotech version of the same crop. Further development of a biotech product can be halted or restricted, however, if initial scientific evaluation and testing procedures determine that significant environmental or safety issues from off-target gene flow exist.

Quantitative economic assessments of gene flow from biotech crops to wild or weedy relatives generally are lacking, possibly because few, if any, instances of significant invasion or introgression have occurred to date, and/or their impacts have been modest. Data from long-term survival studies in the field generally have not supported the concept of aggressive hybrid invasion (Stewart 2004). Studies of coexistence of major biotech and nonbiotech crops in the EU and North America have indicated that significant introgression of biotech genes to date has been lacking and that biotech and nonbiotech crops and systems generally are coexisting with minimal economic adversity (Brookes and Barfoot 2003, 2004a, b). A recent study in Mexico failed to detect transgenic maize in a small region near Oaxaca, where it had been reported previously, indicating that there is no evidence that biotech corn or its derivatives are established and spreading into native corn landraces or *germplasm* collections (Ortiz-Garcia et al. 2005).

The economic consequences due to gene flow from biotech crops primarily will impact the agricultural fields in which those crops are grown, but potentially could impact natural areas given the proper rare combination of sexually compatible relatives, favorable environment, and reproductive/fitness advantages (Table 1, Table 2). As an example, rice grown in tropical countries may be relatively more prone to such processes because of the substantial populations of its wild/weedy relatives that grow naturally in or adjacent to the rice-producing areas (Lu and Snow 2005).

If biotech crop-derived hybrids with biotech traits damaging to the environment were to establish and spread in a natural ecosystem, the cost of such gene flow theoretically could be estimated as the discounted cost from loss of benefits from the invaded species plus the cost of restoration. For the majority of biotech traits presently available commercially or under development (Table 1, Table 3), however, there is essentially no basis for calculating such discounted costs because novel genes are a standard feature of evolution in natural environments. The idea that new genes in a population are inevitably harmful has been shown repeatedly to be false. Economic techniques also can be applied to assess the theoretical benefits of crop biodiversity (Rausser and Small 2000; Simpson, Sedjo, and Reid 1996).

Achieving Seed Standards

Developing and propagating high-quality, uniform seeds for planting are major economic considerations for seed producers and suppliers. Long before the introduction of biotech crops, seed producers had put in place pragmatic procedures for seed production to

maintain genetic integrity (Bradford 2006). All seed production carries the possibility of some amount of admixture, whether through pollen transfer or mechanical means. Once public breeders began to release improved crop varieties, it became evident that without a system to monitor and preserve the genetic pedigree and seed production conditions, the varieties quickly deteriorated. Volunteer plants from a previous crop, outcrossing, and mechanical mixtures in harvesting equipment and storage bins led to an increase in the presence of nonstandard material in seed varieties and a consequent erosion of their advantageous features. Poor-quality seed lots also often contained weeds and diseases, which were spread efficiently through planting contaminated seed.

Seed certification programs were initiated in the early 1900s to address this problem and are now active in the United States, most developed countries, and many developing countries. These programs typically use a pedigree system in which seed from the breeder is used to produce foundation or basic seed under stringent conditions. Foundation seed then is used to produce registered seed, which is used to produce certified seed that is sold to farmers for planting the commercial crop (AOSCA 2004; OECD 2004).

At each step, specific requirements must be met with respect to the previous crop history, the presence of noxious weeds, the occurrence of off-type plants not typical of the variety, isolation from other varieties of the same species to prevent pollen flow or mechanical mixtures, cleaning of harvesting and hauling equipment, and procedures in seed processing facilities to maintain the identity and integrity of the seed lot. Once a seed lot has passed the criteria for a specific class of seed, it can be labeled with a tag unique to that class to indicate that it is certified. These procedures ensure that farmers who purchase certified seeds are receiving the genetic variety they are expecting with low amounts of other crop seeds or weeds (Sundstrom et al. 2002). In the United States, seed labeling laws have been a primary means for growers to understand the quality of the product they are purchasing.

Despite these procedures and precautions, seed certification schemes and seed labeling laws recognize the impossibility of achieving zero-tolerance thresholds. As seeds are multiplied to increase their quantity for sale, it is increasingly difficult to eliminate every off-type or volunteer plant or every weed, so the standards for certified seeds are less stringent than for foundation seeds. Specific thresholds are established for each crop and type of undesired component, but it is expected that, except for prohibited weeds, there will be some amount of undesired components in the seed lot. The thresholds and standards have been established based on experience with the percentages of off-types that will affect the quality of the final product for its intended use.

Even the most stringent seed production schemes (e.g., hand-pollinated hybrid vegetables and flowers), however, cannot guarantee 100% genetic purity. Thus, even strict seed production systems could have difficulty meeting the EU product labeling standard for no more than 0.9% AP of biotech grain in the commodity (or 0.1% for unapproved traits) once biotech varieties are grown widely.

Presently, there are no thresholds for the allowable levels of biotech substances in seeds for planting. Some commodity buyers seek products that are completely free of detectable biotech elements but seem unwilling to pay what it costs to meet such criteria. It is evident that to meet such standards, high seed quality would be required. As biotech varieties become more widely grown and prevalent, occasional instances of small percentages of AP in conventional seeds likely will occur, just as certified seeds may contain small amounts of off-type seeds, as they always have (Jørgensen, Hauser, and Jørgensen 2007). Such AP already is occurring in EU seed sent to contra season (i.e., winter) nurseries that grow both biotech and nonbiotech trait seed (e.g., Chile). Thus, with a zero threshold for unapproved traits, the EU is becoming a closed loop, single-season region. This occurrence is expected and predictable and would not disrupt the marketing process for seeds if thresholds and tolerances were in place at levels that are standard in the industry for conventional seeds and crops.

Because seed producers are aiming for a higher-value market than commodity producers and also have to meet a higher standard of seed quality, historically they have assumed this responsibility for meeting their self-imposed standards by methods such as field isolation, buffers, planting dates, or harvesting and cleaning practices. In the instance of biotech crops, some markets have established criteria that are not necessarily tied to end-product requirements or to established thresholds.

Seed laws vary globally, however. In the United States, for example, once a trait is deregulated, the trait is treated like any other off-type. Argentina has a 1% threshold for biotech traits in conventional seed. The seed industry historically has worked within a market-established system that requires various standards of seed quality and has achieved these standards at some cost. In a recent study (Kalaitzandonakes and Magnier 2004), industrial/economic simulation models that used data from company records and practices of corn seed production facilities in the midwestern United States (and a repeated study in the EU) quantified the potential economic impact of complying with various AP threshold levels. Average per-unit costs were predicted to increase by 9, 27, and 35% to meet thresholds of 1, 0.5, and 0.3%, respectively. The authors concluded that, "In general, stricter regulatory standards and purity thresholds increase compliance costs at an increasing rate, yielding potentially large cost increases from even small changes in the regulatory standards."

Unrealistically strict standards, therefore, have the potential to disrupt both production and trade of seeds and agricultural commodities, with no counterbalancing benefit to health or environmental safety. Alternatively, establishment and widespread implementation of reasonable trait-based thresholds for the presence of approved

biotech varieties in conventional seed lots and commodities mostly would eliminate these additional costs and marketing issues without the need for expensive changes in production and testing practices.

Trade Implications

Asynchrony in obtaining regulatory clearances for biotech materials within the United States and import clearances in export markets can lead to market-driven concerns regarding the AP of these materials in commodities. Sometimes, the presence of biotech crops in commodity shipments to countries that have not approved those crops can result in the rejection of entire shipments and significant economic loss.

Biotech substances originating from products that are being field tested, but not yet approved for use in any country, are potentially even more problematic than products that have been approved in a limited number of countries. The detection of one of these genetic elements (even at extremely low levels) in international shipments can disrupt trade, as occurred for an unapproved herbicide-resistant biotech rice variety LL601 (Weiss 2006). On the other hand, field trials of unapproved biotech traits in the United States are conducted under notifications or permits using precautions to prevent or drastically decrease gene flow and are generally small relative to commercial plantings, adding an additional level of security that guards against such events.

The Canada and United States Bilateral Agreement on Agricultural Biotechnology (CFIA–HC 2001) seeks to harmonize regulatory requirements and the timing of approvals between these two countries. Approaches such as this represent a standard for harmonization that should be encouraged elsewhere. In the absence of a harmonized approval process, economic burdens of deploying biotech crops may be substantial when approvals are asynchronous, thus limiting the global acceptance of crop biotechnology. These economic ramifications may extend beyond private commercial enterprises to impact the vitality of U.S. agriculture widely.

International trade in seed and grain commodities is governed by phytosanitary regulations that impact the commercial movement of the commodity with respect to unintended trait presence. This impact is a special concern where standards are not well defined or are not scientifically supportable. Many countries have customer protection regulations that require varieties to meet performance standards. Those varieties that do are described, registered, and then eligible for certification. The United States has few regulations of this type.

The Organization for Economic Cooperation and Development certification process provides international mutual recognition of certification. These kinds of certifications are procedurally based and could serve as a basis for harmonization of seed and grain movement in a way consistent with the requirements of the International Plant Protection Convention (IPPC) and the World Trade Organization (WTO), the institutions in which trade and transport authority primarily resides.

Appropriateness of Thresholds and Trait Testing

The unavoidability of trace AP of biotech materials in commodities is a serious concern for international trade, primarily because internationally recognized thresholds for detection and standards for testing are lacking. Considering the potential for trade stabilization, establishing threshold levels for biotech materials seems appropriate and would be relatively straightforward when applied to approved biotech events.

As with other substances for which thresholds have already been established, these materials would invariably be present at low levels because they are typically the outcome of accidents and incidental commingling. Their precise levels would be known through scientifically validated sampling and detection methodologies that could and would be applied anywhere in the world, unlike previous testing methods that often have been inconsistent and had high error rates. Establishing thresholds could provide the regulatory system with a stable, constant, nonarbitrary test criterion or level for action.

The actual levels at which the thresholds would be set, however, could be the subject of considerable debate. In the postcommercialization setting, health and environmental hazards for approved events are not at issue. But excessively low threshold levels set for purposes unrelated to human health or environmental safety may lead to inordinately high compliance costs and a failure to meet obligations under existing international agreements such as the IPPC and WTO. The expense of recalls and refusal of shipments could be applied to the entire channel (exporter and importer), thus diffusing the costs borne by any one component of the system.

The complexities and costs of creating and implementing a viable threshold testing program for biotech materials would need to be considered in the context of existing practices in which minute levels of these materials can potentially halt international trade shipments. Development of harmonized standards and threshold levels for AP within commerce could help resolve substantial economic issues. As presently construed, however, harmonized standards would not account for the variation in national labeling regulations and expectations, as well as costs.

Other Cost Considerations

Regulations implemented to accommodate production of biotech and nonbiotech crops may lead to costly activities aimed at segregation and identity preservation (IP), which may affect the prices of nonbiotech as well as biotech commodities. Policy interventions sometimes may be more costly than the problem they aim to address. To be most useful, assessments of the cost of AP (or its gene flow component) under various policies should distinguish between the overall cost to society and the distribution of costs and benefits among individuals, and between the short- and

long-term impacts of the policy.

Regulations and liability rules may impose undue costs on producers and society without producing commensurate improvements in health or environmental safety. Additional costs from IP policies intended to achieve a 99% biotech-free standard of corn and soybean seed identity likely would include extra cleanup and care of planting and harvesting equipment and all modes of grain transportation, buffer zones between biotech and nonbiotech plants, dedication of separate grain paths for biotech and nonbiotech grain, and continuous testing and sampling for biotech residues. These IP costs for both crops would increase drastically as the required degree of seed identity/quality increases (Bullock, Desquilbet, and Nitsi 2000).

Other cost studies of IP also emphasize the importance of opportunity costs and other economic and business costs. The Maltsbarger and Kalaitzandondakes (2000) IP study of elevator operators distinguished between observed costs—coordination and segregation costs— and hidden costs—such as opportunity costs including underutilized storage, lost grind margins, and lost spread opportunities. This work included three case studies from Missouri and Illinois that showed the opportunity costs were at least twice as high as the observed costs. Baumel and McVey (2005) also stressed the high hidden IP costs of processing, shipping, and selling nonbiotech varieties, including both opportunity costs and extra risks.

In response to various economic realities it is expected, and has been observed, that certain regions will specialize in production of nonbiotech varieties, whereas others will produce mostly biotech varieties. When the varieties are separated physically, the IP costs decline substantially. Technological change and development of cheaper testing, communication, and product-tagging methods will decrease the cost of IP where several varieties are grown in the same vicinity. The IP cost increases as the standard of seed quality increases, and many producers may not be able to survive economically with standards higher than 99%. Uncertainty about future regulation also is a source of inefficiency, because farmers and shippers are unlikely to invest in upgrading their operations without knowing that it will allow them to reach target markets.

Mandatory labeling requirements may have a much stronger effect on the economics of biotech crops than IP costs do, but those requirements are not within the scope of this paper. If the segment of the population willing to pay a positive premium for nonbiotech products grows much larger than its current number, this increase could provide a future incentive for voluntary labeling of nonbiotech materials. In such instances, production and distribution of both biotech and nonbiotech products can be accommodated in the United States, Canada, and other countries (Carter and Gruere 2003). In Europe, mandatory labeling of biotech products limits their availability because retail chains are reluctant to be associated with those products. The results are losses in overall economic welfare due to efficiency losses in production and increased expenditures by consumers who cannot choose the less expensive biotech products (Moschini and Lapan 2005).

Although there are some direct costs of AP, most costs are associated with regulation that aims to control AP. These regulations increase the cost of operation of both biotech and nonbiotech production, as happens for IP regulation. They also decrease demand for biotech products, as occurs with the mandatory labeling of biotech products. One result of the increased cost and decreased demand for biotech products due to these regulations is that investment in biotech products is becoming less profitable.

One of the main impacts from a decrease of profitability is that the propensity to invest in new biotech products outside the major commodity crops is declining, which may lead to lower levels of adoption and introduction of the technology globally. It also leads to a decrease in the likelihood of discovery of second-generation products and delay of their introduction. Anderson and Jackson (2005) documented the large global potential of the current generation of biotech crops and noted that this potential is far from being used to the fullest at current adoption levels. Perhaps the main cost of the regulations to protect against gene flow is the retardation of the evolution and adoption of biotechnology in agriculture. No risk-reduction benefits have been identified to date that would warrant the cost of this regulatory compliance.

Emerging Policy Issues

The EU (Brookes and Barfoot 2004a; Messean et al. 2006) and the United States (Fernandez and Polansky 2006) recently have begun evaluating coexistence issues for production of biotech, nonbiotech, and organic crops. With respect to this paper, these issues particularly relate to (1) the economic consequences of AP of biotech crop material in nonbiotech crops, and (2) the principle that growers be able to cultivate the crops they choose (e.g., biotech, nonbiotech, or organic) once the crops have been appropriately approved as safe for consumers and the environment (Brookes and Barfoot 2004a).

An example of the potential preference for nonbiotech products can be found in the EU where market demand for nonbiotech soybean and maize is estimated to be 27 and 36%, respectively, of the total use of these commodities (Brookes and Barfoot 2004a). Demand or perceived demand for efficient segregation or IP of biotech or nonbiotech crops inevitably must be reconciled with the fact that, in any practical agricultural production system, AP of unwanted materials rarely can be avoided entirely.

Externality Problems

In an economic sense, AP problems can be considered production externalities, namely, the unintended outcomes of activities that may damage third parties. Government regulations or voluntary arrangements may emerge to control externality problems. Producers' behavior and market outcomes may be altered in response to these policies.

Government or collective actions may establish quality standards for biotech or nonbiotech products. Policy packages might regulate production practices and establish due care standards, liability assignments, and informational requirements.

Thresholds

Thresholds for the AP of a variety of unwanted materials have been set for nearly all agricultural commodities (e.g., in the EU, most cereals have a maximum allowable level of unwanted material such as plant material, weeds, dirt, and seeds of other crop species of 2%, yet the current legal labeling threshold established for biotech material is 0.9%) (Brookes and Barfoot 2004a). Recent investigations of unintended biotech trait presence in nonbiotech commercial seed supplies show less than 1% occurrence (Mellon and Rissler 2004). Protocols for seed and grain analysis for biotech trait presence have detection limits of less than 1%. As with any analytical methodology, there is a high incidence of false positives at or near the limit of detection (Kahlert 2006).

Parallel Use of Biotech and Nonbiotech Systems

The potential need for and feasibility of changing agricultural practices to facilitate parallel use of biotech and nonbiotech maize production systems in the EU have been evaluated recently by Messean and colleagues (2006). They considered three key sources of AP: (1) traces of biotech in nonbiotech seed or grain, (2) cross-pollination from nearby biotech crop fields, and (3) sharing harvesters between biotech and nonbiotech fields. Cross-pollination rates between biotech and nonbiotech maize fields were maintained at 0.9% or less with minimal preventive measures, but rates of 0.1% were essentially unachievable. Cross-pollination was considered the only AP source of biotech substances in nonbiotech maize fields used for seed production; thus, a 0.5 % threshold for biotech maize in these fields can be very difficult to achieve without using substantial isolation distances.

Isolation

Isolation of seed production fields to restrict inflows and outflows of pollen is a well-established practice (Bradford 2006). Physical means of confinement require strict attention to processes and appropriate levels of quality control and auditing to assure process compliance (Christensen et al. 2005). Although isolation and confinement processes can restrict pollen dispersal to very low levels, they cannot assure zero gene flow within the environment (Wolt et al. 2004). Collectively, this information points out the feasibility of coexistence between biotech and nonbiotech crops with pragmatic thresholds, as well as some practical constraints that will limit the ability to eliminate cross-pollination on a landscape level.

Recognition of Standards

In the United States, any policy for AP in seed should recognize the standards of current seed law and the sensitivity of analytical methods. U.S. Federal seed law mandates standards of seed quality. Foundation seed corn and certified seed corn must be 99.9 and 99.5% free of the unintended presence of visual off-types, respectively. Current industry practice for biotech crops meets or exceeds this standard through the use of quality control practices in prefoundation production (Mumm and Walters 2001).

A recent U.S. workshop addressing the coexistence of biotech, conventional, and organic cropping systems noted (1) "lack of standardized, internationally accepted marketing standards, testing methodologies, and protocols poses a significant challenge to the smooth and efficient operation of both domestic and international agricultural marketing chains" and (2) "Overcoming the challenges and capitalizing on the opportunities provided by fostering 'peaceful coexistence' will require a combination of market, research, and farmer-to-farmer communication and Federal, state, and local government efforts" (Fernandez and Polansky 2006).

Policy Development

Biotech crops have been adopted widely both in the United States and internationally. From the perspective of regulation within the United States, if approvals for environmental release of a biotech crop are in place, there is a tolerance for the biotech material; therefore, presence in food is not a safety concern. Additionally, if the USDA has deregulated the biotech crop, the commercial production of seed can take place. Unevenness in the pace and nature of regulatory approvals in export markets can be an economic concern for international trade in biotech crops that are approved and grown in the United States.

Policies to address the consequences of crop-to-crop gene flow and more common forms of AP should, to the extent feasible, encourage coexistence of biotech and nonbiotech crops. Considerable resources within the United States are applied to confinement and channeling of food products to avoid market rejection due to unintended presence of biotech elements. This suggestion in no way implies that the USDA and other agencies should wait for all trading countries to approve biotech crops before approving them domestically. Such an approach would require extensive and potentially costly changes in regulatory policy that will not happen in the near future. Development of viable policies and processes should also be considered through consultation of alternative vehicles, such as the International Plant Protection Convention.

Illegal Planting

Another emerging policy issue is illegal planting of biotech crops in other countries and the implications this activity might have on AP. Glyphosate-resistant soybean was the most egregious example, but now there are reports of soybean in the Ukraine and cotton in other countries, as well as a lack of law enforcement to deal with illegal uses in much of the world. Thus, the United States should be encouraged to develop a workable policy for this type of AP, because crops from

other countries may soon be coming to the United States with low levels of biotech AP.

Brookes and Barfoot (2004a) have concluded that "Evidence to date shows that GM crops growing commercially in the EU and in North America have co-existed with conventional and organic crops without economic and commercial problems—only isolated instances have been reported of AP of GMOs occurring in organic crops, even in North America where GM crops dominate production of soybeans, maize and canola." (Note: in this context, the terms GM or genetically modified and GMO or Genetically Modified Organism are synonymous with biotech crops.)

Brookes and Barfoot (2004a) further indicate that for the future in the EU, "The likelihood of economic and commercial problems of co-existence arising remains very limited, even if a significant development of commercial GM crops and increased plantings of organic crops were to occur. Therefore if highly onerous GM crop stewardship conditions are applied to all EU farmers who might wish to grow GM crops, even though the vast majority of such crops would not be located near to organic-equivalent crops or conventional crops for which the non-GM status is important, this would be disproportionate and inequitable. In effect, conventional farmers, who account for 99.59% of the current, relevant EU arable crop farming area could be discouraged from adopting a new technology that is likely to deliver farm level benefits (yield gains, cost savings) and provide wider environmental gains (reduced pesticide use, switches to more environmentally benign herbicides, reduced levels of greenhouse gas emissions)."

Summary

Gene flow between biotech and nonbiotech crops and their relatives occurs commonly in nature and is not an inherently adverse phenomenon. The potential for pollen-mediated gene flow varies by crop species and is largely determined by the reproductive biology of the plant. Crop species that readily cross-pollinate generally are more prone to gene flow than those that primarily self-pollinate. In addition, only a small fraction of the most important world food crops are genetically compatible and geographically collocated with the world's most damaging weeds, thus gene flow hazards are largely restricted to specific locations.

Gene flow often is a subcomponent or contributor to the much broader and unavoidable phenomenon of adventitious presence in crop production and marketing. Gene flow may contribute to or initiate an AP concern, but AP occurs at many points in the agricultural system due to technical limitations, biological realities, commodity handling systems, and, sometimes, human errors.

Hundreds of useful traits are being introduced into crops using traditional breeding methods as well as biotechnology. Most of these traits are benign to humans and the environment, although some biotech traits in plants (e.g., pharmaceutical or industrial proteins) warrant special precautions. Additionally, promising molecular containment and mitigation strategies are being developed, which should be especially useful for biotech crops used to produce materials such as nutraceuticals or industrial chemicals requiring added safety or isolation procedures. A combination of these practices can help maintain appropriate identity standards in seed and commodity production systems. More restrictive standards may not be economically or practically feasible.

Economic and commercial implications of gene flow are exacerbated by the lack of established thresholds for biotech presence in nonbiotech products. Such trait thresholds in commodities or other commercial products could be valuable tools to facilitate parallel, economically viable practices of biotech, nonbiotech, and organic crop production systems. Realistically achievable thresholds for biotech substances in commodities (and/or seeds) should be established to facilitate long-term coexistence of biotech and nonbiotech or specialty crop systems.

As the number of acres planted to biotech crops increases and the discussion of gene flow from biotech crops continues, several new policies may emerge that would impact the production of biotech, nonbiotech, and organic crops—policies regarding externality problems, thresholds, parallel planting systems, isolation fields, seed law standards, and illegal planting. Global harmonization of regulatory approval could be extremely beneficial to the optimization of crop biotechnology.

To date, there have been no major health or environmental setbacks due to gene flow from biotech crops. In fact, these crops have led to significant, documentable improvements and, in some instances, decreased risks.

Efforts are needed to facilitate public understanding of gene flow as only one component of AP of biotech commodities, which are shipped throughout the world and used for processing and consumption, and the distinction between this scenario and the AP of biotech seeds used for planting. Education addressing the realistic advantages and challenges of continued development and commercialization of biotech crops, as well as nonbiotech crops, will be a key to public understanding and discourse related to future policy issues for biotech crops.

Glossary

Adventitious presence (AP). Unintended, technically unavoidable presence of biotech material in an agricultural commodity used for food and, in some instances, other end-use purposes.

Breed true. Normal reproductive outcome for self-pollinating crops in which plants produce offspring with the same traits (or of the same variety) generation after generation.

Classical breeding. Manual crossing, carried out by breeders, between different varieties or lines of the same crop.

Dicotyledonous. A subclass of flowering plants in which germinating seeds produce two seed leaves or "cotyledons" (e.g., broadleaved plants such as soybean, cotton, and canola).

Exogenous. Introduced from or produced outside the organism or system.

Gene flow. Successful transfer of genetic information between different individuals, populations, and generations (to progeny) and across spatial dimensions.

Germplasm. A collection of genetic resources for an organism. For plants such as corn or rice, the germplasm typically is maintained and stored as a seed collection.

Hectare (ha). Land area equal to 2.47 acres.

Hybridization. Breeding plants of different varieties or species.

Induced mutagenesis. Introduction of desirable mutations in crop seeds through brief exposure to chemicals or radiation.

Input/output traits. Traits introduced through genetic engineering to facilitate decreased amounts of agricultural inputs (i.e., chemicals required for control of insects/diseases/weeds)/those traits targeted directly toward consumers or downstream processors by enhancing the quality of the food and fiber products they use.

Monocotyledonous. A subclass of flowering plants in which germinating seeds produce one seed leaf or "cotyledon" (e.g., grass plants such as wheat, rice, and corn).

Mycotoxins. Toxic substances produced by fungi.

Open-pollinated. A reproductive strategy in which plants release pollen into the environment to ensure cross-pollination.

Outcrossing. A process by which plants whose flowers are not primarily self-pollinated tend to disperse pollen widely so that pollen produced by one plant can readily fertilize flowers borne on other plants.

Output traits. *See* **Input traits**.

Phenotypic characteristics. Observable physical or biochemical characteristics of an organism, determined by genetic makeup and environmental influences.

Selection pressure. A process by which favorable traits that are heritable become more common in successive generations of a population, and unfavorable traits become less common (e.g., repeated application of a herbicide to a plant population containing some individuals that are resistant to the herbicide creates a selection pressure in favor of individuals possessing the resistance trait).

Shattering. Mechanism of seed dispersal by which seeds become disconnected from the seedhead at maturity and are free to fall to the ground. Shattering in weed species is often high, whereas crops often are bred for reduced shattering.

Volunteers. Crop plants produced from seeds that remain on or in field soil after harvest operations.

Wide crossing. Breeding technique in which an agronomically adapted variety is crossed with an unadapted relative to transfer a desirable trait into the adapted variety.

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