Maize and Biodiversity: The Effects of Transgenic Maize in Mexico

Chapter 2

Understanding Benefits and Risks

for the Article 13 Initative on
Maize and Biodiversity

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2.1 Introduction

In 2001, two University of California professors published a scientific paper alleging the introgression of transgenes into Mexican land races of maize (Quist and Chapela, 2001). Although the paper became the subject of an extended controversy in its own right, its publication and the ensuing debate highlighted the possibility that genes and genetic constructs (or more technically *nucleotide sequences*) introduced into maize varieties through genetic engineering could integrate into the gene pool of Mexican maize land races, the genetically diverse varieties of maize developed over centuries of farmer trial and error. The Mexican government had placed a moratorium on commercial varieties of genetically engineered (or *transgenic*) maize in 1998. Nevertheless, between ordinary commerce across the U.S.-Mexico border, informal seed exchange and transport, and tons of U.S. grown transgenic maize being shipped into Mexico for animal feed, there were opportunities for land races to come into contact with transgenic maize. One cannot rule out the possibility that either through deliberate action by Mexican farmers or through inadvertent movement of genes in the environment, transgenes might become established within the gene pools of Mexican land races.

The stakeholders that would be potentially affected by such an event (as well as by attempts to prevent it) are diverse and complex. First there are the farmers and farm communities that grow these land races. Maize cultivation and consumption is a cornerstone for their economic livelihood and for their cultural identity. Was it possible that transgene introgression could threaten their way of life? Next, there is the diversity of these land races itself, widely regarded as a resource for future generations' ability to continue genetic improvement programs in maize, such as finding genes essential to combating disease, increasing yield, and solving other production problems in commercial maize production. And of course there are maize consumers, who may be understandably alarmed by the sheer volume of controversy over transgenic maize and personal beliefs about the risks and benefits of genetic engineering. Beyond these, there are large scale farmers in the U.S., Canada and Mexico who might find transgenic varieties valuable improvements to existing production challenges, but who might be adversely affected either by certain regulatory responses, by the potential to lose export markets, or by the controversy itself. There is also the biotechnology industry, which seeks a favorable reception for its products, and especially the major firms marketing transgenic varieties of maize such as Monsanto and Pioneer Hi-Bred. There are other members of the public interested in the controversy as an episode in a more complex and over-arching debate over the future of genetic technologies. And there are broad trade-related interests that might potentially be affected to the extent that this controversy becomes a model for resolving cross-border environmental disputes in a globalized economy.

This chapter provides an introductory overview of concepts and terminology for reviewing the potential risks and benefits associated with transgenic crops, as well as a general discussion of how these risks and benefits might figure in framing and interpreting the current situation by farmers, consumers, industry, government, indeed by any affected party. More discussion of these risks and benefits follows in latter chapters of this report that discuss the nature of both positive and adverse outcomes in biological, social and economic terms, and that describe some of the mechanisms that determine how and outcomes of any kind are likely to materialize. Chapter 8, in particular, includes a more detailed discussion and development of a conceptual framework for evaluating risks and benefits as they might affect farmers, consumers and others relating to possible transgene introgression into land races in Mexico. The current chapter intentionally does not discuss empirical findings relevant to biologically or socially based risks and benefits from transgenic crops, much less with respect to the likelihood that either beneficial or harmful outcomes will materialize in the present case. This chapter serves a general introduction to the consideration and debate of environmental and social impacts associated with genetically-based agricultural technologies.[1]

Agricultural technology of all kinds is used in producing food and fiber, and the primary rationale for developing new agricultural technology derives from the obvious benefit that human beings derive from the reliable availability of food and fiber commodity goods. Over the centuries, new tools and farming methods have affected humanity's access to food and fiber goods in innumerable ways, though it is difficult to disaggregate impacts associated with technical improvements in transport and public health from those associated with agricultural technology proper. Yields from basic food crops have increased, leading to more reliable food supply and lower prices for consumers. Technical strategies for avoiding catastrophic crop losses have been developed. Agricultural technologies have also reduced the amount of human labor needed to produce crops and animals, or have made farm work more safe and less onerous. Frequently, new agricultural technology has been developed to ameliorate residual problems created by a previous generation of technology that had been adopted because it was thought, on balance, to improve food and fiber production.

It can be exceedingly difficult to reach consensus on the net social value of changes in agricultural technology, even when such changes are in the past, their effects are generally known and there is substantial agreement on the facts. As the 2002 report of the National Research Council *Environmental Effects of Transgenic Crops* notes,

> *Some U.S. citizens see the last 50 years of the twentieth century as a time when hundreds of years of insecurity over food availability came to an end. In their eyes, innovative technologies such as plant breeding, water management, fertilizers, and synthetic pesticides played a heroic role in this drama. Others look back on the same events and see an era when for the first time in history human activity threatened the basic stability of global ecosystems on which all life, including human society, depends. In their eyes, modern agricultural science and technology are inimical to the natural environment.* (NRC, 2002, p. 17)

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[1] Throughout this chapter, the term *agricultural biotechnology* will be used to indicate the new generation of reproductive technologies that are based upon the discovery and characterization of recombinant DNA. These include methods for sequencing and manipulating DNA, somatic cell nuclear transfer (or animal cloning), microinjection for genetic manipulation of animals, and the use of agrobacter tumiferens and ballistic methods of introducing nucleotide sequences into plant genomes. Plants or animals developed using recombinant methods for introducing nucleotide sequences will be described as *transgenic* without regard to the source of these sequences. The term *transgene* will be used to refer to the nucleotide sequences so introduced without regard to whether these sequences code for proteins or perform regulatory functions, or indeed whether they are functional within the transgenic organism in any way.

Unlike some of the technologies mentioned in the NRC report, the development of recombinant DNA techniques to introduce nucleotide sequences into the genome of agricultural plants and animals (i.e., *genetic engineering* or *genetic modification*) has been accompanied by significant debate over the wisdom of adopting such plants and animals for agricultural use. A significant component of this debate focuses on the likely consequences that production and consumption of such plants and animals will have. [2]

2.2 The Products of Agricultural Biotechnology

Although there has been extensive research and development of both microbial and animal applications of recombinant DNA, the focus will here be limited to plant biotechnology, with emphasis on products of greatest relevance to the Mexico. So far, both public and private research organizations have developed, patented and in many cases marketed a large number of laboratory and crop development techniques using recombinant DNA, including methods for introducing and controlling gene products within plant systems, as well as a number of nucleotide sequences that may be introduced into future agricultural crops. This report is primarily concerned with *transgenic crops,* that is, crops that have developed for agricultural production using rDNA techniques for insertion of genes and accompanying regulatory DNA. Two of the most widely discussed transgenic crops, infertile (or so-called "terminator") seeds and Vitamin A enhanced (or "golden") rice have not been and may never be released for use by farmers. Transgenic crops currently being grown for commercial purposes include virus resistant varieties of squash and papaya, as well as a few crops (including maize) that have been developed to produce products for use outside the food chain. However, the majority of transgenic crops currently in production have been developed for resistance to the chemical herbicides glyphosate (e.g., RoundUp) or glufosinate, or incorporate versions of bacillus thuringiensus (Bt) genes, which produce toxins that control infestations of caterpillars (but are not toxic to other species).

Herbicide tolerant varieties have been released by both public and private laboratories in a number of agricultural crops, including soy, cotton, canola and flax. Bt has been studied in a number of crops, but commercial applications currently in production are almost exclusively in maize and cotton, and are offered for sale by for-profit companies. The case at hand focuses primarily on Bt maize, a crop that is currently estimated to make up approximately 40% of U. S. maize production. Transgenic varieties

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[2] In general, to regard an event or outcome as advantageous is to think of as *beneficial*, and the specific ways in which it creates advantages or rewards constitute the *benefits* of technology that leads to said outcomes. The terminology for characterizing adverse or disadvantageous outcomes is more problematic. One option favored in economics is to characterize adverse outcomes as *costs.* This use suffers from strong association with monetary payment, so that by common convention the cost of a good is the monetary price that someone pays to acquire it. Another option favored in ethics is to describe adverse outcomes as *harms*, but this terminology may imply more particular or severe forms of adversity (such as physical pain or emotional suffering) than is warranted in discussing the impacts of technical change. Another convention is to contrast benefits with *risk*, implying that all adverse outcomes can be characterized as forms of technological risk. This terminology suffers both from the problem that some forms of risk are not regarded as adverse (for example, thrill-seeking and certain investment activities), and a more specific problem discussed below in connection with a standard risk analysis distinction between hazard and risk. This terminology choice is not resolved in the report and readers are advised to note that the precise meaning of such terms will depend partially on context.

of maize have also been developed for herbicide tolerance and for production of biologics (biologically active substances used by industry) and drugs. Although these varieties are in current production, acreage is small they have not been released for adoption by farmers. The pharmaceutical and industrial substances produced in maize crops are not approved for use in food, and the production of these crops is tightly controlled by the regulatory agencies.

In the future, transgenic crops may be developed for a large variety of purposes, including enhanced nutrition (such as golden rice), enhanced flavor or cooking characteristics, altered flowering control, disease resistance, and tolerance to soil and climate variations. However, many of the products expected to be placed in commercial use during the next decade will not be intended for use as human food or animal feed. These include more pharmaceutical or biologic producing crops like those discussed above, as well as crop varieties (including maize varieties) developed primarily for conversion to fuels. Some, but not all, of these non-food crops will need to be carefully segregated from the human food system. Many of these crops developed for pharmaceutical or industrial products will not be released as commercial varieties available to farmers, but fuel crops will have a large acreage (NRC, 2002).

2.3 Using Science to Understand the Impact of Transgenic Crops

The subsequent chapters of this report discuss the role that biological and social sciences can play in clarifying the consequences that using transgenic crops will have (that is, the quality and relative importance of both advantageous and adverse outcomes), as well as the likelihood that such outcomes will, in fact, occur. Predictive applications of science are fraught with many sources of uncertainty. Models or data for estimating the probability of an event may be incomplete. Even when this is not the case, the accuracy of predictions is subject to statistically measurable margins of error, and there can be differences of opinion about how such margins of error should be reflected in reporting the likely consequences of transgenic technology. Additionally, there remain large areas of ignorance in any attempt to predict outcomes, areas where science may simply not be capable of conceptualizing, much less anticipating an entire class of possible events. Differing views about how to respond to such uncertainties can lead to dramatic differences of opinion about what science can and cannot say about the likely consequences of agricultural biotechnology.

Other value judgments can be implicit within scientific characterizations of risk and benefit. For example, there are cases where an outcome that is advantageous to one person or group is disadvantageous for others; hence there may be no neutral or objective way to characterize such outcomes as either beneficial or harmful. There are also straightforward disagreements about what should be counted as helpful or hurtful. This may, for example, be the case with respect to the simple occurrence of transgene migration. Is a transgene “in the wrong place,” (e.g., anywhere beyond the crop into which it was deliberately introduced) already a harmful event, or does harm occur only when that transgene is maintained in a population, or has demonstrable adverse impact on human or non-target species? This is not the sort of question that the biological sciences are equipped to answer. Yet any attempt to use science in anticipating the consequences of technology demands some sort of provisional stance with respect to which outcomes are worth predicting. As such value judgments are always implicit even within the most neutral or scientifically objective attempts to characterize benefit and risk. With these qualifications in mind, the balance of this chapter attempts to provide a broad catalog of the ways in which agricultural biotechnology might be regarded as beneficial, on the one hand, or risky, on the other (Lynn and coauthors, 1998).

Over the past twenty-five years, the multi-disciplinary field of risk analysis has evolved to improve scientific methods for anticipating and managing unintended and unwanted outcomes of many kinds. A fairly standard approach to risk assessment has emerged within this field. This approach has been valuably applied to a variety of societal and scientific issues such as the one under consideration of the impact of transgenic maize in Mexico. Although the main elements of risk assessment are widely accepted, there are some variations in the stages of this approach reflecting the particular problem to be studied, as well as some variations in terminology that can be a source of confusion. In the present case, assessment of risks associated with the introduction of transgenes into Mexican land races can be usefully framed as a three stage process consisting of *hazard identification, risk measurement* (or risk quantification), and *risk management*. It will also be important to identify processes of *risk communication* that should be conducted throughout the entire process of risk assessment. It will be useful to provide a short discussion of how each of these four elements are to be understood in the present case (see NRC, 1983).

Hazard identification includes a characterization of the forms of danger, harm or injury that may be associated with the agent or activity in question, as well as a characterization of the features thought to have the potential to cause danger, harm or injury. With such a characterization in hand, it is possible to use a variety of scientific techniques to determine how likely it is that danger, harm or injury will actually materialize. Studies intended to assign or describe the probability that unwanted events or harms will actually occur represent the **risk measurement** phase of risk analysis. In describing these two activities as distinct phases of risk assessment, risk analysts make a key distinction between *hazard* or the potential for danger a harmful or injurious outcome, and *exposure*, or the sequence and combination of events that transpire in order for that potential to be realized. *Risk* is thus said to be a function of hazard and exposure. Thus, being ill with a cold is a hazard of the winter season, but this hazard materializes only when events such as being in the presence of a rhino virus occurs in conjunction with vulnerabilities in the immune system create exposure to this hazard. The risk of a cold is reflects both the degree and seriousness of the hazard, as well as the likelihood that the hazard will materialize.

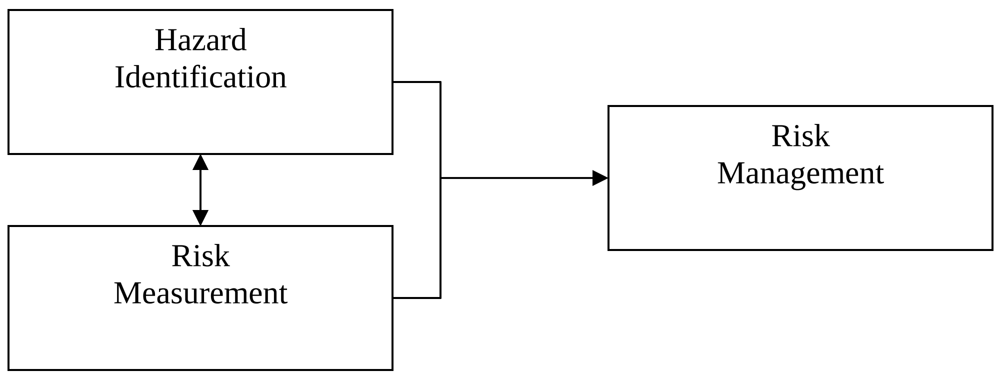
The process of attempting to measure the probability of harmful or injurious impacts often gives rise to the recognition of new hazards, unanticipated in the early stages of risk assessment. As a result, there is typically a process of iteration between the stages of hazard identification and risk quantification. Subsequent chapters will discuss elements of hazard identification and **risk quantification** in more detail, and will provide elaboration of each with respect to introgression of transgenes into Mexico. For present purposes, the key point to note is that simply because one has identified a hazard—a possible adverse or unwanted outcome—one has not necessarily identified a risk. Risk implies an estimate of both hazard and exposure (NRC, 1983).

Risk management is the process of deciding what to do about risks. The fact that a risk exists does not necessarily imply that anything should be done about it. Some risks are simply tolerated or accepted as a component of daily life. If there is a decision to take active steps in response to risk, a number of options are available. Government agencies may take direct regulatory action to reduce the likelihood of harm or damage, or they may use strategies that empower private actors to do this. Policies that help industry or farmer groups to cooperate in risk-reducing activities (such as voluntary bans on the sale or use of given substance) or that provide reliable information through standardized product labels are examples of the later strategy. It is possible to manage risk through insurance schemes that compensate those who experience damages. Many factors influence risk management, including the distribution of risk and benefit, the ability or risk bearers obtain information and voluntarily accept or reject risk, as well as societal and cultural values that make certain types of risks (e.g. catastrophic or irreversible risks) seem more worthy of active management than others. It is also important to place risks into a comparative context, so that one can be confident that steps to mitigate one risk do not create even greater risks from another source (Sunstein, 2002). For example, minimizing risk from biotechnology could lead to greater use of agricultural chemicals. If this were the case, a comparison of the relative risks of these two options is needed in risk management.

Risk management may also involve weighing the risks associated with an activity such as the release of any given transgenic crop against the benefits of release (see, for example, EPA, 2000). Thus some applications of risk assessment may add an explicit phase of *benefits assessment.* Like risk, benefits have two dimensions, the added or positive value associated with a possible outcome or state of affairs, and the probability that this value will actually materialize if a given course of action is taken. As the concept of risk implies a value judgment, so does the concept of benefit. As such, benefits assessment, like risk assessment, cannot be construed as a purely scientific activity. Methods for estimating economic benefits associated with agricultural production technologies have been used for many years, and can be applied to the assessment of farm profitability as well as to returns to food and fiber consumers (Rossmiller, 1978). These methods have been developed independently from risk assessment, and are frequently represented within an alternative framework for considering net social impact in which benefits are compared to costs. Methods for estimating environmental or social benefits are considerably less well developed. While risk management frequently does weigh benefit against risk, it is fair to say that the formal integration of benefits assessment into the risk assessment framework is less standard than the other four components.

Risk communication refers to a number of interactions that risk assessors and risk managers undertake throughout the process of analyzing and managing risks. Experience has shown that public policies for managing risk often go awry because of poor communication with the broader public. There are a number of junctures in the process of identifying hazards, quantifying risks and developing risk management strategies where public input may be valuable. For example, it will be important to be sure that the assessment process does not neglect hazards that may be very obvious to affected parties, but unknown to technical experts who may have little knowledge of local circumstances. Such detailed knowledge of local farming methods or market structures will also be critical in the process of quantifying risks. Finally, risk assessment processes that appear to take place entirely behind closed doors can provoke anger and mistrust. Risk management strategies that neglect the role of public involvement can backfire, creating a greater perception of risk than ever before (NRC, 1997). This report and the associated public comment period and public symposium are, in themselves, part of the iterative process of assessing and communicating the risks and benefits of a technology.

The stages of risk assessment are sometimes represented in a sequential fashion, so that hazard identification and risk measurement are described as initial, scientific stages in the process that provide information to be used in risk management.



While this representation provides insight into the underlying logic of risk assessment, it can be misleading, especially if “risk communication” is added as a fourth box emerging from “risk management.” In fact, risk management decisions can be undertaken with no formal processes of hazard identification or risk measurement, especially when uncertainties or the costs of acquiring such information are judged to be excessive. Furthermore, risk management processes penetrate into hazard identification and risk measurement, especially with regard to establishing priorities for which outcomes and exposure pathways are important to investigate. Placing “risk communication” at the end of this process can convey the impression that communication is a one-way process whereby experts inform the public about risks. In fact, obtaining information from practitioners and affected parties is often a critical component of the other three phases of risk assessment. It is only in a few well-structured regulatory agencies operating under clear legal mandates stipulating which risks are actionable that risk assessment can be characterized as sequential activity of research into hazards and exposure followed by management decision making and finally by dissemination of information. In fact, each phase of risk assessment is typically conducted in an iterative dialog with the other three. In situations such as the case of transgenic maize where there is little agreement on priorities and problem identification, the distinction between one phase of risk assessment and another has less to do with the temporal sequence for conducting these activities than with the different tasks and methods appropriate to each. With these qualifications in mind, the diagram provides some insight into the underlying logic of risk assessment and its role in decision-making.

The framework for considering risks and benefits as applied to transgenic crops and Mexican maize is developed in some detail in Chapter 8. The balance of this chapter provides a general discussion of benefits and risks that have been associated with agricultural biotechnology both through scientific studies and through processes of public discussion and debate. The chapter concludes with a brief review of some alternative philosophies for managing the risk benefit trade-off.

2.3 Benefits of Agricultural Biotechnology

As noted above, agricultural technologies are developed as a means to improving circumstances for at least some human beings, most frequently those involved either directly or indirectly in their development. Biotechnologies, including transgenic crops, are not exceptions. But technologies can also have both collateral benefits (e.g. benefits the were foreseeable but were not motivations for developing the technology), as well as wholly unforeseen and unintended benefits. Agricultural technologies are used in producing food and fiber commodities, which have use value to consumers. The value that people deriving from eating food and from using plant fibers in clothing and other materials represent the most basic benefits associated with agricultural production. Some farmers, including many Mexican farmers, produce crops with these immediate use values directly in mind. Nevertheless, the most immediate benefit that most North American farmers derive from cultivating crops is income, and this is also true for the owners and employees of firms that supply commercial agriculture. The current generation of transgenic crops has been developed as a source of income for private corporations and their stockholders. Research and development officers at agricultural chemical and seed companies foresaw an opportunity to develop products, such as herbicide tolerate or pest-resistant (Bt) crops, and expected that these products would be purchased by commercial farmers who were already their customers for seeds, chemical fertilizers and pesticides, and other products used in agricultural production. Developing these products was projected to generate profits for the companies, as well as furthering other business objectives such as maintaining market share. Profits from the sale of transgenic seeds generate further benefits to the shareholders in these companies in the form of dividends and increased stock value. Farmers in turn were expected to purchase transgenic seeds because such seeds provide more cost effective ways for them to achieve production goals such as weed and insect control. The role of transgenic seeds in helping farmers achieve these production goals represents benefit to farmers who adopt the technology. Depending on other economic circumstances, achieving such goals in a cost effective way can also help these farmers maintain or increase their own profitability, which provides the link to farm income.

The current generation of transgenic seeds was not expected to create direct benefits for consumers of agricultural products in the form of improved quality or other advantages that would be evident at the point of consumer purchase. Technologies that increase producer profitability often do so through reducing production costs, and throughout the 20th century, a drop in farm prices and a decline in food costs have typically followed reductions in production cost for agricultural commodities for food consumers. There is some long term potential for agricultural biotechnology to achieve increases in the cost-efficiency of farm production that would be passed on to consumers in the form of lower prices for food and fiber commodities. The net value of these benefits to consumers could be quite large, though given the relatively small role that on-farm production cost place in the off-the-shelf price for food and fiber goods, these benefits may not be perceived as significant by consumers or may not be measurable in the retail price (Moschini, 2001).

In addition to the above benefits to farmers and to the developers of transgenic seeds, collateral environmental benefits were anticipated in the form of reduced use of agricultural chemicals, both in total volume and with respect to the overall toxic burden of chemicals on the environment due to a substitution of relatively less damaging substances. A recent meta-analysis of multiple studies concluded that total pesticide use reduction have occurred for U.S. production of cotton and soybeans, though results for maize are more equivocal (Carpenter and coauthors, 2002). It is, perhaps, too early to know whether unforeseen benefits may arise in conjunction with first generation products from agricultural biotechnology. Such benefits are by their very nature unlikely to evident until after technologies have been in use for some time. One example of a possible unforeseen benefit from Bt maize is speculation that Bt maize varieties may be more resistant to aflatoxin infestations (Brown and coauthors, 2003), though at present the reasons why this might be the case are unclear. Such environmental benefits may be valued by society as whole, communities adjacent to agricultural lands, and by the farmers who regard themselves as long-term stewards of the land.

Future products from biotechnology will be developed with a host of applications, with potential benefits that extend well beyond those of the current generation. Products currently being researched include those like Bt maize and herbicide tolerant crops whose benefits would largely arise through improvements in production practice such as drought or salt tolerance, more controlled flowering times, and various forms of pest and disease resistance. In addition, a number of crops are under development that would have benefits directly to consumers in the form of enhanced nutrition, or other product quality traits (including taste and appearance) that might be deemed benefits for consumers. Finally, transgenic crops that are being developed to produce non-food products, including industrial biologics, pharmaceuticals and altered-composition plants for use as fuels are projected to have significant effects on production efficiencies for these industrial products and should produce price benefits for consumers.

2.4 Environmental Hazards and Today's Transgenic Crops

In the present context, an environmental hazard is an unintended event regarded as adverse to the environment, as distinct from harm to human health or from socio-economic impact. Some possible impacts on the ecosystem from transgenic crops are not adverse. As described above, if adoption of a transgenic crop allowed for a decrease in the net application of toxic chemicals for pest protection, this impact would not (all things being equal) be regarded as adverse. Other possible impacts might be adverse but would not be regarded as unintended. A transgenic crop that extends the temperature range at which a plant such as soybeans can be planted will very likely displace other types of land use that might be environmentally preferable. Such intended impacts from agricultural production are not typically characterized as environmental risks.

For convenience, environmental hazards can be classified into two fairly comprehensive categories: *loss of or reduced ecosystem functioning* and *decreased biodiversity*, including genetic diversity. Loss of or reduced ecosystem functioning refers to effects on key ecological processes such as soil, water and nutrient cycles. Affects on microbiota or on the mix and complexity of organisms that altered soil formation would be one example of such an impact. Dramatic changes in water use might be associated with any number of possible transgenic modifications, and might affect rates of salinization or the availability of water for other organisms in the environment. The category of decreased biodiversity includes a wide array of possible affects on non-target organisms that register as changes in the number and composition of organisms within an ecosystem. Such effects include toxicity to beneficial insects, loss or contamination of food and water supplies to wildlife, and displacement of either flora or fauna as a result of invasive properties that might be associated with a transgenic crop or with a wild relative affected by transgene migration. In addition, any decline in the genetic diversity within land races or within wild relatives would be regarded as an adverse effect on biodiversity. These effects may be direct or indirect. A direct effect may be an environmental toxicity from the transgene whereas indirect effects may be that the introduced trait leads the farmer to destroy more forest or consume more water (Snow and Palma, 1997; Kareiva and Marvier, 2000; Wolfenbarger and Phifer, 2000).

For completeness, it is important to reiterate that there is also the potential for offsetting environmental benefits that correlate with each of these categories of environmental risk. Thus, just as a transgenic crop poses a hazard with respect to biodiversity, it may also create the possibility of an increase in biodiversity, if for example, the introduction of the transgenic crop leads to a substantial reduction in the amount of land planted under very intensive production systems that provide relatively few opportunities for non-crop organisms to thrive. One measured impact of the herbicide-tolerant crops, is an increase of low-till and no-till farming that increases soil organic matter and in-field and off-field biodiversity.

Before any of these hazards can be conceptualized as a risk, it is necessary to stipulate and then measure the likelihood associated with any sequence of events leading to the realization of a hazard. Subsequent chapters will provide a much more detailed discussion, but it is useful to indicate three pathways that such a sequence of events would follow. The first of these begins with intentional release of the transgenic organism. What would follow from this is the introduction of transgene products into the environment at a rate that should be fairly straightforward to calculate. This provides the basis for anticipating phenomena such as toxicity and bioaccumulation that would be expected as a direct but unintended result of the introduction of gene products into the environment. A second possible route for exposure is associated with invasive, volunteer transgenic organisms. Invasives include crop plants originally introduced by farmers but capable of reproducing and spreading without cultivation, and also plants that are introduced into environments inadvertently through shipments or other movement of seed and grain. Invasive volunteers might lead to forms of toxicity and bioaccumulation, much like intentional introductions. They might also lead to unintended displacement of a species or community and subsequent effects on biodiversity. The third exposure scenario involves introgression of transgenes into feral populations or wild relatives. These feral populations might then become invasive, leading to displacement of a species or community, exposure to a hazard if there is toxicity, decreases in genetic diversity (Wolfenberger and Pfifer, 2000).

Exposure pathways for indirect effects are exceedingly complex. For example, it is possible that introduction of transgenic crops could be an important element in a scenario leading to greater use of chemicals, habitat conversion and agricultural expansion. Here, the environmental impacts would only indirectly be associated with a specific transgene, yet the net environmental affects from such scenarios might be much more significant than those associated with more direct impact. Quantification of such risks is a difficult and daunting task.

2.5Public Health Risks

As distinct from environmental risks, public health risks are those that can adversely affect human and animal health. At this juncture, the most likely exposure route for such risks is through human animal consumption of foods from transgenic crops. Although there has been a strong consensus on the safety of known gene products in transgenic crops developed for pest resistance (e.g. Bt crops) and for herbicide tolerance (Texas Medical Association, 2002), there continues to be debate about the possibility that gene introductions may have led to unanticipated gene products, for which the safety is largely unknown (VIB, 2001). In addition, the adoption of transgenic crops may lead to a change in farmers' use of chemical inputs. Such change may be beneficial to public health, if the overall pattern is one of reduced chemical use or the substitution of less toxic for more toxic substances. However, the causality is complex and there can also be increases in chemical use, or changes in the pattern of use that may increase exposure to humans and other animals. Phenomena such as competitive changes in the pricing of agricultural chemicals may lead farmers *not* adopting the transgenic crop to actually increase their use of relatively more toxic chemicals.

Finally, it is important to note that the use of transgenic maize as a platform for the production of non-food substances intended for pharmaceutical or industrial use poses a new class of potentially serious food safety hazards. The likelihood that such hazards will materialize may be very low, especially if plans to contain the production of such plants are successful and regulations are monitored and enforced. However, it is possible that such products may have secondary agronomic benefits, and as such, they might prove tempting to farmers to plant for other uses who are unaware of the food safety risks that they pose (Kramer, 2000).

2.6 Socio-economic Risks

Adoption of transgenic crops or environmental impacts from the introgression of transgenes into land races or wild relatives can have impact on the economic well-being of farmers and food consumers, and also social and cultural values that are difficult to quantify or represent in economic terms. The most basic economic risks are *farmer production risks.* In weighing the use of any production technology, farmers consider how the technology affects their basic food security, the short-run profitability of their operation over the course of a growing season, and finally the long-run economic stability and viability of their farming operation. Food security concerns whether farmers and others directly dependent on farm production will have social, physical and economic access to sufficient food. Within fully monetized industrial food economies, basic food security for farmers is a function of income and social programs (such as food stamps)

(Sen, 1981; 1999). Commercial farmers who suffer crop losses suffer loss of income, which in turn can create many personal hardships, but farmers who depend solely on their primary production for subsistence face much more immediate food security risks. Smallholder farmers in Mexico are dependent on their own production for food on the table and crop failures are a significant risk. Short-run profitability is determined by the ratio between input costs, including seeds, energy, chemicals, services and credit costs, and the payment received for the crop after harvest. Losses can occur due to crop failures, but in monetized economies price volatility is often a more likely form of exposure to short-term losses. Long-term stability concerns the ability of the farming operation to continue over a period of years. Here, damage to agro-ecosystem function in the form of fertility losses can have economic as well as environmental consequences. All these risks are faced by farmers without regard to whether they are growing genetically modified crops. Thus although a given crop with a specific agronomic profile might be more or less vulnerable to a given exposure pathway for materialization of economic losses, these risks are not different in kind from those faced by farmers every year. Furthermore, transgenic crops, or land races interbred with transgenic seed, might compare favorably to conventional crops with respect to economic risks, a result which, from the farmer's perspective, would be perceived as a benefit associated with transgenic crops.

Two sources of economic risk that are at present uniquely associated with agricultural biotechnology are consumer confidence risks and market access risks. A loss of consumer confidence in the safety or desirability could have a downward influence on the price that farmers receive for their crop (or an upward influence, if the farmer can prove that the crop is not transgenic or "non-GM"). Market access refers to trade, environmental or other restrictions that might limit the location or conditions under which transgenic products can be sold. Europe, Japan, and a number of African countries are among the nations that have restricted import of either all transgenic crops or of unprocessed genetically engineered seeds. Consumer confidence and market access are both sources of price volatility that can affect farmer profitability.

Economic risks are not distributed equally across society. Trade related risks in particular might appear quite different from the point of view of a Mexican industrial maize farmer versus that of a rural, poor, smallholder. Economic risks associated with the rise of proprietary and improved seed varieties may also be important for the poor farmer. If transgenic seeds are more expensive and only accessible to larger and more sophisticated farms, the smallholder farmer may be at a competitive disadvantage in the marketplace. There is also an economic risk that the import of lower priced maize produced from transgenic varieties may undercut domestic production, leaving the farmer with crops for household food security but no income for other needs or for alleviating poverty. Or, the possibility of transgene movement but limited resources for testing, monitoring, and containment may prevent the smallholder from accessing markets the pay a GM-free premium. Finally, the entry of GM seeds into the market may lower the monetized and intrinsic value of a farmer's stock of land races and their seeds.

Exposure to the hazards of economic adversity arises through the complex workings of the economic system. Despite the complexity, economic models are available for estimating both probability of economic gains and losses, as well as their severity. Other kinds of socio-economic harm are more difficult to quantify. One is the feeling of loss that individual farmers and food consumers when market structures evolve in ways that foreclose their ability to express religious, cultural and personal values through the preparation and consumption of food. This loss is sometimes articulated as the loss of a “right to choose.” Such impacts may be better understood as challenges to the legitimacy of social relations than as the loss of some quantity of value (Thompson 2002)

A further and somewhat less specific source of socio-cultural risk can be found in possibly adverse developments with respect to cultural identity and community integrity. While the most straightforward examples of this have been concerns expressed by consumers that eating GMO food products is inconsistent with religious or other personal values discussed above, it is possible that traditional rural communities experience a more pervasive and fundamental kind of cultural identity in the form of specific farming practices, harvest and market patterns, and longstanding farm-to-table relationships. If so it is conceivable that transgenic technologies could threaten such forms of community solidarity. Even classifying such impacts strictly in terms of social risk can be controversial, for people in almost all societies tend to articulate and conceptualize challenges to personal values and ways of life in terms of danger to health and well-being (Douglas and Wildavsky, 1982)

It is also worth noting that when people feel that their values and concerns have been subverted in a systematic way, there is the potential for fairly widespread damage to public confidence in public and private institutions. Some of the public fears of genetic engineering are inextricably linked to fears and uncertainties or value judgments associated with the growth of powerful multi-national companies, increasing privatization of intellectual property, and the integration of global trade and financial markets. When scientific studies are used to legitimate such actions, the upshot may be a decline in public support for science-based activities, or for the use of science to inform public decision-making. Several authors have examined the possibility that controversies over genetically engineered food might be having this kind of impact (Barling and coauthors, 1999; Bauer and Gaskell, 2002) Such broad ranging types of damage to social institutions are almost never addressed in formal risk assessment processes, which have historically tended to assume that risk assessment and risk management will not themselves have further impacts on social institutions.

2.7 Strategies in Risk Management: Risk Benefit Optimization, Informed Consent, and The Precautionary Approach

The case of transgene migration into Mexican land races is one in which hazard identification, risk quantification, and the goals and strategies for risk management are yet to be decided. Subsequent chapters will frame the possibilities for risk management in view of three broad philosophical approaches. The first of these, *risk optimization* has been widely used in public health contexts and as a strategy for coping with environmental risk. A second, but long standing and traditional approach to risk management has been to create social structures in which persons exposed to risk have opportunity to give or withhold consent to risk exposures. Although this approach has long been used in workplace and commercial settings, it has more recently been formalized for research contexts and can be characterized as *informed consent.* A third approach has emerged especially in debates over genetic engineering in agriculture that call for use of the *precautionary principle.*

The basic idea behind **risk optimization** is that risk management should aim for an optimal (or at least satisfactory) balance of risk and benefit. The general strategy of risk management using risk optimization is to consider a number of policy or management alternatives, estimate risks and benefits associated with each, and to select the option having the most attractive outcomes. Applying this strategy is not simple and requires a number of judgments about how options are defined, and what criteria are used to rank outcomes. The key point is that risk management decisions are based on principles of risk optimization look to the potential impact of practices or policies on affected parties, and frame the management decision in terms of finding some acceptable balance among negative and positive impacts.

Informed consent stresses the role of independent decision makers in making evaluations about the acceptability of risks. Here the task of risk management may involve much less actual assessment of outcomes, and may instead emphasize social institutions that place affected parties in a position to accept or reject risks. The most critical element in such approaches is that potential risk bearers have some means of exit, some opportunity to "opt out" of a risky situation. The positive role of risk management under a philosophy of informed consent may be confined to insuring that potential risk bearers have options, and to providing information so that their choices can be well informed. As with risk optimization, there can be many ways in which the basic orientation of informed consent is operationalized. Different parties face different risks. For example, consumers may be most focused on personal autonomy, favoring labels for genetically modified foods, while commercial growers may be more focused on economic gains or losses and be more concerned about access to international markets. One party's ability to opt out in such a situation may be perceived as foreclosing another's opportunity to accept risk.

The **precautionary principle** has emerged as a prominent alternative to risk optimization in debates over genetically modified foods. Like risk optimization, it is an approach that places emphasis on the evaluation of outcomes. However, proponents of this approach see it as placing more emphasis on uncertainty and the reversibility of damages than do many applications of risk optimization. When the potential hazards associated with a practice are highly uncertain, or when they are perceived as irreversible, a precautionary approach advises against attempts to quantify these risks or to weigh them against potential benefits and advises precautionary action. Opponents of using the precautionary principle as a regulatory framework have argued that to the extent it can be meaningfully applied in risk management, it is already reflected in risk management (see NRC, 2002).

The difference that each of these approaches might have for evaluating and managing the impact of transgenes in Mexico is discussed specifically in Chapter 8. One broad implication is that both risk optimization and the precautionary approach tend to construe the role of public involvement as one of advising risk managers about important values, and providing information that will be useful in weighing trade-offs between risk and benefit. Risk communication then becomes interpreted as a mechanism for eliciting this information, and for managing public reactions so that mistrust and misinformation do not subvert the goals of risk management. In contrast, an informed consent approach may tend to see affected parties as key decision makers. Risk communication may then be seen both as facilitating affected parties' decision making, and as a mechanism for coordinating and reconciling differences of perspective and orientation that may exist among these groups. A result may be "successful" in terms of informed consent because key decision makers have determined the result, but may be "unsuccessful" from a perspective that emphasizes the trade-off between beneficial and harmful impacts. In recent years, attempts to emphasize informed consent have been especially sensitive to the rights of those affected parties that operate from positions of economic or political disadvantage. In the Mexican case, these orientations could lead to very different processes for involving Mexican smallholders, as well as other members of the public.

2.8 Issues in Governance with Respect to risk

In addition to this catalog of categories for risks that may be relevant to transgenic maize, management of risk can be complicated by a host of factors rooted in the nature of governance, and in the disparate and often unequal power, information and ability to displace risk experienced by affected parties. Such issues can often be neglected in technical discussions of risk when risk assessment is conducted purely as an exercise in decision support. In the most typical regulatory situation, a regulatory agency operates with specific legislative authority to manage a specific class of risks as stipulated in the authorizing legislation. Thus for example the U.S. Toxic Substances Control Act stipulates a fairly specific set of human health hazards that are to be the focus of risk management for hazardous substances. In such circumstances, important judgmental elements of risk management have been incorporated into the authorizing legislation. Within such a situation, regulators have been given a specific mandate to base decisions on specific criteria and not others. Not only do such circumstances make the selection of hazards and exposures relatively straightforward, they also create a situation in which risk analysis can be perennially revisited and revised as the decision process matures or as the problem identification changes. However, flexibility must be created for the consideration and management of newly discovered risks.

Increasingly, however, risk assessment is being expected to play a much less well-defined role in shaping public decision-making For example, risk assessment and risk management are mentioned in international conventions where there is no clear agreement about the nature of relevant risks or the balance between criteria of consent and optimization in the management philosophy (see NRC, 2000). In such circumstances, a risk analysis report is completed and the document is made public. This means that any gaps or omissions from the assessment can have enormous consequences. In the normal regulatory setting where risk analysis serves as decision support, regulators simply go back and collect new information. In a setting where risk assessment is put forward to structure a debate or to provide a rationale for a particular course of action, failure to note a category of risk that is extremely important to one group of affected parties can either bias the results unfairly, or can undermine the credibility and legitimacy of the entire effort to base decisions on a scientific assessment of risks. Such sources of significant (though usually unintended) bias may arise when technical experts more accustomed to analyzing risk as a form of decision support are enlisted to prepare documents that have a more ambiguous and less easily controlled function.

The situation with respect to evaluating the impact of transgenic maize on Mexican farmers and the Mexican environment is an instance in which the specific role of risk assessment is unclear. The subsequent chapters of this report offer a great deal of important discussion on the various elements that a risk assessment might contribute to a general understanding of the issues. However, there has not been a specific decision about which hazards (if any) are actionable in the present case. While there are reasonably clear public mandates for regulation of hazards associated with public health, intervention to prevent erosion of cultural values has a much weaker basis in law and governmental practice. Arguably, environmental hazards occupy a position somewhere between the two. This report itself, as well as any subsequent empirical risk analysis that might be done to fill in gaps in our knowledge, may reflect existing practices utilized in risk analyses designed for much narrower advisory purposes more than it reflects a complete or balanced compendium of the benefits and risks relevant to open-ended political decision making and debate. Such would be a limitation of any similar study, and this fact should simply be noted.

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