

Maize and Biodiversity: The Effects of Transgenic Maize in Mexico

Chapter 8 A Framework for Judging Potential Benefits and Risks

for the Article 13 Initiative on
Maize and Biodiversity

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8.1 Introduction

The aim in this chapter is to give an overview of the approaches and methods to assess and judge the potential benefits and risks of the introduction of transgenic maize in Mexico. These approaches and methods provide the basis for a framework to judge these benefits and risks. Particular attention is paid to the question of how risks are defined, and which interests are presumed to be relevant in regulatory decision making. We describe the special case of maize in Mexico and discuss the implications for assessing these benefits and risks.

This chapter addresses the following questions:

- What is the philosophical basis for judging the potential benefits and risks of the introduction of transgenic maize in Mexico?
- Do the available methodologies for risk assessment and management provide a basis for decision making in evaluating human health and environmental risks arising from farm-scale and commercial releases of transgenic maize under the conditions of Mexico?
- Do the special conditions of Mexico as a center of origin and of diversity of maize, with a dual agricultural sector require modifications to the available methodologies for risk assessment and management? If so, what modifications are required and why? If not, why not?
- How do the public and regulators understand Genetically Modified Organism (GMO)-related risks?
- Should private and public benefits and risks associated with the introduction of transgenic maize in Mexico be weighted? If so, how?

The chapter is divided conceptually in two parts. The first provides a broad view of the approaches and methods used to assess the risks of transgenic technologies. The emphasis is mostly on the experience of developed countries, where transgenic technologies have been developed. The second part reviews the special conditions of maize in Mexico, and examines the issues raised in the first part in the light of these special conditions. The first section starts by discussing the philosophical principle on which risk assessment is based in democratic societies and the approaches that are used to address and manage risk: *prior informed consent*, *risk optimization* and the *precautionary approach*. The next sections review the methodologies derived from the risk optimization approach, which traditionally have been used to assess transgenic technologies around the world, examining their assumptions and constraints, particularly the role of uncertainty. This is followed by a section that describes the special circumstances of maize in Mexico and analyzes their implications for risk assessment and management of transgenic maize. The next section deals with the analysis of benefits, distinguishing between private and public benefits, and particularly with their distribution among different social groups, it

also examines the importance of baselines to assess benefits and risks. This is followed by a presentation and discussion of a draft for a Mexican biosafety law for genetically modified organisms currently under discussion in the Mexican congress. Finally, the conclusions are presented.

The key message of this chapter is that while available approaches and methodologies for risk assessment and management of transgenic technologies can be used in the case of transgenic maize in Mexico, they also require certain modifications to take into account the special conditions of maize in this country. These special conditions have important implications for risk evaluation and risk management, and should be explicitly incorporated into the evaluation process. Assessing these risks and benefits may require a combination of different approaches. Social participation in the evaluation process is important, particularly of those groups that may be influenced—positively or negatively—by the introduction and use of transgenic maize in Mexico.

8.2 Risk and Democracy

The basic principles that guide democratic societies' attempts to cope with risk are fairly simple. In a free society, people should be at liberty to take whatever risks they freely choose to take, but they should also be protected against risks that are imposed on them by others, whether by coercion, deceit, or even inadvertent action. Implementation of this ideal can be very complex, however, not in the least because almost everything we do in advanced societies can be interpreted to impose risk on others through indirect and sometimes convoluted routes. In practice, the implementation of these basic principles for risk in a free society has led to a broad array of policy responses. These responses can be summarized within a schema that notes two broad philosophical approaches: *informed consent* and *risk optimization*. Both approaches also involve key value judgements regarding who defines risk within democratic societies.

Within domains such as commercial activities (including employment), medical treatment and research on human subjects the key principle for dealing with risk has been *informed consent*. It approaches the ethics of risk as a problem of insuring that people who bear risk do so voluntarily. Under this principle, risks may not be imposed on others except under exacting conditions that require the party initiating a risky activity to provide potentially affected parties with both information about the nature and extent of the risk and an opportunity to refuse permission or to exit from the risky circumstance. Although the exact nature of the information and exit requirements may vary, this is the principle that has implicitly guided policy for ordinary commercial transactions as well as employment in risky occupations, but also recently it has been instituted as the standard approach for involving human subjects in various forms of scientific research.¹

Within domains such as public health policy and environmental policy, the operative principle that has emerged is one of *risk optimization*, whereby risks are seen as

¹ It should be pointed out however, that if the proposed action affects any other person besides the one that can freely give the informed consent, then informed consent may depend on many factors that may or may not have to be limited by societal action.

justifiable when they are offset by significant benefits. This should not be understood as a strict quantitative rule of cost-benefit balancing, for there may be qualitative elements that are judged to be relevant to the optimization judgment. Research indicates that catastrophic events, such as an airplane crash, are viewed as particularly worthy of a policy response. Under this principle, it has been possible to initiate a number of public health measures (such as public sanitation) that address natural hazards present in the environment, and often not the result of some risk imposing action that might be subject to a rule of informed consent. This has allowed public health officials to deliver enormous health benefits at reasonable cost, as societies began to regulate the use of environmental pollutants in the last half of the 20th century; it was this approach in public health policy that became the template for their thinking. In some cases the benefits of a policy are clear; however this is not always the case. The offsetting of risk through a benefit depends heavily on value judgments regarding what are the benefits, whether they are for a greater good or affect the individual at risk directly and therefore on society values.

A third principle is emerging, particularly in relation to the impacts of new technologies and the environment: the *precautionary principle*. While its definition and application are still fuzzy and continue to be debated, it is becoming very important in the biosafety legislation of many countries, as well as international treaties. This principle is an important component of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety (SCBD 2000) and, as will be discussed later, is a part of the Mexican draft legislation regarding biosafety for genetically modified² organisms that currently is going through the legislative process. The precautionary principle is becoming part of the European Union (EU) framework to address concerns about potentially dangerous effects on the environment, human, animal or plant health, which may be inconsistent with the high level of protection chosen for the Community (CEC, 2000).

The precautionary principle tries to address explicitly the relationship between scientific uncertainty and risk. The 1992 Rio Declaration on the Environment and Development states in its Principle 15 that: “[I]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” (Rio Declaration on Environment and Development 1992). The Cartagena Protocol on Biosafety states that “lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.” (SCBD 2000). According to this principle then, scientific uncertainty in the phase of threats of serious or irreversible damage to the environment, and one may add to human health as well, should not be used as a pretext not to do something to avoid this damage. Clearly, not carrying the action that could create the

² Currently a draft Biosafety Law for Genetically Modified Organisms approved by the Mexican Senate on April 2003 is being discussed in the Mexican House of Representatives (Cámara de Diputados). A short presentation of the law as it pertains to this chapter will be presented in section 8.7. See Chapter 10 for a discussion of the national biosafety system in Mexico.

damage is the only option if the probability of such damage occurring is irrefutable. Where it is not, i.e. in the face of scientific uncertainty, precaution cannot be invoked to impose a permanent moratorium on action. Instead whereas pertinent information may allow the provisional measures should be adopted such measures should be accompanied by efforts seeking to obtain additional information necessary for a more objective assessment of risk. This is consistent with the practical exigencies arising from the need to comply with national and international legal instruments but also with ethical imperatives. For example, as pointed out by the Nuffield Council (2004), rather than interpreting precaution as an inflexible rule, often implied in the term “principle,” one should look at precaution as an approach—a way to apply a set of interacting criteria to a give situation. The council concludes that an adequate interpretation of this approach would require comparison of the risks of the status quo with those posed by possible paths of action.

The actual record of law and policy in modern democracy indicates a mixture of attempts to apply either one or another of these approaches. Some strongly worded laws may have been written with the presumption that certain kinds of activities should be banned altogether because it was presumed that no one would consent to be exposed to the risks in question. Such was the case with respect to suspected carcinogens in the United States, for example. However, as it became clear that implementation of this principle would entail substantial costs while yielding little reduction in the rate of morbidity and mortality, agencies regulating carcinogens began to argue that a risk optimization approach might be more appropriate.

Risk optimization and prior informed consent continue to influence public attitudes toward risk. Informed consent continues to provide a rationale for ignoring trade-offs when responding to risk, but more importantly, it indicates that those who bear risk should be the key decision makers whenever possible. It is a principle that stresses the empowerment of affected parties, and that assigns risk assessment the role of generating the information for individuals who will accept or reject the risk. Principles of risk optimization are most appropriate when a particular agency has clearly mandated authority to regulate based on risk. In such circumstances, a legislative body has directed administrative decision makers to intervene in private decision making, and to make decisions on the management of risk that are consistent with the public interest. As pointed out above, the precautionary principle is increasingly becoming part of both national and international legislation, at least in principle, though the specifics of implementing it still are evolving.

Law and policy for new technologies often emerge under circumstances in which it is less clear which of these philosophies is to take precedence. With respect to genetic engineering in food and agricultural, there have been persistent calls for public involvement in decision making and for empowering individuals through the provision of information. In the case of the United States, regulatory decision making at governmental agencies has largely been conducted under existing statutes that direct administrators to apply fairly specific risk optimization principles to proposals for the testing or release of genetically engineered crops. In other countries, particularly the members of the EU and

in the case of Mexico, new legal frameworks are being set up. Transparency and communication of risks are important components of many of these frameworks.

The case of transgene migration into Mexican land races is one in which the underlying orientation—risk optimization, informed consent, precautionary approach or some combination of them—is still not clear. The draft Mexican legislation on biosafety has elements of the three approaches. Whatever framework is ultimately developed for addressing transgene migration, a blend of implicit assumptions and formal legal specifications determine who has the authority to decide that an actionable risk is present. Questions about who decides whether there is a risk have arisen frequently in the debate over GMOs. The underlying basis for such questions resides in the underlying conceptual logic of risk itself. Interpreted broadly, to be at risk is to be in circumstances where the potential for experiencing an adverse outcome can be uncertain or unknown, although one could also be at risk when a potential for harm is clearly known. However, people in different social positions have different access to knowledge and evidence about the likelihood, nature and severity of possible adverse events. It is neither uncommon nor irrational for people with relatively little useful information about the likelihood of adverse events to take themselves to be at significant risk, in part because their lack of information is itself a source of vulnerability.

Other parties having access to better information may dispute the judgment that risks are significant, but it can be difficult to resolve this difference of opinion simply by sharing information because information is not value-free or at least it may not be trusted to be. Furthermore, the interests of different groups with a stake in the issue may be in conflict. If those having better information are perceived to have an interest in the outcome of a risk management policy, or if they are believed to have made erroneous policy judgments in the past, there will be little basis for trustworthy communication. In fact, statements to the effect that risks are low or acceptable may even increase the feeling that one is at risk when such statements come from a source that is not trusted. Thus, risk communication is never a matter of simply disseminating information relevant to the likelihood, nature or severity of a possible adverse event. Risk communication is even more difficult when the experts are not in agreement about the magnitude and probability of risks. Effective risk communication always involves an extensive effort to build a community of trust among all parties. In practice, this means the affected parties must have confidence that their concerns and perspectives have been adequately accounted for in the process of identifying, quantifying and managing risks. For example, the Cartagena Protocol on Biosafety recognizes the need for public engagement and communication.

In addition to the problem of unequal access to information, there have been many documented cases where risk experts failed to anticipate adverse outcomes that were of extreme importance to affected parties. The source of these errors often lies in the experts' incomplete understanding of the interests and values of affected parties. Thus, expert risk assessments have at times failed because they focused solely on public or environmental health questions and ignored the economic interests or values (religious or otherwise) of affected parties, or because they failed to appreciate how certain events would be viewed as adverse in light of their impact on local practices or institutions. It is thus almost always critical for people with a rich and locally informed understanding of

the values, institutions and practices at risk in a given setting to be intimately involved in the process of identifying and conceptualizing risk.

At the same time, most legal statutes and formal procedures for developing risk policies have tended to place a number of constraints on regulators' authority to define risk. Affected parties may see risk as involving an indecipherable blend of health, environmental, social, economic and personal interests, but the rules under which regulators take action with respect to risk generally recognize only a subset of these issues as legally actionable. Thus, adverse impact on public health is generally an actionable risk, but responses to economic risk may or may not be actionable. This has been particularly true in the United States. The boundaries of what can and cannot be included in the definitions of risks are changing worldwide. For example, the Cartagena Protocol on Biosafety recognizes that countries may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

8.3 The Risk Assessment Approach: Overview of distinct methodologies for risk assessment and approaches/models for risk management

Traditionally, technological safety has been scrutinized on the basis of perceived risks on human health and, occasionally, on socio-economic life. In the last 20 years the perception of risk has been broadened to include potential impacts on the environment including non-human life. In the case of agriculture, the application of new technologies largely ignored environmental impacts until relatively recently, when legislators and the society at large became cognizant of the fact that technological impacts extend beyond the agroecosystem and actually affect broader ecosystems and processes. Furthermore, the application of recombinant technologies in agriculture has triggered in many parts of the world legislation that requires the assessment of potential risks to human health and the environment arising from any given genetically modified organism or derivative product prior to the importation, release or marketing. This effectively establishes a proactive approach to risk assessment.

When the emphasis of risk assessment is on potential impacts on an ecosystem, rather than on humans, the term "Ecological Risk Assessment" is often used. Different approaches can be identified for risk assessment, and these approaches continue to evolve. **Table 1** presents examples of different risk assessment frameworks, from the early approach developed by the National Research Council of the USA to the one proposed in the Cartagena Protocol on Biosafety. The earlier NRC framework for the safety assessment of GMOs has been questioned on the grounds that the terms "magnitude of exposure" and "extent of exposure," derived from toxicological risk assessment, imply quantification that would be difficult or even impossible to measure as GMOs have the ability to mutate, reproduce and disperse. Furthermore, this framework cannot easily deal with data for biological interactions much of which is qualitative in nature. Two variants of that framework attempt to overcome this limitation by adopting a

Table 1 Examples of different risk assessment frameworks

National Research Council (1993)	US Environmental Protection Agency (1998)	UK Department of the Environment (1994)	Cartagena Protocol on Biosafety (SCBD, 2000)*
<ul style="list-style-type: none"> • Hazard identification: The determination of whether a particular chemical (stress agent) is or is not causally linked to particular ecological effects. • Dose-response assessment: The determination of the relation between the magnitude of exposure and the probability of occurrence of the effect in question. • Exposure assessment: The determination of the extent of exposure before or after application of regulatory controls. • Risk characterization: The description of the nature and of the magnitude of ecological risk, including attendant uncertainty. 	<ul style="list-style-type: none"> • Problem formulation involving planning, information collection and selection of assessment end point, as well as the preparation of a conceptual model. • Analysis involving acquisition and integration of data into existing datasets as well as characterization of exposure and effects (ecological responses). • Risk characterization involving estimation of risk, evaluation of exposure and description of risk. • Risk management involving practices to mitigate or manage risks and an iteration process integrating information into model. 	<ul style="list-style-type: none"> • Hazard identification, • Risk estimation, • Risk evaluation 	<ul style="list-style-type: none"> • An identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health; • An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism; • An evaluation of the consequences should these adverse effects be realized; • An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized; • A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and • Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

* The similar framework is proposed in the draft of the Mexican Biosafety Law
LMO= living modified organism

more qualitative approach: the US EPA (1998) and the UK Department of the Environment (1994). Clearly there are many other possible frameworks, but of particular interest is the one presented in the Cartagena Protocol on Biosafety (SCBD, 2000) as this protocol is becoming the basis for biosafety legislation in many countries including Mexico.

In these frameworks, the term hazard is used to refer to an innate property of an organism (e.g. toxicity, pathogenicity) but also to a situation that could occur during the lifetime of a product, system or plant that has potential for human injury, damage to property, damage to the environment, or economic loss. The Cartagena Protocol on Biosafety refers to adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Although risk can be defined in several ways, a particularly appropriate one is one in which it is defined as the probability that a particular adverse event occurs during a stated period of time, or results from a particular challenge. This definition imposes a timeframe during which risk should be estimated. Estimation of risk is composite of the magnitude or the severity of the specified undesirable event, and the probability that the specified event will occur. In the above definition severity is used interchangeably with magnitude for those cases where quantification is not appropriate. In such cases risk cannot be reduced to a single numerical quantity.

Hazard identification and risk estimation are presumed to be essentially the technical stages of the risk assessment process based primarily on scientific data and expertise. However, this is not quite clear-cut. Scientific uncertainty biases expert opinion and often different stages of risk assessment are replete with value judgments. Whenever this is the case, it is important that this be stated. It is important to point out that one cannot call something a “hazard” without having decided that there is something adverse associated with it. Judgments that something is or is not adverse however are not scientific. They are value judgments.

Risk evaluation is the complex process of determining the significance or value of the identified hazards and estimated risks to those concerned with or affected by the decision. It therefore includes the study of risk perception and the trade-off between perceived risks and perceived benefits. It is apparent that this stage of risk assessment allows for value judgments and consideration of benefits associated with the technology to enter into the decision making process.

8.3.1 Hazard Identification

Risk assessment is a systematic attempt to anticipate and respond to the potential for events, outcomes or situations that are regarded as adverse, harmful or in some way unwanted. As such, the first or *hazard identification* stage in a risk assessment is to conceptualize the problem in terms of the specific circumstance suspected of creating or instigating this potential, and to conduct an inventory of the possible events and outcomes that are regarded as adverse. This phase of the analysis provides neither an indication of

the likelihood of such adverse outcomes to occur, nor of the magnitude or severity of any damage that might arise. It is a critical phase of risk assessment, however, because it shapes the nature of the ensuing data collection and analysis.

The identification of specific hazards within each of the above categories varies according to whether the case is trivial or complex. This stage of risk assessment is of paramount importance as “unidentified” hazards are probably the biggest source of “uncertainty”. The process of hazard identification may be seen as an end in itself, as potential identifiable hazards can give valuable insights on appropriate risk mitigation.

In some cases, such as an epidemiological risk assessment associated with a disease outbreak, the nature of the adverse event is very clear: observed morbidity and mortality. Here “hazard” may be identified largely in terms of these adverse outcomes, and the cause or precipitating circumstance may not only be largely unknown, but also the main focus of the data collection, modeling and clinical analysis that follow in succeeding phases of risk assessment. In standard toxicological risk assessments, the precipitating event is well characterized: the introduction of the alleged toxin into a given system or environment. Here, any problems caused by the alleged toxin may be identified as the “hazard” and risk assessment focuses on the exposure scenarios under which such adverse outcome might ensue.

In the specific case we are dealing here, the presence of transgenes in maize landraces in Mexico, the nature of the triggering event is known: introgression of transgenes into Mexican landraces. But the nature of this event is not as well characterized as in a standard toxicological risk assessment, where the specific toxin and its chemical structure are completely known. The introgression of transgenes may be thought of as the hazard, but exposure to this hazard and the magnitude of the adverse effect depends on the nature of the transgene and environmental conditions.³ Hazards associated with genes for pest or herbicide resistance present a very different profile from genes conferring traits such as drought tolerance or that code for biologics and pharmaceuticals. Thus one element of hazard identification is to characterize an innate property of the transgenic system that may lead to an adverse effect in a manner that is relevant to the key policy issues and that suggests appropriate measures for risk quantification.

Furthermore, as mentioned above, to characterize any event or outcome as adverse involves value judgments. For example, whereas hazards to human health such as death and disease are non-controversially considered hazards, environmental hazards are more controversial. The literature is rife with statements in which “risk” is equated with “exposure” or “gene flow” to “hazard” (Bartsch and Schmitz 2002).

The maize case may involve less tangible hazards to, for example, non-target species and to biodiversity, as well as economic hazards and hazards to the cultural integrity of Mexican farming communities. In each of these cases, the nature of the perceived adversity may be somewhat unclear, disputed and difficult to quantify. For example, a popular conception of pollution presumes that pure or unsullied environments are harmed

³ See also Chapter 2 for the identification of potential risks and risks.

by anything that compromises their pristine character. Whether this popular conception should be adopted by policy-makers is, however, not all certain.

Hazard identification and risk evaluation are not solely determined by the current level of scientific expertise but also by societal values regarding what constitutes an attribute of an entity or a system that needs to be protected. Regulatory systems and risk assessment frameworks (see above) reflect differing approaches to identifying hazard end points and characterizing risks. However, current international agreements (e.g., World Trade Organization (WTO), Cartagena Protocol) impose restrictions on the expansiveness of risk assessment frameworks.⁴

8.3.2 Risk Evaluation

The conceptual difference between hazard and risk is that while hazards are regarded as adverse, one does not have a grasp of risk until one has estimated the likelihood that adversity materializes and the extent of the harm done. The quantification process thus involves the use of systematic methods to determine the probability of adverse outcomes and the possible extent of the damage. There are a host of methods that can be applied to this task, depending on the nature of the quantification problems involved. In some circumstances data permit fairly specific estimates of the probable death rate associated with some activity or practice, and the problem of quantifying the extent of harm becomes an economic exercise in “putting a price on life.” In other cases, such as attempts to quantify the risk of a nuclear power accident, the quantification effort produces a set of probability distributions that represent the likelihood of low-consequence as well as high-consequence events.

Given the multiplicity of hazard types under investigation in the maize case, the quantification methods appropriate to each will almost certainly be left to analysts having expertise in each of the relevant areas. One of the critical questions that must be addressed in risk quantification is the extent to which indirect effects should be included in the analysis.

The multiplicity of potential hazards also points toward methodological challenges in quantifying risks in the maize case. Established methods for anticipating outcomes such as impact on biodiversity or cultural integrity are weak, at best. As a result, there may need to be some iteration between the stages of hazard identification and risk quantification, so that measurable outcomes are allowed to serve as a proxy for more vague or difficult to quantify kinds of outcome.

8.3.3 Risk Management

Risk assessment is only a component in an overall risk management strategy. Risk management involves deciding what to do about risks. Should steps be taken to mitigate

⁴ See also Chapter 10 for a discussion on the relationship between WTO and the Cartagena Protocol regarding GMOs.

the likelihood that harm will occur? Should methods of compensation for harm be implemented? Or should the risks simply be accepted? Traditionally, risk management focused on assessing the probability and the consequences of tangible risks such as mortality or environmental damage. However, more recently, public acceptance of a technology is also influenced by ethical values and other dimensions of risk, such as: the degree of scientific certainty; the potential for catastrophic consequences; inability to reduce or reverse harm; the occasionally involuntary nature of exposure; the potential of harm to future generations; and the degree of equitability of risk. Risk management also entails key questions about who is involved in making these decisions. It is thus at the risk management stage that the basic tension between risk optimization and informed consent becomes most apparent.

However, as options for responding to risk begin to take shape, there is often a need to consider whether the implementation of a policy is itself a source of new risks. Several carefully studied cases of attempts to mitigate risk through regulation have encouraged manufacturers to undertake alternatives that had far more serious health consequences than the original regulated activity. There is thus something of an iterative relationship between each stage of the risk assessment process, as attempts to manage risk may spark new phases of hazard identification and risk estimation.

In some instances, risk assessments are conducted within an agency or organization that has clear responsibility to undertake risk management activities. Most regulatory agencies, for example, both evaluate risks and formulate policy responses to them. Here the iterative relationships among the various phases of risk assessment can be managed in a fairly straightforward manner. In other cases, risk assessment and risk management are conducted by distinctly different authorities.

In view of the above, it is essential to engage all interested parties early during the decision-making process, ensuring that the different dimensions of risk are adequately communicated to the different stakeholders. As mentioned earlier, value judgments are often made during the early stages of risk assessment (e.g. during hazard identification). It is, therefore, important that such judgments are communicated and discussed to prevent or at least minimize confrontation and resistance. Risk communication is also essential for policy makers as they become aware of public concerns, and take them into account in formulating policies and decisions.

8.4 The assumptions behind methodologies for risk assessment and approaches/models for risk management

Some of the basic assumptions underpinning risk assessment and management are considered below. A critical evaluation of whether these assumptions hold in the specific case of transgenic maize in Mexico is provided in section 8.6.

Assumption 1. The introduction of a few transgenes in a crop variety with a good safety record poses only incremental risks related to the potential toxicity of the gene product(s), the consequences of outcrossing of the transgene(s) and possible evolutionary effects on target populations in the case of pesticidal transgenes. Such risks can be assessed by

using standard methodologies and models as mentioned earlier and expert opinion. In general we try to manage risks on the basis of:

- familiarity with all components of the system under consideration (donor organism(s) and recipient plant, receiving ecosystem);
- containment and/or confinement of the transgenic organism; and
- mitigation and remediation.

All other things being equal, the higher the level of familiarity, the lesser the requirements for containment/confinement and mitigation/remediation and vice versa.

Two models can be identified regarding the level of familiarity with the trait, the crop and the system: the “familiarity” model and the “exotic” introduction model.

The “familiarity” model argues that a Genetically Modified (GM) crop plant should behave like an untransformed plant other than for the introduced trait, which introduces only a small amount of novel genetic information into the ecosystem. The “exotic” introduction model, on the contrary, treats a GM crop plant as the introduction of non-indigenous plant species. The former predicts, for example, that the environmental introduction of a transgenic crop should rarely convert a non-weedy crop into a weedy one, whereas the latter predicts that such introduction should relatively frequently result in new weedy varieties. Current evidence (Crawley et al. 2001) supports the “familiarity” model, but clearly this could depend upon the crop-trait combination and the environmental background. However, other evidence looking into the movement of transgenes into other species, points out how those transgenes may alter the fitness of these other species, which may become more weedy (Snow et al. 2003). Clearly, the applicability of the “familiarity” model may depend where the boundaries of the issue are set.

A report of the NRC (2002) concludes that on the basis of empirical evidence of impacts involving environmental introductions of small and large amounts of genetic novelty can be profound. For example, the introduction of T male cytoplasmic sterility into U.S crops resulting from a very small change in the maize genome, was the cause of Southern corn leaf blight through the rapid spread of *Biopolaris maydis*. The report documents similar examples involving other plant species where relatively small genetic changes resulted in major ecological impacts. However it should be stressed that while the ecological consequences resulting from the introduction of biological novelty depend on the recipient ecosystem, their significance depends also on societal values. In conclusion, the introduction of biological novelty may have unintended and unpredicted effects on the recipient community and ecosystem.

A priori there is no strict dichotomy between the possibility of environmental hazards associated with releases of cultivated plants with novel traits and the introduction of non-indigenous plant species, although the highly domesticated character of the former

decrease the potential of certain hazards, but the consequences of transgene movement into related species remains a concern.

Assumption 2. In comparing risk between transgenic and non-transgenic plants, what matters is the trait, not the process by which the trait was incorporated.

Typically, genetic improvement either through recombinant technologies or conventional breeding involves the introduction of genetic variation to existing cultivars. In the case of transgenic technologies, many changes take place in genes and cells; for example, transformation results in a genetically heterogeneous population of cells. Only those cells with the desired properties are selected following the transformation process and regenerated.⁵ However, in statistical terms variation related to both of these steps (e.g. transformation and regeneration) is not greater than that resulting from the crossing of non-identical parent plants (Boulter 1995).

Variability in expressed traits may also result either from the transferred genetic cassette affecting the regulation of other genes present in the host (such interactions are called pleiotropy) or the interaction of gene products (called epistasis). However, both phenomena are also known to operate in crossings in natural populations. Similarly, conventional breeding has resulted inadvertently in numerous well documented cases of products with undesirable properties (e.g. toxic levels of psoralen in celery and of solanin in potato, to mention but two). Unwanted phenotypes are removed from breeding lines by repeated screening for individuals that have only desirable traits. Thus, the creation of reproductively and genetically unstable individuals as part of the sequence of events leading to a released of a commercial transgenic variety can be ignored.⁶

In line with the above, a report of NRC (2002, 5, 63) contends that both the transgenic and conventional methods of crop improvement can result in unintended effects on crop traits: “.. the transgenic process presents no new categories of risk compared to conventional methods of crop improvement, but specific traits introduced by both approaches can pose unique risks.” The implications of this are twofold: namely, that risk assessment should proceed on a case-by-case basis and secondly that regulatory oversight should be triggered by the “novelty” of a given product rather than by the method by which it has been produced.

However, the method of transformation does provide useful insights on the identification of potential hazards and risk mitigation procedures. Some transformation methods are more likely to result in clean insertion events than others.

⁵ These include the random insertion of sequences which is known to give rise to mutagenesis or gene fusion resulting in untoward effects such as gene 'silencing' or switching-on of lowly expressed genes. Regeneration of the selected transformants results in considerable clonal variation (somaclonal variation). The basis of somaclonal variation remains unclear but it has been suggested that epigenetic factors play an important role (Matzke and Matzke 1999).

⁶ As noted by Thompson (2003), proponents of the comparability of transgenic and non transgenic crops ignored the creation of reproductively and genetically unstable individuals, while those who defend the non comparability consider these individuals as part of the data about hazards and the uncertainty created by the process of transformation.

Assumption 3. It is not possible to demonstrate absolute safety (zero risk) for any technology or activity; all technologies and activities carry some risk.

Given the impossibility of assuring absolute safety, it is important instead to measure the relative safety of a given technology or technological system against a comparable alternative technology in current application, the latter being the baseline of comparison.⁷ Depending on the potential hazard, various reference scenarios or proxies could be chosen. Conventional plant breeding and established agricultural practice are not always appropriate proxies, as there may be specific risks associated with certain transgenic crops. Allowing for proxies may serve the purposes of risk assessment, but the rationale for using proxies should be stated clearly, and outside parties keenly exposed to the risk in question should have an opportunity to be involved in these methodological judgments when possible.

Alternatively, the regulator may compare the net benefit (benefit-risk balance) for the product. Note that this risk-benefit balance will reflect local views on the importance of risk and uncertainty, and thus regulators in different regions may make different decisions based on the same data. The assessment then should consider the relative risks and benefits of the new product relative to current practices, and should include the potentially important ecological impacts of these technologies. For an insect-control product like Bt corn, current practices typically involve the use of conventional insecticides. For herbicide-tolerant crops, that would be other herbicide regimes. These comparisons must be carried out based on local conditions.

8.5 Uncertainty and Irreversibility in decision-making

It is important to bear in mind that scientific certainty has boundaries. The failure to 'prove' scientifically a product unsafe does not amount to having 'proved' that it is safe. And, also failure to prove a product safe does not mean having proved it unsafe. What is more, the unequal distribution of information, expertise and power in society gives rise to forms of uncertainty that are seldom reflected in scientific studies. Evaluation and management of risk requires attention to both scientific and social uncertainty.

8.5.1 *Scientific Uncertainty*

Scientific uncertainties can be divided into three broad conceptual classes. Virtually all empirical studies in science are bounded by *statistical uncertainty*, which is a quantifiable measure of confidence in an inference relative to the data on which it is based. Statistical uncertainties have given rise to a significant amount of debate in risk analysis because studies designed to measure the correlation between harm and a specified exposure to a hazard produce a statistical confidence interval between the Type

⁷ As pointed out by one reviewer, the choice of a baseline is more complex than it may seem. It involves views about the current alternative technologies, but also about trajectories and desirable states in the future, and hence about social and political choices. For example, Bt maize should be compared to the current use or lack thereof of pesticides or to the potential use of Integrated Pest Management methodologies?

I Error, attributing a correlation where none exists, and the Type II error, failing to attribute a correlation where one does exist. Although standard scientific practice has been to minimize Type I errors, many have argued that regulatory science should minimize Type II errors.

These well characterized measures of statistical uncertainty may not reflect additional sources of ignorance or predictive error that arise in connection with gaps or errors in the model on which the study has been based. *Modeling uncertainty* arises because some phenomena are not well enough understood to develop adequate representations of exposure that allow collection of relevant data, or because technical problems make it impossible to collect meaningful data. There is considerably less consensus on how modeling uncertainties should be reflected in estimates of risk. One extreme point of view is that when modeling uncertainties exist, risk managers should adopt a posture of minimizing opportunities for exposure. This perspective neglects two important considerations. One is that considerable amounts of useful information can be derived from incomplete models. The other is that virtually all attempts to measure risk suffer from some degree of modeling uncertainty; hence the extreme view leaves one with no guidance of how to proceed in risk-risk comparisons. Perhaps the most responsible way to address modeling uncertainty is to acknowledge gaps as clearly as possible and to note that risk estimates are the best available, given current knowledge.

The third form of uncertainty is sometimes referred to as simple *ignorance*. It is the possibility that there is something that has not been thought of at all. The possibility that there are types of adverse outcome that are wholly unknown to risk assessors, and hence not characterized as hazards, represents one form of ignorance. History provides many examples where an entire class of hazards is wholly unknown at the time that an activity is initiated: bioaccumulation as a hazard from chemical pesticides and climate change as hazard from carbon emissions represent two examples. Some have argued that ignorance provides a sufficient reason to be extremely cautious in developing new technology. Like modeling uncertainty, however, ignorance is to some degree ubiquitous, applying as much to the status quo technologies as to the novel ones. Hence the practice among risk managers has been to base decisions on what is known, but with a degree of humility, and to encourage monitoring systems that will detect unanticipated hazards as quickly as possible.

Recognizing uncertainties and our ignorance are most critical when considering the interaction of transgenes with the receiving environment. This is partly because of the patchy state of research in this area and also because effects resulting from such interactions are also time and scale dependent. The consequences of releasing any novel organism—not only GMOs—into all environments is not predictable nor quantifiable. However, on the grounds of current scientific knowledge it is possible to discern potential risks but these are not qualitatively different from those arising from conventional breeding. Most of the perceived technology-related adverse impacts of GMOs have historical precedents in conventional agriculture. Current risk assessment procedures have limitations that cannot easily be overlooked. *A priori* assessment of the probability and magnitude of the consequences of adverse ecological impacts is often confounded by knowledge gaps concerning the interaction of novel phenotypes with their immediate

environment. Results of small-scale field tests cannot readily be extrapolated to accurately evaluate ecological risks arising from large-scale tests or commercial applications. However, lack of evidence of adverse effects at the organismal and population levels in small-scale trials is a good indicator that no adverse effects are likely to occur at the community and ecosystem levels.

Experimental data from field trials of transgenic organisms have increased the level of confidence in the technology. Current evidence does not point to potential global calamities but for certain transgene/environment combinations (e.g. plants engineered with fitness-altering genes and capable of interbreeding with wild relatives) there is need for pro-active research to assess potential long-term impacts as well as for the establishment of monitoring mechanisms (Steward 1996). Avoiding the commercialization and release of high risk GMOs is certainly prudent, but to advocate a moratorium on all genetic engineering applications would mean forfeiting tangible benefits for the sake of speculative long-term adverse impacts. However, these benefits cannot be taken for granted either and can also be speculative, an issue that is further discussed in section 8.6.6. With this caveat notwithstanding, risk management and mitigation may, therefore, be taken as the preferred approach. The success of this approach ultimately depends on regulatory policies that are neutral to special interest groups.

8.5.2 Social Uncertainty

The need for neutral regulatory policies calls attention to the importance of regulatory policies that are impartial to special interest groups. Because the concept of uncertainty is open to multiple interpretations, it is possible to make almost contradictory statements about what is and what is not known about GMOs on the basis of scientific studies, for example by emphasizing whether GMOs have been proven risky vs. whether they have been proven safe. Because so many different scientific disciplines are involved in estimating risks from GMOs, virtually no one is in a position to command all the information and expertise relevant to risk. Even highly educated and interested members of the public and government officials, in particular, must thus rely on expert testimony for their interpretation of the risks from GMOs. This situation of unequal access to expertise and knowledge creates a form of uncertainty about risks that is seldom discussed in scientific studies.

In effect, anyone who has not actually collected data and conducted risk analysis is in a position such that their assessment of the risks of GMOs reflects two factors: the content of the risk estimate, and one's confidence in the competence, neutrality and reliability of the analysis. Confidence derives from the social relationship between any given individual and the group that has conducted the risk analysis. In situations where confidence in the group doing the analysis is very low, statements to the effect that risks are acceptable can actually increase a person's estimate of the risk associated with the activity in question. Social sources of uncertainty cannot be eliminated by conducting more scientific studies.

One of the most significant sources of social uncertainty is grounded in the difference between local knowledge and more conventional scientific techniques. Wynne (1992) conducted a series of studies on attempts to quantify and manage risk in the wake of the Chernobyl accident which revealed that scientifically trained risk managers made a number of errors in mitigating radiation contamination risks among sheep farmers because they did not understand local conditions and practices. Farmers lost confidence in the scientists when it became clear that they did not understand a number of relationships crucial to the economic viability of sheep farmers. This loss of confidence exacerbated public health risks when communications between public officials and farmers became mired in misunderstanding and distrust.

Social uncertainty has arguably been at the root of much controversy over GMOs. GMOs were introduced into Europe at a time when confidence in the competence of risk assessment and regulatory decision making was quite low. Highly publicized public health disasters, from Chernobyl to mad cow disease, had rocked confidence in scientific risk assessment. Harmonization of regulatory regimes among European nations created a situation in which incompatible standards and the economic interests served by any given risk standard were at the forefront. U.S. corporations and the U.S. government were perceived as promoting an interest-based view on global agricultural trade, and the social relationships amongst European regulators and the European public, on the one hand, and the biotechnology industry and the U.S. government, on the other, created a situation in which each of these groups took a rather jaundiced view of the risk estimates for GMOs being put forward by the others. In particular, European suspicions about the motives, competence and willingness of Americans with respect to health and especially environmental risk provided a setting in which scientific uncertainties were amplified by distrust. The result was a collective judgment on the part of many Europeans that GMOs are quite risky.

Social uncertainties may also be quite relevant to the present case. Scientific views of ecological risks associated with transgenes have not been formed in light of agricultural practices, economic imperatives or environmental values that might be peculiar to Southern Mexico. Ecological risk assessments from the U.S. may reflect the social reality of U.S. agriculture. One should not rule out the possibility that special agronomic practices, economic relationships or community standards for agricultural land use might not be adequately reflected in conceptualizations of risk that have been based on large-scale monocultures typical of the U.S., where widespread ecological impact from conventional agriculture is taken to be the norm. Furthermore, Mexican farmers will have standing relationships with their own community organizations, government officials and with non-governmental organizations that may (or may not) make them view technical risk assessments with suspicion. If such a setting exists, the attempt to force a “science-based” risk estimate may have unforeseen social, economic, political *and* ecological consequences.

8.6 The special case of Mexico and implications for risk assessment and management

In the previous sections we have given a broad view of the approaches and methods used to assess the risks of transgenic technologies. The emphasis has been mostly on the experience of developed countries, where transgenic technologies have developed and where their use started. Obviously, the conditions of developing countries in general and particularly of Mexico differ from the circumstances of developed countries. In this section we will present and analyze the special circumstances of Mexico. Some of these have to do with the fact that Mexico is still a developing country, with large social inequalities and where millions of small-scale farmers, mostly poor, depend on maize for their subsistence. Others are related to Mexico's status as a center of domestication and diversity for maize. We can divide these circumstances into five categories: (1) the bimodal structure of maize agriculture; (2) maize as an open genetic system; (3) the cultural significance of the crop; (4) the presence of the wild relative of maize; (5) the maize consumption patterns of the Mexican population. The section also addresses the analysis of benefits, and the need for baselines.

8.6.1 *The bimodal structure of maize agriculture in Mexico*

Mexican agriculture, including maize agriculture, is characterized by a bimodal structure (Bailey and Roberts 1983; Nadal 2000).⁸ On the one hand, there is a large sector of small-scale farmers in rainfed areas who produce mainly for self-consumption, though they may sell some surpluses. These farmers are referred to in the rest of the chapter as *campesino* farmers. On the other hand, there is a relatively small sector of larger-scale commercially-oriented farmers mainly in irrigated areas, with objectives and technological needs similar to those of commercial farmers in the developed world. These two groups have different objectives for producing maize, face different environments and constraints, control different resources, and have differing ability to bear and manage risks as well as to be heard in the political debate.

Commercial farmers are the logical market for transgenic varieties if introduced commercially; *campesino* farmers are unlikely to be an important market for these varieties, particularly because they usually do not purchase commercial seed. But there may be strong externalities⁹ from the adoption of transgenic maize varieties by commercial farmers to *campesino* farmers. Although transgenic varieties may be aimed at commercial farmers, their introduction may have important consequences for *campesino* farmers. Due to the particular characteristics of *campesino* agricultural systems—which can be characterized as an open genetic system—if transgenic varieties are introduced commercially it is almost certain that transgenes will diffuse to the non-transgenic maize populations, including landraces and improved varieties—that these farmers plant.

⁸ Chapter 6 discusses in more length the structure of the Mexican maize agricultural sector and the typologies of maize farmers.

⁹ Externalities are uncompensated impacts of one agent's actions over the welfare of another.

Externalities could be positive, if transgenes code for traits that are considered useful by *campesino* farmers, which they may incorporate into their maize populations and benefit from them. Externalities could also be negative, and this should be considered in the hazard identification stage of risk assessment. A particular externality is that small-scale farmers may have to deal with adventitious transgenes,¹⁰ which most likely will be unknown to the farmers, and their effects may be untested or unknown under their specific conditions.

The existing inequalities between the two sectors of maize producers, particularly the differential ability to bear and manage risk, raise the issue of the distribution of benefits and risks associated with the introduction of transgenic varieties in Mexico. If a risk optimization approach is chosen as a framework to judge the merits of transgenic technologies for Mexico, should one distinguish how the benefits and risks are distributed between groups? Should these benefits and risks be weighted equally or not? If not, how should weights be assigned? Clearly these are political and social decisions with a strong value-judgment component, where scientific arguments cannot provide an answer. These issues are particularly important for the risk evaluation part of the risk optimization process, that is, the process of determining the significance or value of the identified hazards and estimated risks to those concerned with or affected by the decision. This stage of risk assessment allows for value judgments and consideration of benefits associated with the technology.

8.6.2 Maize as an open genetic system under the conditions of campesino farmers¹¹

The maize agricultural systems of small-scale, subsistence-oriented farmers can be characterized as open genetic systems (Louette et al. 1997). In these systems, multiple maize populations coexist (Bellon and Brush 1994). Most seed is saved from the previous harvest (Morris and López-Pereira 1999), though some seed may also be acquired from other farmers or even commercial sources (Louette et al. 1997; Louette and Smale 2000). Farmers may mix seed from different sources if they lack sufficient seed or if they wish to experiment with or expressly modify a maize population (Aguirre 1999; Perales et al. 2003). Farmers may incorporate improved varieties and expose them to their conditions and management, fostering their local adaptation, a process known as “*creolization*” (Bellon and Risopoulos 2001). New alleles are introduced and, through recombination, incorporated into new genetic backgrounds. These practices and conditions are conducive to gene flow and the development of maize populations with a long life that extends over many generations (Louette et al. 1997). The conditions described above depart strongly, both genetically and socially, from the commercial agriculture for which transgenic varieties were developed and are commercialized today.

If transgenic varieties are introduced into these systems, it is likely that they will be managed like the local maize populations. Genes will be exchanged between transgenic

¹⁰ Adventitious means added from another source or occurring in other than the usual location. We use this term because it is neutral (unlike contamination or pollution) to refer to transgenes that simply should not be in a particular place, crop, etc., for whatever reason.

¹¹ This section is based on Bellon and Berthaud (2004).

varieties and local landraces through pollen flow between plants as well as by mixing seeds at several steps in the cropping process, and transgenes will diffuse into local landraces. Like any gene, the transgene will behave independently of the other genes in the transgenic variety, and its dynamics in local maize populations will depend on rates of selection and migration, which are regulated by natural factors and human management.¹² Depending on whether the transgene is expressed, and, if it is expressed, whether farmers perceive its phenotypic expression as beneficial, deleterious, or neutral, farmers' actions may foster or hinder its diffusion. One could say that transgenes will enter into the evolution of local maize populations.

The natural and human factors that control these processes may act antagonistically, making it difficult to foresee precisely how rapidly a transgene might diffuse to local maize populations and how widespread it might become within them. We can nevertheless foresee some situations that are rarely considered in risk assessment and management.

First, an uncontrolled diffusion of transgenes to non-transgenic populations may take place. Second, if varieties with different transgenes become available and are planted, it is possible that, due to gene flow and recombination, maize populations may end harboring multiple transgenes (a phenomenon known as gene stacking) (Hall et al 2000). These combinations may include transgenes that were never tested together. Third, if transgenic varieties that have been designed and produced with several transgenes, which may or may not be linked, enter the system, the same process of recombination and migration may cause the multiple transgenes to diffuse, although links between transgenes may be broken by recombination during diffusion. Fourth, the introgressed transgene(s) will be introduced into different genetic backgrounds—those of the local maize populations—and since the expression of a gene depends on the genetic background in which it exists (Fagard and Vaucheret 2000), the expression (or lack) of the transgene may be very different from the expression in the original phenotype.

In most cases, the introgressed transgenes would not cause the expression of a trait because parts of the gene may be missing, and would therefore remain unnoticed, but in other cases they would result in expression of a trait. The new genetic material in farmers' local populations could include active genes (which will be expressed to a greater or lesser extent, or not at all, depending on how they interact in the new background) as well as inactive genes and pieces of genes, which can remain in populations in a stable manner.

In terms of the impact of transgenes on maize diversity, it is unlikely that the presence of transgenes *per se* will automatically reduce the diversity of alleles in local maize populations or the morphological variants managed by *campesino* farmers in Mexico. This diversity is the result of natural selection as well as farmers' selection that reflect multiple interests and the diverse environments in which they farm. A trait coded by a

¹² A more detail analysis of these processes and their consequences is presented in Chapter 3. In this chapter the different genetic factors that should influence the rates and extent of diffusion and the likelihood of the permanence of transgenes into landraces are examined at length.

transgene would likely be only one among many other traits that farmers observe and assess. Rather than reducing diversity, this process may result in the same amount of diversity as before, in terms of alleles and phenotypes, but with a transgenic component.

The open genetic nature of the maize agricultural systems in Mexico should be incorporated into the risk assessment. This means that hazard identification and risk evaluation should examine the probabilities and consequences of: the diffusion of transgenes to non-transgenic maize populations; the probability of gene stacking and its likely consequences if multiple transgenes eventually become available; and the expression of transgenes if they are incorporated into the genetic backgrounds of local landraces. This also points up the uncertainty concerning the consequences of these phenomena. While we know that a transgene will interact with the different genetic backgrounds of landraces, we do not know exactly how and what will be its expression, nor the consequences of gene stacking. Thus, the link between transgenes and traits for which they are supposed to code becomes much more convoluted and uncertain in the conditions of *campesino* farmers. Many of these issues are researchable,¹³ but an important point is that once transgenes are under the management of *campesino* farmers they will be in evolution. Unlike transgenes in developed countries, where evolution is in the hands of breeders and companies (although they do escape as well) and under tight controls (at least in theory), in Mexico the evolution of transgenes will be in the hands of farmers and obviously under human and natural selection. Evolution is unpredictable or at least uncertain under these conditions, because so many variables interact together and so many scenarios can be imagined and surprises can happen.

In terms of risk management this means that we should be prepared for surprises, which in turn suggests the need for a management system that allows reversibility (i.e., the ability to return to the previous state in which local maize populations existed without transgenes). As Chapter 10 points out, this may be impossible, although as the authors of the chapter also note, there may be ways to go back to the original state, for example by the complete substitution of GM crops by the conventional equivalent varieties. The reversibility of the diffusion of transgenes to non-transgenic maize populations is still an open research issue.¹⁴ If reversibility is not possible however, then farmers who may not want to have transgenes in their maize may not be able to opt out. This certainly could be an important externality to those farmers. Chapter 10 deals explicitly with the tools and policy options to manage potential risks.

These issues call into question some of the assumptions presented earlier regarding transgenic varieties. First, the assumption that the introduction of a few transgenes in a crop variety with a good safety record poses only incremental risks may not be completely warranted. As discussed above, the diffusion of transgenes to non-transgenic maize populations and their inclusion into the evolution of these populations—

¹³ Chapter 3 identifies several important research issues that merit further investigation.

¹⁴ The issue of reversibility seems to be a contentious issue. One reviewer questioned the need for reversibility regarding transgenes since this is not required for conventional breeding. Another reviewer said that we must accept that transgene escape in Mexico will be irreversible, and cited the example of the persistence of Starklink transgene in US corn as an example of this. For a further discussion of the issue also see Bellon and Berthaud (2004).

particularly given the possibility of gene stacking and the inclusion of transgenes in new genetic backgrounds—suggest that interactions may be important and unknown. This does not mean that such phenomena necessarily are hazards, but that we cannot apply a simple “familiarity” model to the problem. Thus, there may be a greater need for containment and/or confinement as well as mitigation and remediation measures, when dealing with the introduction of transgenes in maize in Mexico.¹⁵ Another related assumption is that we can ignore the creation of unstable individuals during the formal breeding process. While it may be true that unstable individuals generated prior to release can be ignored, it is possible that some sort of unstable individuals may appear after release, if and once transgenes diffuse to landraces and appear in different genetic backgrounds.

8.6.3 *The cultural significance of maize in Mexico*

In Mexico, maize has a great cultural significance for *campesino* farmers. These farmers are both producers and consumers of the crop and heirs to those that domesticated the crop several thousand years ago. Hence, there is long history of co-evolution between local human populations and maize. The diversity of maize types that we observe in Mexico is related to the constant divergent selection that farmers continue to exert on maize populations to meet their cultural and agronomic needs (Hernandez 1985; Pressoir and Berthaud 2004).¹⁶ This cultural significance is evidenced by the diversity of maize types cultivated, as well as the wealth of dishes prepared from maize and the rituals and beliefs associated with its cultivation and preparation (Alarcón-Cháires et al. 2001; Museo de Culturas Populares 1982; Olivo et al. 2001). Farmers talk about maize with much affection and respect. Some compare maize to water, as some farmers in the Central Valleys of Oaxaca said: Aye, dear god! If there is no maize, what do we eat! It is the same as if there was no water – without water, what would we drink? “Maize is like water. If there is no water, there is no life. ...If there is no food, well... one is not well” (Badstue 2003, 12). Clearly, maize for *campesino* farmers has significance beyond that of a commodity produced simply for profit.

The cultural significance of maize adds a new and less tangible dimension to the hazards that the introgression of transgenes into local maize population may create, particularly hazards to the cultural integrity of Mexican farming communities. The nature of the perceived adversity may be somewhat unclear, disputed and difficult to quantify. For example, a popular conception of pollution presumes that pure or unsullied environments are harmed by anything that compromises their pristine character. Thus, careless littering of wilderness by tourists is often thought of as polluting activity, even if it causes no further damage to wildlife or the wilderness ecosystem. The public record suggests that

¹⁵ Yet, as one reviewer noted, containment and confinement are strategies that have repeatedly broken down in other settings, hence there is no basis to anticipate reversibility of transgene escape. As noted in the previous footnote, the issue of reversibility seems contentious.

¹⁶ It is important to emphasize that the conservation of local landraces in farmers’ fields should not be seen as an attempt to keep people poor or deny them access to improve technologies. It is to provide farmers with choices and recognizing that crop diversity still plays an important role in their livelihoods. For an in-depth discussion of these issues see Bellon (2004).

some individuals tend to think of transgenes in a similar way. So any evidence of transgenes found in non-transgenic crops is regarded as contamination, without regard to whether the transgene is maintained in the gene pool or can be shown to have any further consequences for non-target species or farming practices. This view of hazards has been rejected by a number of scientific committees convened to review the risks of transgenic crops.

However, although one should not accept *a priori* that the introgression of transgenes into local maize populations is a form of pollution, one should not reject the need of examining this issue, in light of the cultural importance of this crop. In any case, hazard identification requires a value judgment and it is important to provide an explicit rationale for why certain events are or are not regarded as adverse.

It should be pointed out that farmers' landraces are not "pristine" or antique vases held in a museum. They are constantly changing under both human and natural selections, and gene flow plays a key role in their evolution. The incorporation of foreign germplasm, particularly from improved varieties, into local landraces has been common and does not seem to be viewed as negative by *campesino* farmers, and it is and has been part of the open-genetic system that characterizes maize in Mexico. In many instances farmers consider it positive and they actively try to mix seed from their local materials with foreign varieties to improve the former (Aguirre 1999; Perales et al. 2003). Foreign materials are considered as local after a few years of successful cultivation under farmers' conditions. These results suggest that *a priori* the incorporation of transgenes into local maize populations need not be considered "bad" by farmers, unless the transgenes code for traits that may be disadvantageous under their circumstances, in which case the plants carrying the deleterious traits will be eliminated from the system by natural or human selection. The problem may be more related to the perceptions from other groups in society and to whether a stigma is associated with transgenes, as implied by the use of words such as "pollution" or "contamination." In the end, the farmers who may end up having the transgenes in their maize populations should decide how they view the transgenes, but this view should be based on accurate information and sound reasoning.

Clearly, the cultural significance of maize to small-scale subsistence-oriented farmers in Mexico is important for the process of hazard identification and risk evaluation. To incorporate this aspect however, may be complicated due the difficulty of measuring "cultural significance," though this difficulty does not make the issue less real. Also, as part of assessing benefits and risks, farmers should have access to accurate information on transgenic maize and those potentially affected should be directly consulted regarding their views and desires.¹⁷

¹⁷ As one reviewer noted that just as we want that farmers and consumers views to be informed by accurate information, so we should want their views to be informed by sound reasoning techniques. We should not simply accept whatever the views and desires may happen to be, especially if they are not coherent, clear, or fair. The problem is who decides what is reasonable; as our daily life illustrates, what we consider reasonable, coherent and fair may not be considered as such by others and vice versa.

8.6.4 The presence of the wild relative of maize

An important concern in assessing the risk of growing a genetically modified crop in its center of domestication (i.e., where its wild relatives are present) is the occurrence of gene flow between the transgenic crop and its wild relatives, in the case of maize, between this crop and its wild relative teosinte. Even though data on this subject are still limited, the potential impact of such gene flow has been under discussion for some time (Blancas et al. 2002; Gepts and Papa 2003; Serratos et al. 1997; also see Chapter 3 in this volume).

Despite the factual and scientifically proven gene flow from modern traits towards teosinte and maize landraces, there is evidence of stability among the landraces and their wild relatives and no negative processes were detected. Extensive analysis of chromosome morphology with Mexican maize and its wild relative teosinte hints at a stable diversity of the landraces and teosintes, despite the fact of heavy gene flow for decades from modern traits to landraces and teosintes (Kato 1997). In fact, hybrid corn has been cultivated in the vicinity of landraces and teosinte for more than 50 years without any documented damage to landraces and teosinte. A reliable summary has been given by (Alvarez-Morales 2000) and more comprehensively recently by Wisniewski et al. (2002). However, it has been argued that even rare events may provide an opportunity for persistence and may even result in changes in genetic diversity of natural populations (Ellstrand et al. 1999).

8.6.5 Maize consumption patterns of the Mexican population

Maize is very important in the diets of the Mexican population, particularly in the rural areas and among the poor. The level of consumption and the ways maize is prepared for its consumption are very different from the way that maize is used and consumed in developed countries where most of the toxicological studies of transgenes have been done. Therefore, those studies may not necessarily be applicable or valid under the circumstances of Mexican consumers. This suggests the need to conduct toxicological studies of transgenic maize products in the country, that reflect the conditions and at the levels of consumption of maize of the Mexican population.¹⁸

8.6.6 Assessing the benefits and their distribution

The previous sections have dealt mainly with risk assessment under the conditions of Mexico, but a key component of the decision on whether transgenic maize should be introduced or not in Mexico has to do with the benefits that introduction may bring. The benefits cannot be taken for granted; they have probabilities of occurrence and different magnitudes, and may accrue to benefit certain groups in society more than others. Since benefits may be distributed differently among different groups in society, they will have to be weighted. Furthermore, as pointed out in Chapter 5, current available transgenes are only marginally attractive, but future advances may be very helpful for the conditions of

¹⁸ See also Chapter 7.

many Mexican farmers. It is important to bear in mind also that the benefits that would have been generated if transgenic maize were introduced in Mexico represent the opportunity cost of not introducing this technology.

Related to the distribution of benefits and risks among different groups of society is the distinction between private and public benefits and risks. Distinguishing and balancing both types of benefits and risks will be important for the acceptability of this technology. As argued above, the introduction of transgenic varieties may generate externalities, a certain degree of uncertainty, and irreversible consequences, but their existence should not be construed as making decisions impossible or that transgenic varieties should not be introduced in Mexico—humans constantly make decisions that lead to externalities, as well as to uncertain and irreversible consequences. The decision may have to do with the extent of the benefits that are created, their certainty and their distribution across different groups in society. Large, certain and well distributed benefits may justify embarking on courses that lead to uncertain and irreversible consequences. Given these considerations, it may not be enough for transgenic varieties to generate large private benefits to one or a few groups in society. Large public benefits to the environment or to society may be required, such as the use of less pesticide and reduced pollution, or greater equity in the distribution of benefits, particularly benefits to the poor. The requirement of large public benefits is particularly important because if the uncertain and irreversible consequences turn out to be negative for society or groups within it, society as a whole may have to deal with them. Another important factor is how to engage the farmers that may be affected by the externalities identified above and let their voices be heard since they may have to bear a high proportion of the costs. Engaging these farmers in decision making is desirable, but will be complex and costly, though the costs of not engaging them will be complex and objectionable as well.

Establishing baselines will be necessary to assess the benefits and risks that transgenic maize may have in Mexican agriculture, because they set the standard to which we can compare the benefits and risks incurred as well as monitor their impacts. As will be discussed in the next section, the draft of the Mexican Biosafety Law establishes that the minimum baseline to compare potential risks due to the release of GMOs should be the risks that would be generated due to the release of similar non GMO organisms or the parental organisms, when they were released in that environment.

One can think of at least two types of baselines in this respect. One should deal with the impact of a specific trait for which a transgene will code. For example, for a Bt variety, a baseline should include: the current level of crop losses associated with the target insects for different types of farmers and regions of the country; the current measures used to counter these losses, such as which farmers may adopt the technology and which may not; the use of pesticides; and the impacts of those pesticides on human health and the environment. An understanding of all these issues is needed so that one could compare the benefits of the new technology with that of the current ones used, as well as the distribution of the benefits and risks.

Another type of baseline is more systemic and has to do with the fact that Mexico is a center of origin and of diversity of maize and, as such, a reservoir of genetic resources for

humanity. Hence a baseline of the maize diversity present is fundamental to assess how it might be affected by the introduction of transgenic maize varieties, particularly since this introduction will imply a certain degree of externalities to farmers, uncertainty and probably irreversibility. This suggests the need for a systematic study of maize diversity in Mexico. In addition to the above-mentioned aim, the study could serve to increase the collections of maize landraces in gene bank collections, and more resources may be invested in ex situ conservation.

Regarding ex situ conservation, the collections in gene banks should be protected against the inadvertent introduction of transgenes in accessions that may constitute the sole fall-back, if transgenic maize has a negative impact on maize diversity.

Finally, a monitoring system should be implemented to follow up the impact of transgenes if they diffuse to other organisms, particularly landraces.¹⁹

8.6.7 Balancing benefits and risks

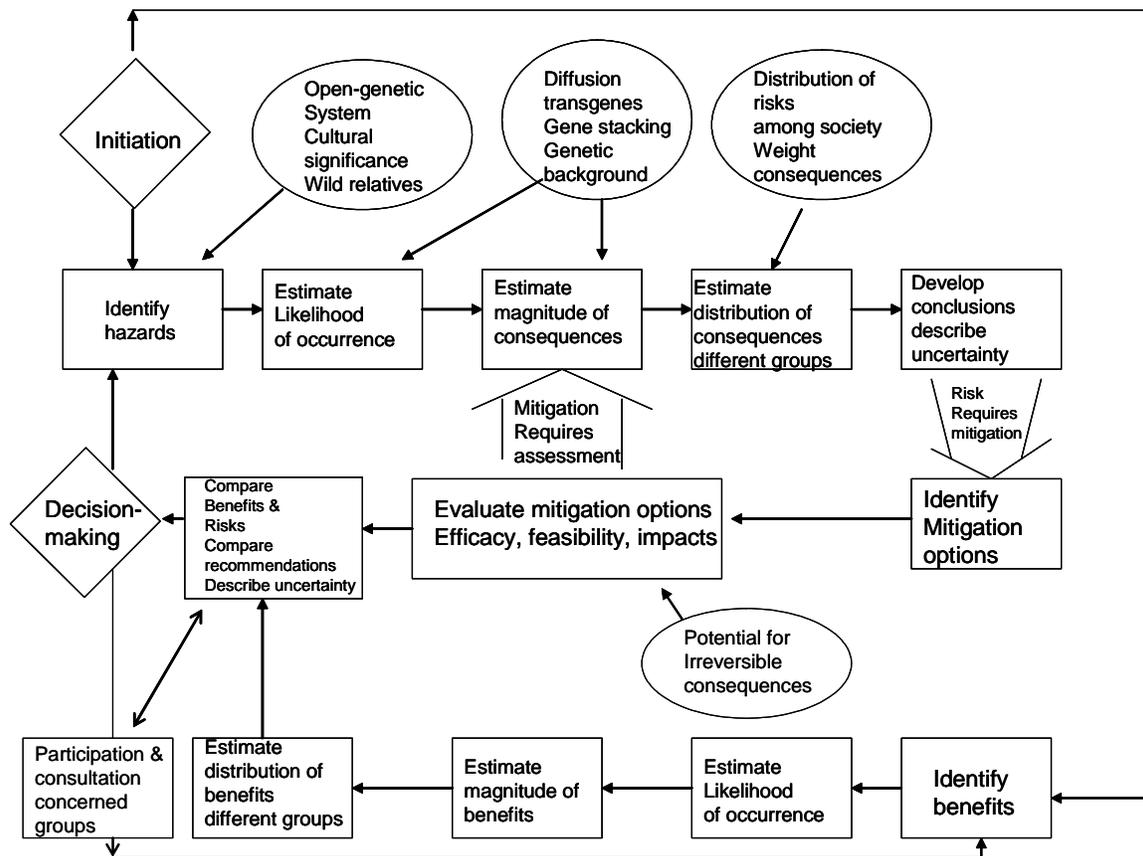
At the end of the day, benefits and risks would have to be balanced and decisions will have to be reached regarding the planting of transgenic varieties in Mexico, or the future of the importation of transgenic maize products into the country, or actions to avoid the potential spread of transgenes to landraces. As it has been argued here with regards to the introduction of transgenic maize in Mexico: (1) benefits cannot be taken for granted, (2) both benefits and risks are still not well known or understood, and (3) hence there is a large degree of uncertainty regarding what may happen, including the possibility that irreversible consequences may occur. This does not mean that decisions cannot be reached, because we take them in other spheres under similar circumstances; rather it means that benefits and risks will have to be weighted acknowledging the uncertainty involved, and that this process is not value free. As argued above, the distribution of benefits and risks among different social groups matters. This suggests that different weights may have to be given to the benefits and risks faced by these different groups, but this also entails judgments about the importance of equity as a social goal. Assigning these weights and balancing benefits and risks is clearly very complex. It is not just a scientific issue, but also a social and political question in an increasingly democratic Mexico. The most we can do here is to acknowledge the great complexity that balancing these benefits and risks entail.

Figure 1 presents a schematic view of a process to judge the benefits and risks associated with the introduction of transgenic maize in Mexico, summarizing many of the issues that this chapter has dealt with. The process starts by identifying both the hazards and the benefits; in both cases the likelihood of their occurrence are estimated, as well as their magnitude. In the case of the risks, the figure describes some of the risks that were identified as particularly relevant for the case of maize in Mexico. The process continues by looking at the distribution of the risks and benefits among society and possibly attaching some weights to them. In the case of the risk assessment, this leads to

¹⁹ See Chapter 10 for a further discussion on monitoring the post-market releases of GMOs.

conclusions and a description of uncertainty, which then leads to the identification of mitigation options that are then evaluated in terms of their efficacy, feasibility and impacts (here irreversible consequences are taken into account). The results regarding risks and benefits are then compared and a decision is reached. These comparisons should take into account baselines as controls to be used for judgment. Participation and consultation of concerned groups is done since the early stage of hazard identification, as well as during the comparison of risks and benefits. If for example, the decision was to proceed with the release of transgenic maize, then monitoring should take place and should feed back to decision-making.

Figure 1. Diagram of the components of a framework for benefit and risk assessment of transgenic maize in Mexico



The complexity of the issues suggests that a precautionary approach should be considered together with a risk optimization approach concerning the decisions about the introduction of transgenic maize in Mexico.²⁰ It should be noted however that there is still debate and controversy about the precautionary approach and its implementation, although it is an important component of the Cartagena Protocol on Biosafety.

An important development to address the issues dealt in this chapter is the recent draft of a biosafety law for Mexico. This law once is approved and signed into law, will establish the framework by which many of the benefits and risks will be judged. The next section presents some relevant parts of the draft law and discusses them in the context of what has been presented in this chapter.

8.8 Institutional approaches for risk assessment and management: The Draft Mexican Biosafety Law²¹

The draft Biosafety Law for Genetically Modified Organisms approved by the Mexican Senate on April 2003 (Senado de la República, 2003), and currently under review and discussion by the House of Representatives (Cámara de Diputados) will establish the legal framework to regulate the activities of confined utilization, experimental release, commercial release, commercialization, importation and export of genetically modified organisms. Its goal is to prevent, avoid or reduce the potential risks that these activities could produce on human health or the environment, as well as to biological diversity or to animal, plant or fish health.

The draft law establishes that biosafety regulation should be the purview of mainly three government Departments: Secretaría de Salud (SS, Department of Health), Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA, Department of Agriculture, Rural Development, Fisheries and Food), Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT, Department of the Environment and Natural Resources), although other departments may participate in particular instances, e.g., Secretaría de Hacienda y Crédito Público (Department of the Treasury, SHCP), Secretaría de Economía (SE, Department of Economy). It creates as special body to deal with biosafety: Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM, Interdepartmental Commission for the Biosafety of GMOs).

The draft law is broadly based on a risk optimization approach, science-based and with a case-by-case method. The law defines and describes in general terms the stages for a risk assessment. It incorporates into the biosafety regulatory process important elements from

²⁰ If the draft Mexican law on biosafety to be discussed in the next section is not widely modified, it is clear that the precautionary principle would have to be taken into account on how these issues are addressed. This will depend also on how the principle is made operational in the implementation of the law.

²¹ See Chapter 10 for a description and discussion of the national biosafety system in Mexico.

the Cartagena Protocol, to which Mexico is a signatory. These include an explicit recognition of the precautionary principle, of mechanisms for public consultation and participation,²² and the possibility to incorporate considerations about antecedents regarding use, production and consumption in the risk assessment, and establish the criteria for a minimum baseline to compare potential risks due to the release of GMOs into the environment. It defines centers of origin and diversity and establishes guidelines about the release of GMOs in them. Particularly it restricts the release of GMOs in them, although some exceptions are defined as well. It also recognizes the need for studies that take into account socioeconomic considerations resulting from the release of GMOs into the environment, particularly in relation to the value that biological diversity has for indigenous and local communities. An important difference with other approaches is that the law establishes the need to take into account the nature and method of the genetic modification in the risk assessment, not just the trait and its novelty.

Although difficult to anticipate at this time, the reconciliation of the law with the mandatory provisions of other agreements may raise some issues particularly concerning the importation of transgenic maize. The latter would fall, primarily, under the provisions of the WTO agreements and the North American Plant Protection Organization (NAPPO Regional) Standard for Phytosanitary Measures (RSPM) No. 14 adopted in 2003.

The draft law is innovative and presents a multidimensional framework for biosafety regulation. Furthermore, its implementation will depend on the development of specific directives and guidance documents such as the Official Mexican Norms. These directives and guidance documents will have to deal with some of the issues raised in this chapter, for example the specifics of how the precautionary principle should be made operational or how hazards should be identified and by whom. The latter is an important issue since according to the draft law, the risk assessment procedure should be developed by the interested parties—which are not explicitly defined, but that may mean those who want to introduce the GMO—there is a real possibility for an *ad hoc* and subjective process of hazard identification which only takes into account one point of view, but not others, potentially leading to ignoring important hazards. While the draft law recognizes the possibility of incorporating socioeconomic considerations and the interests of indigenous and local communities in regards to the value they place on biodiversity into the assessment process, it is the directives and guidance documents that will have to define how this will be done and by whom. Clearly, the draft law does not address many of the issues raised in this chapter—and one could not expect it to do so—but establishes a general framework that recognizes at least in principle many of these issues.

8.9 Conclusions

- Available methodologies for risk assessment and management can be used in the case of transgenic maize in Mexico.

²² The draft law directs the CIBIOGEM to establish mechanisms for public consultation and access to information, particularly the creation of a consultative council with wide representation, as well as public consultations about applications to release GMOs into the environment

- These methodologies however, require modifications to take into account the special circumstances of maize in Mexico.
- These circumstances have important implications for risk assessment and management, providing new dimensions for the risk evaluation process and should be incorporated in it.
- Benefits of transgenic maize cannot be taken for granted, and must be identified and weighted in terms of their magnitude and probability of occurrence.
- The distribution of potential benefits and risks among different social groups should be taken into consideration for judging them.
- Distributional issues also pertain to the extent that benefits and risks are private or public, and how both are weighted. Distinguishing and balancing both types of benefits and risks will be complex, but important for the acceptability of this technology.
- Social participation in the evaluation process is important, particularly of those groups that may be influenced—positively or negatively—by the introduction and use of transgenic maize in Mexico. Consultation with these groups is fundamental.
- Consultation cannot be left to the end of the assessment process and should be done early and ideally as the assessment process unfolds.
- Judging the benefits and risk of the introduction of transgenic maize in Mexico is a complex process that may require a combination of approaches, as well as social participation and consideration of social values, particularly the important cultural significance of this crop for many Mexican farmers and consumers.
- Science has a very important role to play in the process and can illuminate many of the choices faced by society, but it cannot provide all the answers and be the sole basis for decision making.

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