

Value Judgments and Risk Comparisons. The Case of Genetically Engineered Crops

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This paper aims to identify and elucidate some of the philosophical issues and value judgments associated with the claim that risks from transgenic and conventional crops are comparable from a scientific perspective. Crops produced using techniques that insert DNA directly into the genome of the plant, by *Agrobacterium tumefaciens*-mediated transformation or by the gene gun, will be referred to as "transgenic or genetically modified (GM) crops," and the terms "conventionally bred" or simply "conventional crops" will be used to indicate all other agricultural crop varieties. Breeders distinguish farmer-bred land races from conventionally bred crops, but the critical requirement in this context is simply that the crops have been developed without the use of recombinant DNA techniques for gene transfer.

I will not discuss food safety and socioeconomic issues so that I can concentrate on other aspects of GM technology. Although critics of transgenic technology have insisted that these socioeconomic impacts have been unjustly overlooked by scientists and regulators (Krimsky and Wrubel, 1996), they are not material to any substantive differences of opinion about the comparability of risks. For both food safety and environmental safety, U.S. regulatory decision making has been based on the assumption that once transgenes are integrated into the genome of a transformed crop and both gene function and reproductive stability have been verified, risks may be evaluated exclusively with respect to phenotypic traits (Miller, 2000). This assumption is critical to debates over food safety and environmental impact of transgenic crops. However, the scientific basis for the justification of this assumption and subsequent attempts to evaluate and compare risks with respect to food consumption and environmental impact of crop production proceed from different principles. Although biochemistry and toxicology are the primary bases for evaluating food safety risks, environmental risks are evaluated on the basis of ecology, population genetics, and evolutionary biology. Hence, the discussion that follows is not really relevant to food safety.

I will not assess the claim that environmental risks of GM and conventional crops are comparable, either with respect to its accuracy or with respect to regu-

latory policy for new crops. The aim of this paper is to identify key places in the conceptualization, assessment, and comparison of environmental risk from both types of crops where value judgments would tend to produce contrasting judgments about the equivalence or comparability of these risks. Arguments for or against any of the contrasting value judgments that are identified would prove to be complex, and as such even a philosophical evaluation of these value judgments exceeds the scope of the present discussion.

A "value judgment" in this context is a working assumption for the purposes of risk comparison, often implicit, that involves assumptions about the goodness or badness of an action or outcome or that draws broadly upon philosophical framing assumptions about the nature of environmental risk and the propriety of various human and social responses to it. To say that such assumptions are philosophical is simply to say that differences between judgments based on these assumptions would not be easily settled by data collection or scientific experiment. This does not mean that all parties would regard them as subjective or arbitrary.

THE SIGNIFICANCE OF THE COMPARATIVE FRAMEWORK

The claim that risks from transgenic and conventionally bred crops are "comparable" has been central to the debate over agricultural genetic engineering since its inception. Writing in the mid-1980s, Winston Brill suggested that crop scientists' long experience with developing new crops through breeding provides a scientifically valid basis for anticipating environmental hazards associated with the then-novel techniques for introducing new genes using recombinant DNA techniques (Brill, 1985, 1986). Brill argued that the use of rDNA gene transfer techniques would not, in itself, be the source of new or novel types of ecological impact from new crops. His view became the basis for U.S. policy toward environmental risks expressed in the aphorism that evaluations would be based on "product, not process," meaning that the use of recombinant gene transfer (e.g. the process) would not be a rationale for unusual regulatory scrutiny.

Brill's argument was endorsed by a series of reports from the U.S. National Research Council (NRC; 1987, 1989, 2000, 2002). None of these publications

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Figure 1. A collection of ears of maize from landraces grown in Mexico. When a landrace is grown in proximity to elite lines, gene flow will occur. Is such gene flow harmful and a form of genetic pollution, or is it part of the continuous development of the landrace? Is it only harmful if it is a transgene even if the transgene does not persist in the population because there is no selection pressure? Courtesy of International Center for Development of Maize and Wheat (Mexico City).

offer well-quantified expressions of environmental risk; hence, the statement that the risks of transgenic and conventional crops are comparable both in nature and in magnitude must be understood as making a largely qualitative and conceptual claim. The claim that environmental risks from transgenics do not differ from those associated with conventional crops has been important for the debate over agricultural biotechnology in two related respects. First, there has been a general presumption that conventional crops do not pose large environmental risks; hence, to claim or deny that the risks of transgenic crops are comparable has been interpreted respectively as an endorsement or criticism of biotechnology. Second, before the advent of rDNA techniques in plant science, new crop varieties were not being subjected to routine regulatory oversight on environmental grounds. Those who have argued for regulatory evaluation of transgenic crops before commercial release have been in the position of needing to justify special treatment for this class of plants, whereas those who have opposed special regulatory handling have tended to defend the claim that the environmental risks of GM and conventional crops are comparable and that additional regulatory requirements for transgenic crops would be unduly burdensome.

Claims about comparability of risk are important for both normative and rhetorical reasons. Many authors have argued that the acceptability of risks associated with new technology should always be determined through a comparison with feasible alternatives, including and especially the risks associated with nonadoption or rejection of the new technique (see Graham and Wiener, 1995). Even quite risky technologies may prove normatively acceptable in circumstances where the status quo involves a high level of adverse health or environmental impact.

Emphasizing claims about the comparability of risk is rhetorically attractive because one appears to be making straightforward factual claims. As such, it is possible to express an argument about the acceptability of a novel technology without making overtly normative or value-laden claims simply by asserting whether risks of the novel technology are greater than, less than, or roughly equal to those of existing technologies. Each of these assertions appears to be making a straightforward factual claim that can be verified or falsified by data collection and scientific analysis. Confining one's rhetoric to such claims has proved to be a particularly effective device for authors and bodies that wish to represent themselves as scientific in origin or method (Thompson, 1988).

Boulter (1997), Stewart et al. (2000), and Saner (2000) have discussed the role of values in comparing transgenic and conventional crops. Boulter reviews some of the procedures proposed for quantifying environmental risk and summarizes the scientific viewpoint as endorsing the "product not process view." The public's views are characterized as being driven by largely qualitative factors such as voluntariness, dread, and trust. Stewart et al. (2000) also characterize the scientific viewpoint as endorsing the comparability of risks and characterizing the public's view in terms of a general lack of knowledge about plant science. Saner suggests that the belief that transgenic and conventional crops have noncomparable risks derives from the application of non-consequentialist ethical values. One common theme of these studies is that those who tend to see transgenic crops as posing novel risks tend to apply broad philosophical conceptualizations of nature and natural processes that are inconsistent with a scientific emphasis on quantifying the probability that harmful outcomes will occur.

However, it has become generally acknowledged that although claims about the relative level of risk for two or more courses of action make claims that are, in principle, refutable with evidence and further analysis, these claims are not at all straightforward. Even within a scientifically oriented and consequence-evaluating approach, conceptualization and comparison of risks involves an array of interpretive judgments. Reasonable and often defensible differences in the interpretation of many parameters in the framing and measurement of risk can result in very different estimates of risk and can produce contradictory comparative estimates (Brunk et al., 1991; Caruso, 2002).

Although it seems reasonable to insist that the comparative evaluation of risks from transgenic and conventional crops should be "based on science," setting up a comparison of the environmental risks from transgenic and conventional crops requires a series of value judgments. Philosophical differences of viewpoint involve both normative judgments about what is and is not harmful from an environmental perspective and pragmatic or working assumptions about problem definition. The latter often involve uneliminable but also unverifiable assumptions about the behavior of relevant phenomena. Thus, for example, to evaluate most agriculturally based environmental risks, one must make assumptions about farmer and farm worker handling of key materials, yet the empirical basis for such human factors in agriculture is virtually nonexistent.

Clearly, other differences of viewpoint refer back to economic interests and power and the more qualitative considerations noted by the three studies mentioned above. Like philosophical differences, they may be shielded from falsifying experiments or data analysis both because of the inherent difficulty in subjecting them to test and because powerful actors may prevent them from being subjected to test. In either case, differences of opinion in any of these three areas cannot be settled by scientific studies. Thus, it is possible to have a view of the environmental risks of transgenic crops that is contrary to science in the sense that it contradicts those elements of the comparative judgment that are well established by theory and data, but it is not possible to have a view that is based wholly on scientific methods and findings.

HAZARD IDENTIFICATION

Environmental risks are typically understood as a combination of hazard and exposure. Although the conceptualization and measurement of exposure can make extensive use of scientific theory and methods of quantification, the identification of potential hazards is by all accounts deeply value laden (NRC, 1996). To describe a potential state of affairs as an environmental hazard implies the value judgment that this state of affairs is bad, harmful, unwanted, or

in some way less preferred than other possible states of affairs. Some environmental hazards derive their negative value from such non-controversially bad outcomes such as human death and disease, but environmental risks from transgenic crops more typically have been characterized in terms of negative effects on the environment itself, effects that eventuate in harm to human health only through extremely indirect, convoluted, and highly contingent further causes. Specifying these environmental hazards is a prime source for differing opinions on the relative risks of transgenic and conventional crops.

Criteria for healthy and well-functioning ecosystems have been acknowledged as inherently value laden. The range of values that can be applied to agriculture's impact on the environment is quite broad. Some philosophers have suggested that agriculture is inherently inimical to ecosystem health or integrity (Westra, 1998), whereas others have argued that traditional notions of agrarian stewardship can supply a model that would be applicable in other areas of environmental ethics (Thompson, 1995). The former view, in particular, would provide a philosophical basis for thinking that any trace of human impact on wild ecosystems from transgenic crops would constitute a hazard to be avoided.

NRC committees have tended to draw upon templates for specifying environmental hazards developed by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture. Historically, APHIS characterized environmental risk primarily in terms of hazards to U.S. agricultural production in the form of pests. The principal pest hazards have been unintended introduction of plant and animal diseases from products brought into the United States and through unintended effects of invasive species (including insects), some of which were planned introductions. Although APHIS was originally established to guard against such hazards to U.S. agricultural production, APHIS authority and practice have gradually expanded to include protection of uncultivated and natural ecosystems from similar threats of infestation and invasion (McKenzie, 2000).

This expansion permits a broad definition of unwanted environmental effects in terms of rapid and substantial change in the number and composition of species occupying an ecosystem. Thus, an environmental or ecological hazard is the potential to cause a relatively rapid and permanent decline in the number of individual organisms from one or more species currently extant in a natural or agricultural ecosystem. This general characterization of environmental hazards has been utilized by several authors offering scientifically based surveys of the risks associated with transgenic crops (Stewart et al., 2000; Wolfenbarger and Phifer, 2000; Marvier, 2001; Carpenter et al., 2002).

This definition should not be regarded as stating either necessary or sufficient conditions for an unwanted environmental impact. For example, some large-scale changes in agricultural ecosystems are not regarded as adverse. Nevertheless, it does capture in broad terms the main thrust of scientific thinking on the possible environmental hazards that can be associated with transgenic crops. It encompasses the basis for environmental concerns associated with pesticides and other pollutants and with invasive species and microorganisms. Furthermore, it is capable of recognizing that agriculture itself can be a source of unwanted environmental impact, as when crop or livestock production displaces habitat for native plant and animal species. NRC committees have specified a number of specific hazards in some detail, ranging from the potential for weedy herbicide-resistant plants and the evolution of resistance to the *Bacillus thuringiensis* toxin—two events whose adversity is primarily with respect to the prospects for productive agriculture—to the potential for large-scale displacement of natural ecosystems (NRC, 1989, 2000, 2002).

The recent NRC committees charged with revisiting environmental risks from transgenic crops in general and pest-protected crops (e.g. *Bacillus thuringiensis* (Bt) maize [*Zea mays*]) in particular both concluded that hazards involving both the number and composition of species in an ecosystem can be posed by phenotypic traits of specific GM crops and by attendant cultural practices and technologies (such as the use of chemical insecticides or herbicides) that may be associated with specific GM crops. The process through which these traits are introduced into the crop, be it through recombinant gene transfer or conventional methods, was not deemed to be material. Hence, the NRC committees effectively concluded that transgenic and conventional crops have comparable environmental risks, though certainly some specific crop traits could have a relatively high likelihood of causing environmental damage; however, by whatever method these traits had been introduced into the crop (NRC, 2000, 2002).

Hazard identification is subject to a systematic ambiguity that plagues many forms of risk analysis. In common parlance, the word “hazard” is often used to describe situations in which the likelihood of a harmful outcome is substantially greater than might normally be the case, but where there may be dispute that any harmful events have actually materialized. Such situations qualify as hazards in the terminology used in risk analysis only if the analyst has judged that they constitute a form of harm or damage in themselves. Although the NRC committee views the presence of a transgene or transgenic plant “in the wrong place” as an event contributing to exposure and to the probability that harm will occur, it is also possible to view such gene flow as a form of pollution and as an event that is adverse in itself without

regard to any further effects on other plant and animal species. If after gene flow has occurred a transgene is not maintained in the population because positive selection pressure is absent, is this a harmful event? Discussions after the discovery of Bt maize growing in the fields of small-scale Mexican farmers growing open-pollinated land races often took the tone that this event was itself the materialization of an environmental hazard, irrespective of the potential for further impact on the agro-ecosystem of Mexican maize cultivation (Dalton, 2001; Fig 1). Similarly, some have characterized the possibility for hybridization or gene flow to non-transgenic crops or wild relatives as a hazard (Rissler and Mellon, 1996; Löfstedt et al., 2002), rather than as a mechanism that might promote the kind of ecological change that has been viewed as a hazard in the NRC studies.

It should be evident that on conceptual grounds alone, if the presence of a transgene or transgenic plant anywhere outside the field in which transgenic crops are intentionally planted (including within the genome of other crops or wild relatives) is considered to be an environmental hazard, then the environmental risks of transgenic and conventional crops cannot be comparable in any of the senses alluded to above. Transgenic crops have transgenes and conventional crops don't; therefore, only transgenic crops can be associated with hazards defined as a transgene in the wrong place. Conventional crops may have phenotypic traits capable of disrupting the composition of species in an ecosystem, but they do not have transgenes. Hence, the chance that a transgene or transgenic plant will be found as a result of growing a conventional crop is vanishingly small. Only a crop with a transgene can pose the risk of transgenes in the environment, and this hazard can materialize without regard to whether transgenes produce traits that do pose hazards to the number and composition of species.

EXPOSURE PATHWAYS

Those who have argued against the comparability of environmental risks from transgenic and conventional crops have stressed the way that recombinant techniques involve gene insertions that can disrupt proper functioning of plant genes and have the potential to produce quite anomalous behavior on the part of modified plants. Conventional crops, in contrast, are portrayed as crosses between genetically related and sexually compatible varieties, resulting in the kind of normal gene functioning we associate with standard forms of sexual reproduction (Palumbi, 2001; VIB, 2001). The typical response to this criticism has been to note that genetic engineering results in a much more precise and well-characterized introduction of genetic novelty than conventional approaches do, hence suggesting that variability and unexpected results should be even

less in transgenic than in conventionally bred crops. This unhelpful exchange of views actually conceals a difference of perspective in terms of the way that the sequence of events that can lead to an unwanted event is being understood.

As the 2002 NRC report notes, analytic modeling approaches to risk assessment quantify exposure by modeling the sequence of events and causal processes that contribute to the occurrence of hazards, and the overall probability is derived from probabilities that can be assigned to each sequence in the series of events. Those who find risks of transgenic and conventional crops to be noncomparable are noting an acknowledged point of difference in the reproductive success of plants undergoing standard forms of crossbreeding on the one hand and genetic engineering on the other. Having reached a point in characterizing sequence of events leading to a possible environmental hazard at which transgenic plants are behaving far less predictably than conventional plants, they conclude that the risks cannot be comparable. To say that a transgenic plant improvement process is "more precise" seems to be a form of dissembling, for what matters if a form of plant reproduction that results in dysfunctional and unpredictable performance of the individual organisms does so with greater precision?

However, defenders of genetic engineering see crop development as an extended process that only begins with the introduction of a novel trait, either through genetic engineering, crossbreeding, or any of the other techniques currently used in crop development. From the perspective of a plant breeder, this step almost always results in a plant that has a less desirable overall profile of agronomic traits than do current commercial varieties. The subsequent steps of crop development involve further back crossing of the improved plant with established seed lines, generally through six or more generations, finally resulting in a viable crop variety. In the case of genetic engineering, the first step—introduction of genetic novelty—produces far fewer viable offspring than does ordinary crossbreeding (though not necessarily fewer than other forms of inducing mutations by chemicals or irradiation). This is the difference that the critic of genetic engineering seizes upon in deriving a judgment of risk. However, the few stable individuals produced by genetic engineering can and will be backcrossed with founder stock to produce reproductively stable, genetically functional, and agronomically valuable varieties for commercial release. Because it is these plants that will be released into the environment, and not the dysfunctional individuals that are discarded after the initial attempt at transformation, the model for exposure is based solely on the performance of these apparently healthy and genetically stable plants (NRC, 2002).

In short, those who defend the comparability of risks from transgenic and conventional crops do not

see the creation of reproductively and genetically unstable individuals as part of the sequence of events leading to the release of a commercial variety. Anomalous individuals associated with the disruption of a genome from the process of plant transformation are removed from the sequence of events leading to the hazard, and their various dysfunctions are not seen as material to it. In contrast, those who defend the noncomparability of these classes see anomalous individuals as part of a data set highly relevant to the range of uncertainty associated with predicting the behavior of transgenic crops in the environment.

In what sense is this difference of perspective the result of a value judgment? There are several possibilities. One is simply that the creation of a model for exposure involves a number of framing judgments about the systems in question and that for whatever reason, critics and proponents of biotechnology have envisioned the relevant sequence of events very differently. Another is that there is a legitimate difference of scientific opinion about the relevance of the many anomalous results occurring as an immediate consequence of transformation for the probability that varieties developed from apparently stable transformation events will continue to behave in a standard and predictable fashion when subjected to the wide variety of different environmental conditions and stimuli associated with widespread commercial production. This is a value judgment somewhat akin to the kind of theoretical clashes and paradigmatic disputes characteristic of science, and one that may be resolved as experience, data, and theoretical developments clarify the issues. A third possibility, compatible with the first two, is that both ways of characterizing the model for exposure are open possibilities at present and that political or economic interests thrive upon such situations where key questions in framing the mechanisms of risk are underdetermined by existing scientific consensus.

COMPARISON POPULATIONS

When transgenic crops were being discussed in the 1980s, there was a general presumption that recombinant DNA techniques would eventually become the preferred method for introducing genetic novelty into plants. In some instances, the presumption went so far as a belief that the traditional skills of plant breeders would soon be obsolete and that all new crops would be developed using transgenic methods (Busch et al., 1991). A corollary to this belief that was seldom articulated in the literature of the 1980s and early 1990s was that the traits being introduced using transgenic methods would be the same kind of agronomically valuable traits that had long been the aim of conventional breeding programs. Such traits were introduced to enhance yield, either in general or in conjunction with specific conditions such as pests or disease, and drought, climatic variation, and both

soil-based and externally applied chemicals. Thus, those who asserted the comparability risks of transgenic and conventional crops were assuming that the crops developed with transgenic and conventional would be broadly similar with respect to their traits and purpose.

The regulatory posture toward environmental risk that developed on the U.S.-coordinated framework clearly reflects such an assumption. The U.S. Department of Agriculture APHIS developed a regulatory approach that permitted small-scale production of transgenic crops with relatively little oversight or prior approval. The intent was to permit field trials needed both for backcrossing and generating data, with the expectation that seed companies would need to go through the approval process before releasing a transgenic variety for commercial production. However, by 2002 it was clear that some biotechnology companies were capable of servicing the entire production run for some high-value crops developed to service non-commodity markets on field-trial sized plots. The lack of appropriate regulatory oversight for these crops was noted by the NRC (2002).

The potential for using plants as systems to produce an entirely new class of products, including pharmaceuticals and industrial biologics in cropping systems, was clearly recognized early on. Yet, it is doubtful that anyone who asserted the comparable risk hypothesis had these crops in mind. However, by the time that the most recent NRC committee convened, a number of things had changed. First, the plant science community had more experience with transgenic techniques and a more realistic understanding of their potential when compared with conventional techniques. More importantly, consumer resistance to GM crops has created an economic environment that has reduced the attractiveness of transgenic techniques for food crops. As a result, a much larger than expected percentage of the transgenic crops that are likely to be used in a production setting during the next decade are those in which a food crop, often maize, has been transformed to produce nonfood pharmaceuticals or biologics.

The key value judgments from a risk assessment perspective have to do with establishing comparison populations or defining what is meant by a transgenic crop. If T is the population of all transgenic crops, T_h is the harmful subset, C is the population of conventional crops, and C_h is the harmful subset, then the risks of transgenic and conventional crops are comparable if and only if:

$$T_h/T = C_h/C$$

In this formula, T and C represent reference populations for expressing risk in statistical terms. Although quantification of this formula would be very difficult given existing data, it does provide an apparently clear statement of what it means to say that the risks

of transgenic and conventional crops are equivalent. However, the clarity of the expression depends upon unambiguous and agreed-upon definitions of the relevant classes. Disagreements about hazard identification or exposure characterization can produce different interpretations of T_h , as discussed above, but changing assumptions about the kinds of traits being introduced involve the interpretation of T.

The whole point of analogizing risks from transgenic and conventional crops is to gain predictive insight into the risks of transgenic crops. This demands that C be interpreted historically as the class of all crops developed for commercial release using conventional techniques and that T be understood to include some crops that are yet to be developed. Clearly, T does not include all conceivable plants that could be developed using transgenic technology, for any competent biologist will concede that it is possible to produce some very dangerous transformation events not suitable for agricultural production. However, one should not confine T to those crops that will actually be commercially released because to do so begs precisely the regulatory assessment questions that a risk comparison is intended to address. Although the reference population is not specifically defined in NRC reports, these committees have implicitly understood T to include all and only crops that are prospective candidates for commercial production. This would include crops intended to be grown under proprietary management and not released for commercial sale and conventional registered varieties made available to farmers.

Given the expectation that transgenic techniques would be used to produce crops with agronomic traits such as alternative coloring, disease resistance, climatic variation tolerances, and increase yield, T and C were expected to be roughly similar in terms of their phenotypic profile, and the ratios T_h to T and C_h to C were expected to be similar as well. Although herbicide-tolerant and Bt crops are notable examples of crops with fairly standard agronomic traits, transgenic plants produced for pharmaceutical or industrial chemical production have phenotypic characteristics that are quite unlike those of crops historically produced through conventional means. As such, it no longer seems reasonable to expect that the phenotypic characteristics of plants in T will be similar to those of plants in C and because the parallelism in the makeup of the reference population shifts, so does the comparability of risks. It is, in part, this difference in comparison populations that accounts for the 2002 report's more precautionary stance when compared with previous NRC committees.

CONCLUSION

Hazard identification, exposure modeling, and comparison populations each involve value judgments that are ethical or pragmatic but in either case

cannot be characterized as following from established scientific findings or theories. It may be the case that many plant scientists share common views with respect to these value judgments. Nevertheless, taking different viewpoints on any of the value-oriented questions is, absent more extensive argument at least, fully consistent with taking a scientific view on the comparison of environmental risk from transgenic and conventional crops. Because of the technical sophistication implicit in the foregoing analysis, it is unlikely that the specific value judgments identified above contribute strongly to non-scientific resistance to transgenic crops. However, resolving the conceptual and definitional ambiguities noted herein, and providing a clear and straightforward rationale for such resolution, are critical to the credibility of risk assessment.

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