

GM crops: balancing predictions of promise and peril



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The use of genetically modified (GM) organisms in agricultural production has grown rapidly around the world. In 2003, for example, an estimated 80% of soybean agriculture in the US used Monsanto's Roundup Ready GM soybeans, and in 2002 over 58 million ha in 16 countries were planted with GM crops (James 2002; USDA 2003). Although GM organisms have primarily focused on insect control and agricultural weed management, future diversification of GM species is underway, including transgenic salmon with faster growth rates and transgenic trees with altered lignin production. Although crops and traits important to the developing world are recognized as a huge potential benefit of agricultural biotechnology, the amount of funding directed at developing these is small relative to the investment in crops and products targeted at US markets.

Like all controversial policy issues, the introduction of GM organisms involves the intersection of environmental, human health, social, economic, and political issues, and requires using science to inform society and decision makers of the potential consequences. The environmental impacts can be broadly summarized into two categories: what the effects are (if any) of the transgenes and their phenotypes on the environments where they are introduced, and whether they will spread (and if so, with what consequences).

A fundamental and unresolved issue is which data can be used most effectively to assess these impacts. This is a particularly thorny question for biological introductions because of the high degree of variation present in ecological systems. An introduced organism interacts within a complex existing ecosystem, with numerous avenues for interaction with adjacent communities, and evolves and responds to the dynamic nature of that ecosystem, a point especially important to consider in the introduction of organisms with high reproductive capacity. As many have pointed out, assessing the environmental impacts of GM organisms requires a case-by-case approach.

The introduction of new agricultural products by plant breeding serves as one model for how environmental risks may be approached. This approach emphasizes the long history of characterizing agronomic traits, which are also correlated with fitness for those crops whose seeds and fruit we eat. The accumulated knowledge can be incorporated into risk assessments and provide a context for changes that may have environmental implications.

Another approach draws upon our experience with the introduction of exotic species or biological control. A small percentage of these have had unanticipated effects, causing an estimated \$137 billion per year in environmental and economic impacts (Pimentel *et al.* 2000). Most important, the predicting or screening of invasive species is not yet well developed.

Much of the controversy associated with assessing environmental risks centers on the quantity and quality of data collected prior to commercial release, and on the extent to which these data will predict negative consequences. Discussions about data quantity revolve around the number of indicator species used, their sensitivity as environmental indicators, the breadth of guilds represented by organisms tested, the range of environments used, and the use of laboratory- versus field-based designs. Small samples and experimental replicates limit the detection of effects on mortality and sub-lethal changes in reproduction of indicator species (Marvier 2002). Of particular importance, however, is that we do not necessarily have specific details on what level of difference an experiment should detect, and at what time interval experiments should be conducted in order to predict environmental impacts. In general, experimental designs with limited power, few indicator species and guilds, and a short duration will emphasize the detection of high magnitude effects; experiments encompassing a larger number of individuals, species, environments, and scales will increase the reliability of predicting cumulative, small-magnitude impacts. Both types of evaluations contain some degree of uncertainty, and there is considerable disagreement about magnitude and significance for assessing risk.

Since the US regulatory system requires companies to prepare and submit data on a product's environmental and human health risks for review prior to commercialization, developers bear the costs of assessing potential impacts. Long-term evaluations of low-probability environmental risks may therefore increase development costs and stifle any benefits. To protect their economic interests, US companies developing transgenic products may classify data as confidential business information, thereby limiting public critique of studies. Transparency for the data and the process used for regulatory reviews has been strongly recommended (NRC 2002), but the conflict between preserving developers' investments and the value of constructive analyses of the submitted data remains unresolved.

A further challenge for evaluating environmental

impacts is integrating anticipated benefits into the decision making process. Changes in agricultural practices associated with the adoption of GM crops may have ecological benefits, although, like the risks, these benefits are dependent upon well-designed experiments with appropriate indicator species. Few studies have yet documented environmentally friendly agricultural practices, but in order to measure environmental impacts, more work needs to incorporate measures to detect the significance of these changes for the environment.

The environmental controversy centers on experimental design and data needs, the importance of any detectable changes in the environment, and the degree of uncertainty in predicting ecological outcomes associated with introductions. Recent discussions have focused on methods for decreasing risk and uncertainty by post-commercialization monitoring to validate risk assessments (NRC 2002) and incorporating principles of safety engineering (Kapusinski *et al.* 2003) through engineering bioconfinement. Such efforts may help resolve the controversy by incorporating risk minimization into all stages of product development, rather than just prior to commercialization.

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The Cartagena Protocol on Biosafety identifies a need for comprehensive, transparent, scientific methods for meaningful risk analysis of transgenic plants to ensure their environmental safety and sustainable use (CBD 2000). This analysis must be environmentally specific and

involve information about the transgene, the recipient plant, and the intended release environment (NRC 1989; Tiedje *et al.* 1989). Policy and regulatory efforts on the part of governments, industry, and civil organizations abound, but the only international effort of public-sector scientists to address this need has been the GMO Guidelines Project, under the International Organization for Biological Control.

The scientific demands of risk analysis are to evaluate hypotheses and develop effective management practices. The Project has identified three issues directly related to risk – non-target and biodiversity effects, gene flow and its consequences, and pest resistance risk and management – as well as two main areas of inquiry: problem formulation (which frames the analysis) and characterizing the transgene genotype and phenotype. The scientific challenges are many and diverse. How can unintended and unexpected effects be assessed ahead of time? How can non-target risks be evaluated in specific cases? If gene flow is possible, is it inevitable (Ellstrand 2003)? If so, what can be done to predict and mitigate its hazards? Is resistance management possible in landscapes dominated by smallholders? What makes a transgenic organism a net benefit to a society? What generalizations are scientifically defensible if risk analysis is to be environmentally specific?

Unintended or unexpected effects are one of the most vexing problems confronting risk assessment. Although they seem impossible to predict, their potential sources can be identified, making it possible to manage these sources to reduce associated risks. An effect can be considered unintended or unexpected only if intended and expected effects are clearly delineated. The first steps in risk assessment, then, are to predict the transgene phenotype from its genotype, and then to test the predictions.

Transgene integration often results in complex transgene loci comprised of multiple or partial copies in tandem, inverted, or interspersed with host DNA (Birch 1997; Pawlowski and Somers 1998; Windels *et al.* 2001). It is therefore possible that a new open reading frame is created (Pawlowski and Somers 1998) and an unintended gene product is expressed. If the transgene locus were sequenced *in vivo*, all gene products could be predicted, and if only simple transgene loci were allowed, then a major potential source of unintended and unexpected effects would be eliminated. Other sources of such effects are pleiotropy (a single gene controlling several distinct and seemingly unrelated phenotypic effects), epistasis (gene-by-gene interaction), and gene-by-environment interaction. Post-translational processing can be detected in the lab, but other effects can best be assessed after the transgenic plant is extensively planted. It seems appropriate, then, to develop strategies to simultaneously assess and manage these potential risks.

Typically, the assessment of non-target effects relies on challenging a few "indicator" species to the environmental stressor, typically a chemical (Forbes and Forbes 1994). If none of the species shows an acute toxic response, then

the stressor is considered safe enough to use in that environment. This approach has been critiqued (Forbes and Forbes 1994; Elmegaard and Jagers op Akkerhuis 2000; Hilbeck and Andow 2003), and we have suggested an alternative (Andow and Hilbeck 2004). The indicator species should ideally be found in the environment in question. Since any habitat typically contains several thousand species, however, how can one select which to use for risk assessment?

One approach is to avoid species entirely and focus on ecological function, which integrates the responses of many species. Function must be evaluated in the field, however, so it is impossible to use it to assess risk prior to release of the transgenic organism. We have suggested that species be classified into a limited number (~10) of functional groups (herbivores, natural enemies, pollinators, etc), and that indicators be selected from these groups (Andow and Hilbeck 2004). Within each group, we have developed a prioritization method called the Species Selection Matrix, using ecological characteristics to identify dominant species (widespread, abundant, and prevalent), which are likely to play an important role in the habitat and be exposed to the transgene products. It is possible to identify a limited number of candidates in an exercise that takes less than a day. One can also construct falsifiable risk hypotheses for each species to guide the process.

A major problem in developing countries is gross underinvestment in scientific infrastructure, which limits the capacity to conduct meaningful risk assessments. The GMO Guidelines Project addresses this problem by conducting workshops on case studies in selected countries, to show local scientists how risk assessment can be conducted. We have already found that the proposals outlined above resonate with scientists in Kenya and Brazil. They find the methods easy to understand and use, and logically compelling. We plan to develop these approaches in the future.

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It is unclear how to respond to a title like “Balancing predictions of promise and peril”, because I do not believe that science plays a significant role in the balance between these two extremes. However, LaReesa Wolfenbarger outlines some of the issues that face biotechnology-derived (GM) crops where science can be discussed. I will focus on ecological risk assessment (ERA) and the role of science within this process relating to GM plants.

There is little doubt that the rapid adoption of some of the previously approved GM crop products, primarily in the US, is both a source of concern to critics and evidence of how valuable this technology can be to farmers (Gianessi et al. 2002). This rapid rate of adoption raises the question of whether we are moving too fast in light of our knowledge of ecological science and its ability to inform decision makers. What data should we be collecting to assess the potential environmental impacts of these crops? Leaving ethics aside for the moment, the challenges surrounding a scientifically sound ERA of GM crops are both epistemological and methodological.

According to the US EPA (1998), ERA is “a process that evaluate[s] the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors”. Despite the fact that their model was developed primarily for chemicals, most of the principles that establish the foundation are applicable to GM crops. Merging the procedural aspect of the EPA’s model with ecological principles like those outlined by Tiedje et al. (1989), one has a secure platform upon which to build product-specific ERAs. Today, information must be provided to regulatory authorities describing the nature of the crop, the trait, and the likely receiving environment, along with an assessment of how these will interact. The possibility that the transgene or the crop itself could move into environments outside that for which they have been developed is also considered in an ERA.

As good a start as this is, it is only a start, because the challenge to a risk assessor is to determine whether an

effect is “adverse”, and whether the data provided are of sufficient quality to do so. In addition, there is the problem that, since there is no such thing as zero risk, both a “no” decision and no decision can be dangerous. One way this uncertainty is managed for GM crops is through the use of a comparative assessment approach, where the new crop is compared to the traditionally bred crop. One then defines those characteristics that differ meaningfully, and conducts an extensive ERA on those differences. It is also important that an ERA should be tiered, with more refined tests, conducted based on the results of initial risk assessment tests. It is not therefore precisely accurate to say that GM crops are assessed using an either/or approach (traditional breeding versus exotic species). Rather, higher tiered experiments would be designed based on the biological principles that would be used to assess the invasiveness of an exotic plant species.

The science behind ERAs for GM crops must address ecosystem complexity, while the resulting decisions must address human values. The risk assessor is challenged to determine whether the absence of an effect in an experiment is the result of using an insensitive or inappropriate test, or whether the method was appropriately sensitive. To some scientists, a negative result is scientifically unsatisfying and philosophically problematic. For the risk assessor, however, an effect must be relevant to safety and the assessment objectives – those human values that are to be protected and promoted. Thus, the scientific challenge is to optimize statistical power and not necessarily maximize it. Experiments need to be sufficiently sensitive to detect a likely effect that is judged also to be adverse. Furthermore, a judgment of “adverse” is made relative to the environmental impacts of current production systems. This approach recognizes that zero environmental risk does not exist in agriculture.

The greatest threats to biodiversity are habitat destruction, pollution, over-harvesting, and invasive species. It is also widely accepted by scientists that current agricultural systems are not environmentally benign. The environmental risk question for GM crops becomes whether they have less, more, or equal impact compared to their conventional counterparts. Our system to address these questions for regulatory approval is based on ERA that has both scientific and ethical components. Basic ecological research complements ERA, bringing the value of creative approaches to scientific problems in characterizing effects and enhancing our understanding of ecological complexity. At the same time, delaying a decision to use a technology that could mitigate a known risk without good cause could adversely affect the environment. As such, the question is not so much one of balancing predictions of peril and promise as it is of balancing risks using the available information to make the best possible decision in a landscape of diverse values.

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In 2002, the US donated 26 000 tons of corn to African nations in danger of famine. Zambia, Zimbabwe, and Mozambique refused the food at first, because this corn contained genetically modified (GM) content. Now, with EU regulations requiring traceability and labeling of GM foods, African nations are even less likely to plant GM crops or accept GM food, for fear of losing export markets and European financial assistance.

President Bush has accused the EU of “causing African nations to avoid investing in biotechnologies, for fear that their products will be shut out of European markets. European governments should join – not hinder – the great cause of ending hunger in Africa”. On grounds that these regulations constitute an illegal trade barrier, the US, joined by a number of other agriculturally important nations, has brought a case against the EU to the World Trade Organization (WTO). Those who study the evidence believe that the US has a solid case, because by WTO Sanitary and Phytosanitary Measures, countries may ban imports only on condition of scientific evidence of risk. Indeed, 81 EU-sponsored scientific studies have shown no evidence of health or environmental risks from genetically modified organisms (GMOs) (Paarlberg 2003).

Legalities and markets aside, if we wish to understand why Europe’s reactions to GMOs have been so harsh, we must consider cultural issues as well. At the 2003 World Congress on Risk in Brussels, the topic of GMOs inevitably found its way into both formal talks and table-side debates. As European risk researchers stated, EU regulators know that there is little evidence of risk from current GMOs. The real issue is culture. Clearly, other factors come into play, but let us focus here on cultural differences across the Atlantic, because while they are rarely discussed in these debates, they are important to understand as a driving force in EU policies.

One cultural difference concerns perceptions of food. Rightly or wrongly, the perception abroad is that Americans view food much as they view technological gadgets such as cars or laptops – a means to an end, not an end in itself (Echols 2002). Food is mostly the fuel by which Americans derive energy for work and play, evidenced by how they bolt their meals and rush from the dining table. In Europe, on the other hand, food is integral

to culture; Europeans can linger at dinner and even lunch for hours. Genetically engineering such a crucial component of culture is abhorrent to many Europeans, giving rise to the commonly used term, “Frankenfood.”

Another cultural difference involves perceptions of agriculture. Whereas much of US farmland is devoted to large-scale, monocropped agribusiness, European farms are smaller, often family-run, with greater crop variety. More people live in the countryside where agricultural production occurs. Therefore, changes in the countryside – particularly industrialization by agribusinesses supporting a small variety of GM crops (or any other homogenization) – may be perceived as threatening to traditional variation in locally produced, distinctive, regional food products in which Europeans take pride.

Yet another difference hinges on perceptions of government trustworthiness. Because of recent food-related scares that shook the EU, from mad cow disease and dioxin in chicken feed to hoof-and-mouth disease, Europeans’ trust in their regulatory bodies has plummeted (Löfstedt and Vogel 2001). Why should they listen if their governments tell them that GM foods are safe? Recent government assurances about food safety have been wrong – fatally so. In comparison, Americans tend to trust their government, even in the wake of their own mad-cow scare. They may not always agree with the administration’s decisions, but Americans generally assume that regulations are made for their good – so when government agencies say that something is safe, it probably is.

Thus, from a cultural perspective, it is understandable that Europeans have a more precautionary stance than Americans on GMOs. The problem is that WTO cases are based on legal, not cultural, criteria, so cultural sensitivities may not influence WTO policymaking.

For that matter, Americans’ own cultural criteria influence agricultural policies that “hinder the great cause of ending hunger in Africa”, in President Bush’s words. The 2002 Farm Bill increased domestic corn, wheat, rice, and cotton subsidies by 150%: \$190 billion over the next decade. These subsidies increase farm incomes by 30% above what they would be at competitive world prices. The USDA estimates that eliminating agricultural protection worldwide would increase annual welfare in developing countries by \$21 billion, by improving their export markets and providing money to purchase food and other goods (Beierle 2002). The EU supports farm subsidies as well, but certainly we are just as guilty in this instance. So why continue such practices? Cultural reasons, in part, play a role. President Bush justified these subsidies in May 2003: “It helps farmer independence and preserves the farm way of life for generations”. Even if this were politics using culture as a shield, it works because Americans care deeply about preserving their “agri-culture”.

Indeed, on both sides of the Atlantic, our cultural sensitivities regarding food and farming – whether through stringent GM crop regulations or through subsidies – increase hardship for farmers and consumers elsewhere.

Maybe it is important to bring culture to the table for policymaking in a legal framework – not to preserve these carefully guarded cultures, but to understand when it may be appropriate to lay aside cultural sensitivities to ensure a better lifestyle for others worldwide.

(The ideas expressed here are those of the author alone, not of RAND.)

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Ethics is the study of norms, values, goals, and decision criteria. In this case, it concerns criteria specifying how the ecological effects of transgenic crops should be perceived and evaluated. Ethical norms relate to both the impact of biotechnology and the way that decisions to develop and use biotechnology are made.

The use or development of any technology poses questions such as what values are in play when a given class of impacts is understood as beneficial or adverse. How should beneficial and adverse consequences be weighed? What norms of accountability or responsibility should guide the use of the technology? How should the risks and benefits of the technology be distributed?

The idea of “genetic pollution” provides an important illustration of the first question. Is a transgene in the “wrong place” automatically an adverse impact? Or must there be some further unintended impact, either on human health, genetic diversity, or on the species composition in an agricultural or wild ecosystem, before the migration is understood as harmful?

Experience has already proven that there are a number of ways in which a transgene can wind up somewhere other than where the developers of a GM crop intended. In addition to phenomena such as gene flow and introgression into wild relatives, which were the initial focus of concern regarding GM plants’ environmental impacts, a number of non-biological mechanisms have also been observed. Starlink maize was mixed with shipments intended for human food use. Volunteer plants from field

trials resulted in “pharma” transgenes being found in a later food crop harvest. Growers of Mexican land races obtained samples of Bt maize and planted them among their crops. Thus far, there has been no demonstration of harm to human or environmental health from any of these incidents, yet each has been characterized as genetic pollution by biotechnology critics.

It is clear that these critics are applying different values to the evaluation of transgene movement than are many scientific groups, especially the series of National Research Council panels that have contributed reports on the ecological impact of agricultural biotechnology (Thompson 2003a). Yet there are many ethical questions and assumptions that need to be articulated before it becomes possible to have a complete discussion of which view is most defensible. The critics’ perspective echoes a long-standing presumption that any traceable and unintended human impact on a natural ecosystem is adverse (Thompson 2003b). Simply finding a transgene outside its modified crop is seen as a form of harm, even when no further ecological impact on species or genetic diversity and composition can be detected.

It is reasonable to assume that similar types of genetic migration have accompanied the introduction of conventional crops and new crop varieties. Does our ability to trace the movement of transgenes justify treating them as involving a different type of environmental impact from that of conventional crops? Or does it mean that we should rethink the ethics of all types of crop improvement in regard to environmental or ecological impact?

These questions, which for now must be regarded as open, demonstrate the ethical complexity of interpreting any ecological impact as adverse. A full ethical evaluation of such impacts must also address them within the framework of agriculture’s broader ethical obligation of meeting human food needs in a responsible way. Yet the tendency to develop agricultural technology in the absence of any deliberate effort to understand the ethical issues is not atypical. The critics may or may not be misguided, but no one bothers to say why. The ethical norms that guide technological practice are implicit in the actions taken, as opposed to having been the result of a conscious or explicit procedure of decision or debate.

This points to the importance of the procedures that ought to be in place to address ethical questions such as what constitutes an environmental harm. While it is extremely important to have defensible answers to such questions, it is possible to arrive at sound ethical norms and values in a manner that is itself indefensible. Questions about the adequacy, appropriateness, and justifiability of a given decision-making approach are also issues of ethics.

This is key to the debate over transgenic crops, because a close reading of agricultural biotechnology’s critics reveals that procedural issues rank high on their list of ethical concerns. While the science community has often done a defensible job addressing the environmental

impact of transgenic crops, they have failed to meet a procedural standard that calls for a full and open discussion of the ethical values and norms implicit in their thinking. More frequently, we have heard that decisions should be “based on science”, as if value judgments are not involved. Lacking such a dialogue, biotechnology has sparked public opposition. This discussion is overdue, but it will require biotechnology developers to devote more time, effort, and resources to articulating and defending the ethical dimensions of their practice.

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The more subtle truths behind Wolfenbarger’s statement that “[a] fundamental, and unresolved, issue for answering these questions is what data most effectively can be used to assess environmental impacts” need investigation. For a deeper understanding, we must delve into the distinctions between natural and agricultural habitats, the first of which is that agriculture is a human invention, existing to serve human needs.

There is a widespread trend, even among ecologists, to treat agricultural systems in the same way as natural ecosystems when planning, modeling, or interpreting ecological field experiments. Although some of the same methods can be applied by comparing natural and agricultural sites, data interpretation must take into account some fundamental differences: biodiversity in agricultural sites is dramatically and artificially reduced (Altieri 1991; Pyke and Archer 1991; McLaughlin and Mineau 1995; Hutton and Giller 2003); crops and many weeds are the result of man’s ingenuity, and most agricultural weeds, such as the widespread hemp-nettle (*Galeopsis tetrahit*) (Müntzing 1930; Ammann *et al.* 2000a), are not truly “wild”, but the outcome of millennia of selective adaptation to human activity; soils are often subjected to heavy tilling, which greatly affects soil microbial life; and crop rotation is important in controlling pest levels, but there is no close counterpart to this activity in nature.

Commonly accepted inputs, such as fertilizers, herbicides, and other pesticides, create environmental disturbances, which never occur at the same high levels in natural habitats. Thus, while it is important to always compare natural and agricultural habitats using the same scientific methods, it is not appropriate to compare them with the same ecosystem and biodiversity standards. It is also important that the risk assessments should be very

different, depending on the situation; in the case of a natural system, such as an alpine grassland, a disturbance can affect species composition for decades (Hegg *et al.* 1992), while agricultural environments are subjected to regular disturbances that cause transient impacts, which are measured primarily in terms of output yields. We must not assume that the same disturbance phenomenon will hold the same risks for both types of site. Instead of applying the same interpretation standards, we should make distinctions in risk assessment methods.

Agricultural systems are highly artificial and dynamic because of activities such as tilling, sowing of monocultures, harvesting, and rotating crops (to name those that have the most dramatic impact on biodiversity). Thus, reports such as the Ecostrat report commissioned by Greenpeace (Hilbeck *et al.* 2000) are factually correct, but incomplete, because they are written as if standards used to evaluate natural habitats could be applied to decisions about how safety standards should be applied to new crops. The sequence and pace of disturbance in a crop regime alone make it nearly impossible that the types of long-term assessments requested by Ecostrat to control experimentally or yield useful information for regulators.

This does not mean that academics do not play an important role in examining basic ecological questions and expanding knowledge. It merely means that, in cases such as agriculture, it would be imprudent to wait for these types of long-term experiments before launching any new, potentially beneficial technology such as GM organisms. It is also interesting that, in hindsight, it is clear that the trends have been interpreted correctly (NRC 1989; Sears *et al.* 2001).

There are further reasons to be more mindful of agricultural dynamics and related long-term experiences. Many gene flow studies have already been published, and it is very likely that there are many more to come (Eastham and Sweet 2002). As a botanist, I am compelled to remind the scientific community of the experience and hybridization data to be found in plant collections such as herbaria (Ammann *et al.* 2000b). An equally valuable source of practical information comes from the long-term experience of seed producers, who have a strong economic interest in keep seed lines genetically well defined for agricultural purposes (OECD 2003).

The challenge for regulators is to make decisions on real products in real environments within a realistic time-

frame. In their evaluations they must include experience from agriculture based on traditional methods and crops. It is important to give thorough consideration to baseline comparisons between traditional and GM crops and agricultural methods of all kinds (Babendreier *et al.* 2003).

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